LEGAL TOOLKIT
FOR PATIENT ADVOCATES

Report on the patients' participation in decision-making and law-making processes

EDU

Boehringer Ingelheim

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Introduction

Despite constant presence of the matter of patient involvement in legal decisions in discussion panels at conferences and expert report recommendations, its practical implementation remains far from ideal. Few countries have yet recognized the expert position of patient representatives and permanently included them in the co-creation of laws and decisions that affect them.

This issue does not divide Europe along the traditional lines of Western countries versus Central-Eastern European countries. This division defies stereotypes. Therefore, we decided to examine the involvement of patients in legal processes across a selection of countries, including Austria, Czech Republic, Hungary, Poland, Romania, and Slovakia.

In this report, we focus primarily on the legal status of patient organizations within the healthcare system. We assess whether the law distinguishes these organizations from other non-profits in a specific way and whether it grants them any special rights.

Additionally, we examine the legal status of representatives of patient organizations (or patients) in healthcare decision-making procedures and legislative processes.

Importantly, we also investigate whether the legal status of these organizations is robust and based on statutory provisions or if it can be altered by a single ministerial decision (e.g., based on ordinance). We explore other tools available to patient representatives to advocate for regulations beneficial to their communities. This includes both legal regulations accessible to all organizations and citizens, as well as alternative advocacy methods that have proven effective in the given locations.

A comparative analysis of these regulations is extremely interesting, revealing a region that breaks stereotypes and, more importantly, sends a coherent message that the participation of patient organizations in these processes is increasing every year.

We invite you to read on!

Adrian Goretzki
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Executive summary

This report provides a comprehensive analysis of the healthcare systems and patient advocacy frameworks in six Central and Eastern European countries: Austria, Czech Republic, Hungary, Poland, Romania, and Slovakia. The primary objective is to evaluate the legal, administrative, and practical aspects of patient involvement in these healthcare systems and identify opportunities for enhancing participation of patients in decision making and law making processes.

Austria

The Austrian healthcare system is characterized by a high degree of organization and a complex structure. According to the Austrian legal tradition of corporatism, many legal regulations promote the engagement of representatives from professional self-governments, trade unions, and industry associations, but not social organizations. Instead of involvement of NGOs, the institution of Patientenanwälte (state-funded Patient Advocates) plays a crucial role in representing patient interests. Those officials are obliged to cooperate with patient organizations, but such a partnership is almost nonexistent in practice. Patient representatives can participate in the works of the Bundesgesundheitskommission (Federal Health Commission), an important pre-legislative body, but there is only one place, occupied by the same organization for many years. Patient organizations still face challenges in health technology assessment (HTA), where their involvement remains mostly advisory, if any.

Czech Republic

The Czech healthcare system seems to be the most patient-centered in the region, with clear provisions for patient rights and a structured approach to patient advocacy. The Ministry of Health collaborates closely with patient organizations, especially through the Patient Council (Pacientská rada), which includes representatives from various patient groups. This council advises on healthcare policies. Moreover, the legal framework for HTA in the area of rare diseases supports direct patient involvement, with patient organizations having one voting right regarding reimbursement recommendations. Patient organizations also have a legal definition and clear position in the system. Nevertheless, there are areas for improvement, particularly in ensuring that patient feedback is consistently integrated into decision-making processes, not only in the area of rare diseases.

Hungary

Hungary's healthcare system is marked by a strong emphasis on universal health coverage, managed by the National Health Insurance Fund (NEAK). Patient organizations, although not explicitly defined in Hungarian law, operate under the broader category of civic organizations. These entities play a role in healthcare advocacy, especially through an NGO called National Patient Forum (Nemzeti Betegfórum) and regional health councils. Recent legislative changes have transferred healthcare management to the Ministry of Interior, which

now oversees health policies and patient advocacy initiatives. While there is a history of successful patient involvement, particularly in the area of rare diseases, formalizing these practices into specific legal frameworks could enhance their impact.

Poland

In Poland, patient organizations have several ways to influence healthcare policies, but all of them are of a consultative manner. The Polish administrative law allows patient organizations to act as parties in administrative proceedings, particularly in the context of drug reimbursement decisions or cases of individual patients (both in the areas of medicine reimbursement and social security cases). The establishment of consultative committees and councils provides a structured platform for patient advocacy, though the integration of patient feedback into policy decisions remains inconsistent. There are also no formal opportunities for POs to be involved in HTA procedures on their demand.

Romania

The Romanian healthcare system faces challenges, including limited resources and infrastructure. Patient organizations play an important role in advocating for better healthcare services and policies. The Social Dialogue Act establishes structures for consultations with civil society, including patient organizations. Despite these provisions, the practical implementation of patient involvement is often seen as a formality, with limited real impact on decision-making. As an alternative, patient organizations sign cooperation agreements with the Ministry of Health, providing their own legal framework for cooperation based on civil law. Enhancing the effectiveness and formalization of consultative processes in Romania seems essential. There are also no formal ways to engage patient organizations in the HTA processes.

Slovakia

Slovakia's healthcare system is characterized by compulsory social health insurance and a structured approach to healthcare delivery. Patient organizations, while not formally recognized in the legal system, operate effectively through associations and advocacy groups. The Ministry of Health includes patient representatives in advisory committees, particularly for rare diseases. However, the selection process for these representatives is unclear, and their influence on broader healthcare policies is limited. Establishing a clear legal framework for patient organizations could strengthen their role in the healthcare system. As in Romania, there is no formal way to engage patients in the HTA proceedings.

Conclusion

Across the six countries analyzed, patient organizations play a vital role in advocating for patient rights and influencing healthcare policies. While there are established mechanisms for patient involvement in some countries, others require significant improvements to ensure that patient voices are heard and integrated into decision-making processes. Key recommendations include formalizing the role of patient organizations in healthcare legislation, preferably at the statutory level, enhancing transparency in policy consultations, and building stronger partnerships between patient groups and HTA authorities (as seen in the Czech Republic). These steps will help create more patient-centered healthcare systems and improve health outcomes across the region.

1 Austria

1. Austria

1.1. The healthcare system in Austria

Austria is a country with a constitutionally established healthcare system financed by public funds and insurance contributions. Health policy law is created at the central level, with implementation matters entrusted to the Austrian Federal Ministry of Social Affairs, the umbrella organization of insurance companies, and the federal states (*Länder*). The role of the payer is carried out by public insurance companies established under a separate act, which are administered by an umbrella organization, while the vast majority of hospitals are owned by the federal states.

The creation of legal acts with nationwide impact is the exclusive prerogative of the Austrian Parliament (*Parlament*). Furthermore, while the federal states have the authority to enact their own laws (*Landesgesetz*), these laws must conform to federal-level legislation (*Bundesgesetz*).

Due to the above, patient advocacy activities, in particular those influencing the shape of legal acts and decisions regarding drugs and medical procedures, take place primarily at the federal level.

1.2. Creation of the healthcare law

The Austrian Parliament has the exclusive power to enact constitutional and statutory law at the federal level. Legislative initiative is vested in the government, parliamentary committees and the Federal Council (the parliamentary chamber of the representatives of the *Länder*).

The minister responsible for health is appointed by the president at the request of the chancellor (the head of government). Currently, the healthcare area falls under the Federal Ministry of Labor, Social Affairs, Health and Consumer Protection (*Bundesministeriums für Arbeit, Soziales, Gesundheit und Konsumentenschutz,* BMASGK). The Minister has the right to issue legal acts in the form of regulations (*Verordnung*), which must be consistent with the laws adopted by the Parliament. The regulations clarify the norms resulting from the acts, in particular where the act leaves detailed solutions to the decision of the ministry. Healthcare law can also be established at the federal states' level, but it must be consistent with federal legislation.

Important part of the healthcare legislation also comes from the bi- and multilateral agreements between the federal government and the federal states.

1.3. Making decisions regarding reimbursement of drugs and medical procedures

The process of drug evaluation and reimbursement in Austria is quite complex, and decisions in this area are made by more than one institution.

The political responsibility for this process lies with the ministry (BMASGK). The federal government's authority to set *economically reasonable* drug prices comes from the Price Act (*Preisgesetz*)[1]. The issue of the reimbursement procedure for drugs used in outpatient treatment is regulated by the General Health Insurance Act (*Allgemeines Sozialversicherungsgesetz*)[2]. It gives decision-making powers to the Austrian umbrella association of social insurers *Österreichische Sozialversicherung. Dachverband der Sozialversicherungsträger,* DVSV, bringing together all public insurers in Austria. It is a self-governing organization established on the basis of the General Health Insurance Act. Its activities are, in principle, independent of the instructions of the BMASGK. The Ministry supervises the organization in terms of compliance of its actions with the law, but also the purposefulness and financial effectiveness. BMASGK has the right to change administrative decisions issued by the association, but it can interfere only in *important matters* and does so very rarely in practice.

In Austria, there are two main reimbursement paths: for outpatient drugs and those used in hospital treatment (inpatient).

Outpatient care

An application for reimbursement of a drug in outpatient (out-of-hospital) treatment is submitted to DVSV by an entrepreneur authorized to distribute the drug or it is done on the initiative of DVSV.[3] The drug must, of course, be previously authorized for marketing in the Federal Office for Healthcare Safety (*Bundesamtes für Sicherheit im Gesundheitswesen,* BMASGK's agency) or in the EU centralized marketing authorization procedure carried out by the European Medicines Agency.

> **"An obligatory element of the procedure is the evaluation of the drug by the Committee for the Evaluation of Therapeutic Products (*Heilmittel-Evaluierungs-Kommission, HEK*)."**

An obligatory element of the procedure is the evaluation of the drug by the Committee for the Evaluation of Therapeutic Products (*Heilmittel-Evaluierungs-Kommission*, HEK). It consists of two representatives of the Federal Office for Healthcare Safety, eight representatives of social security organizations, three independent scientific representatives of the relevant disciplines (pharmacologists and doctors from university institutes), two representatives each of the Chamber of Employees (*die Arbeiterkammer,* AK) and Chamber of Commerce (*die Wirtschaftskammer Österreich*, WKÖ), and the Austrian Medical Association (*Österreichische Ärztekammer*), as well as a representative of the Austrian Chamber of Pharmacists (*Österreichische Apothekerkammer*). A representative of the state patient rights ombudsmen (*Patientenanwälte*) and representatives of the federal states participate in the work of the commission, but without the right to vote[4].

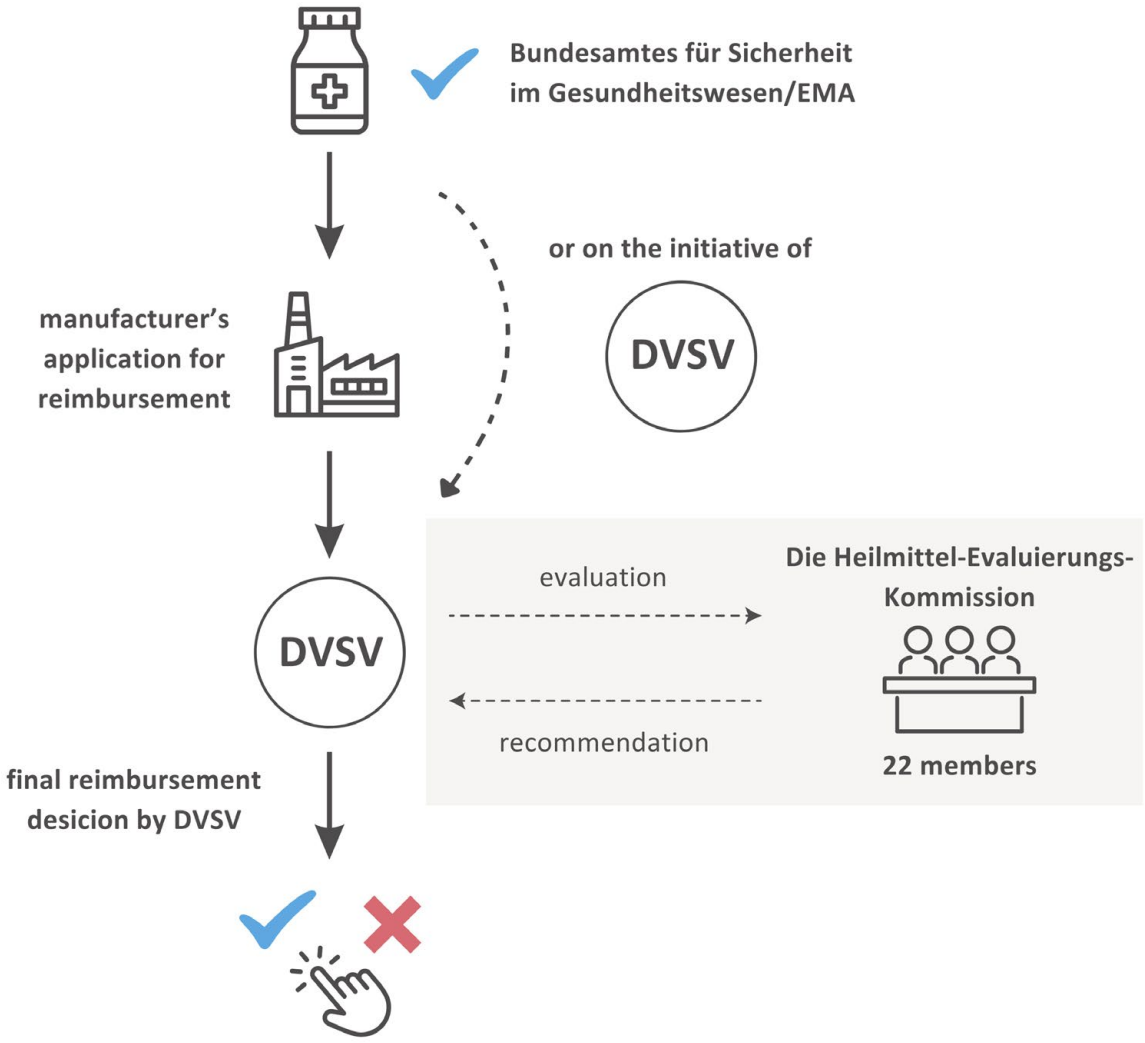
1. § 2 p. 1 Bundesgesetz, mit dem Bestimmungen über Preise für Sachgüter und Leistungen getroffen werden (Preisgesetz 1992).
2. Bundesgesetz vom 9. September 1955 über die Allgemeine Sozialversicherung (Allgemeines Sozialversicherungsgesetz – ASVG.).
3. § 351c. p. (1) leg. cit.
4. § 351c. p. (3) leg. cit.

The committee issues a recommendation regarding including the product on one of the reimbursement lists, and the final decision is made by DVSV. These lists concern prescription drugs, so those used primarily in out-of-hospital treatment. This does not mean, however, that patients cannot receive a given drug in hospital.

The reimbursement list (*Erstattungskodex*) is divided into several categories. The *green group* includes drugs that can be prescribed to patients without restrictions. The *light yellow group* includes medications that can only be prescribed to a patient if specific medical conditions exist. The last, *dark yellow group* includes drugs whose prescription and reimbursement require prior consent of the insurer. Importantly, however, all these drugs are dispensed to patients free of charge (only a fixed administrative fee for filling the prescription is charged).

Inpatient care

In the field of drugs used in hospital treatment, decisions regarding their purchase are made by hospitals. Importantly, the vast majority of Austrian hospitals are publicly owned, mainly by the federal states. Hospital-use drugs are included in the valuation of specific medical procedures under the Austrian hospital financing system, known as LKF (*Leistungsorientierte Krankenanstalten-finanzierung,* Results Driven Financing). The cost of purchasing these drugs should be covered by funds transferred through the system for implementing specific procedures.



Drug reimbursement procedure in outpatient (out-of-hospital) treatment in Austria.

"BGK includes, among others (...) a representative of the umbrella organization of patient organizations (Bundesverband Selbsthilfe Österreich, BVSHOE)."

The Federal Health Agency (*Bundesgesundheitagentur*, BGA), another institution legally affiliated with BMASGK, is responsible for determining the reimbursement of procedures. Specifically, this task is entrusted to the LKF experts group composed of members of the Federal Health Commission (*Bundesgesundheits-kommission*, BGK)[5], a BGA body composed of various stakeholders. BGK includes, among others: representatives of BMASGK, DVSV, Chamber of Employees (*die Arbeiterkammer,* AK) and Chamber of Commerce (*die Wirtschaftskammer Österreich*, WKÖ), Austrian Medical Association (*Österreichische Ärztekammer*) but also a representative of the umbrella organization of patient organizations (*Bundesverband Selbsthilfe Österreich,* BVSHOE)[6]. Drug prices are usually determined based on negotiations between hospitals (specifically, the so-called drug commissions) and drug manufacturers[7]. However, if the sales of a given drug in the system exceed a certain amount per year, the manufacturer is obliged to negotiate the price at the federal level. The price is set by the pricing commission established on the basis of the Price Act. Generally speaking, the reference point in the Austrian pricing system is usually the average price of a given product in the European Union.

Auxiliary institutions

In Austria, there are also public entities supporting the process of health technology assessment and pricing in the field of medicines. First of all, it is the Austrian Institute for Health Technology Assessment (AIHTA). It is a state-owned, non-profit scientific institution that was established on the initiative of the Ministry (BMASGK), the federal states and DVSV[8]. It is primarily responsible for research work and the publication of reports, which, however, do not have to be taken into account *ex officio* when evaluating drugs. Nevertheless, from 2023, the DVSV's Committee for the Evaluation of Therapeutic Products (HEK) is supported by short reports created by AIHTA in the drug evaluation process (so-called *rapid reviews*). AIHTA's opinions are also being requested by the LKF expert group when evaluating the inpatient care medicines and procedures.[9]

Gesundheit Österreich GmbH is also a legally established entity in the system; it is a company whose sole shareholder is BMASGK, to which the Act gives the competence to conduct drug price analysis for the federal pricing commission.

1.4. The place of patient organizations in the legal system

In Austria, patient organizations generally do not have their own specific place in the legal system. They operate on the basis of general regulations regarding social organizations.

Austrian law does not define patient organization, unlike German or Czech solutions. Thus, it does not recognize the unique or expert status of the organization or its representatives. From the legal point of

5. Hagenbichler, E., Das österreichische LKF-System, BMG, 2010.
6. § 30 Vereinbarungsumsetzungsgesetz 2017 - VUG 2017.
7. § 19a Bundesgesetz über Krankenanstalten und Kuranstalten (KAKuG).
8. Goetz, G., et. al., Reimbursement decisions for medical services in Austria: an analysis of influencing factors for the hospital individual services catalogue between 2008 and 2020, BMC Health Services Research volume 22, 2022.
9. Ibidem.

view, in relation to the Ministry of Health, hospitals and insurance organizations, representatives of patient organizations are ordinary natural persons, and the legal status of patient organizations in relation to the above-mentioned entities does not differ from the status of, for example, an organization dealing with environmental protection. However, there are some exceptions.

Regarding patient organizations (*Patientenselbsthilfegruppen*), their mention is primarily found in the Austrian Patient's Charter (*Patientencharta*), which serves as an agreement between the federal state and the Länder. This document highlights the importance of cooperation between regional state patient rights ombudsmen (*Patientenanwälte*, discussed later) and patient self-help organizations.

Patient organizations are also mentioned in one of the key strategic documents in the Austrian health care system, the Federal Act on Partnership-based Health Goals Management (*Bundesgesetz zur partnerschaftlichen Zielsteuerung Gesund-heit*). The document points out the need to cooperate with various interest groups in creating standards of care and treatment, including patient organizations and patient support groups.[10] Attention is also drawn to the need to involve patients themselves in decision-making processes.

The act also mentions the umbrella organization of patient organizations *Bundesverband Selbsthilfe Österreich* (BVSHOE). As mentioned earlier, the association has a seat in the Federal Health Commission responsible for health technology assessment in the inpatient care area as well as for advising the federal and state governments in the area of healthcare.[11]

The another notable exception is the legal status of patient organizations for rare diseases (*Pro Rare Austria*). The association was invited to participate in the commission responsible for developing the Austrian Plan for Rare Diseases. *Pro Rare Austria* had an advisory role during the planning process, and it continue to have the opportunity to participate in the committee overseeing the plan's implementation.

Typically, under the current legal framework, the influence of patient organizations on the legislative and decision-making processes relies heavily on the reputation of the respective organization and its effective engagement in public relations activities, rather than being determined by specific statutory regulations.[12] Public administration bodies may independently invite representatives of patient organizations to participate in various advisory bodies. This occurred, for instance, in the case of the recent Austrian Oncology Plan, where a patient representative is a member of the coordination committee.[13]

1.5. Patient advocacy opportunities in Austria

In Austria, several tools are at the disposal of patient advocates to effectively influence the legislative and decision-making processes. While certain tools are exclusive to organizations focusing on rare diseases, the majority are accessible to any organization or resident of the country.

10. § 6 p. (2) Bundesgesetz zur partnerschaftlichen Zielsteuerung-Gesundheit.
11. § 30 leg. cit.
12. In-depth interviews with Claas Rohl & Elisabeth Weingand, Pro Rare Austria, 16/08/2023.
13. Mitglieder des Onkologiebeirates des Bundesministeriums für Soziales, Gesundheit, Pflege und Konsumentenschutz, 3. Funktionsperiode 2021 – 2025.

1.5.1. Specific framework

Rare Diseases Council

Austrian national plan for rare diseases (*Nationaler Aktionsplan für seltene Erkrankungen,* NAP.se) was implemented in 2015[14] as a BMAGSK's publication. Its goal is to significantly improve the diagnosis and treatment of people with rare diseases. Patient representatives were involved in its creation process from the very beginning.[15] Currently, the plan is coordinated by the National Office for the Implementation and Monitoring of the Rare Diseases Plan (*Nationale Büro für die Umsetzung und Weiterführung des NAP.se*), which is based at the Medical University of Vienna. The implementation of the plan is supervised by the ministry (BMAGSK).

Importantly, however, the role of the Austrian umbrella association of patients with rare diseases is clearly defined in the plan itself, and the organization (*Pro Rare Austria*) is mentioned there by name. Pro Rare Austria is an active and professional patient organization, operating since 2011, which has a major influence on state policy regarding patients with rare diseases.

Pro Rare Austria members are delegated to the Rare Diseases Advisory Council (*Beirat für seltene Erkrankungen*), which is the advisory body of BMGASK for the implementation and monitoring of the Rare Disease Plan. In addition to patient representatives, it includes experts in the health care system, doctors and representatives of the umbrella organization of social insurers (DVSV). The meeting is chaired by a representative of BMGASK. The Council meets twice a year and provides a platform for exchanging opinions on the situation of patients with rare diseases.

In practice, this gives organizations of patients with rare diseases, through contact and agreement with *Pro Rare Austria*, the opportunity to submit their own comments on the implementation of the plan for rare diseases.

Patientenanwälte

The Charter of Patients' Rights mandates the presence of an independent patient ombudsman (*der Patientenanwalt*, plural: *Patientenanwälten*) in each federal state. These officials de facto serve as regional (state) patient rights ombudsmen. Their primary responsibilities include investigating patient and family complaints, identifying shortcomings in healthcare, and providing information to patients. They also generate reports on healthcare quality, which are presented to regional authorities. In practice, their activities predominantly revolve around these two areas.

As such, Austrian *Patientenanwälten* can serve as partners for patient organizations, especially concerning individual patient matters at the state level. This includes addressing issues related to access to treatment at the hospital level, such as situations where a hospital denies treatment or medication to a patient or unlawfully refuses services to a specific group of patients.

Additionally, the provisions of the Patient's Charter grant them intriguing opportunities in terms of influencing the legislative or law-making process. Firstly, regional patient rights ombudsmen are obligated to collaborate with patient organizations. The necessity for such cooperation is explicitly stated in the Patient's Charter: *The independent patient representatives must seek cooperation with patient self-help groups that represent patient interests*[16]. The quote leaves no doubt that state advocates should establish agreements with

14. Fröschl, B., Gaiswinkler, S., Evaluierung des NAP für seltene Erkrankungen, Gesundheit Österreich, Wien 2020, p. 5.
15. Ibidem.
16. § 29 p. (2) Vereinbarung zur Sicherstellung der Patientenrechte (Patientencharta).

patient organizations and cooperate in representing patients.

> **"Firstly, regional patient rights ombudsmen are obligated to collaborate with patient organizations."**

What is additionally worth noting, *Patientenanwälten* can also submit comments on legislative proposals, both at federal and state levels. The regulations also mention giving opinions in the decision-making process: *It must be ensured that independent patient representatives are given the opportunity to give their opinion before making decisions on fundamental general patient-relevant questions.*[17]

The structure of the agreement does not limit this right only to matters of regional scope. The desire to implement the assumptions of this provision is most likely also due to the recent change in federal legislation: from 2023, one of the representatives of *Patientenanwälten* may sit on the DVSV's Committee for the Evaluation of Therapeutic Products. He can express his opinion, but has no right to vote. Representative of this group also has a seat in the *Bundesgesundheitskommission*.

It therefore seems that *Patientenanwälte*n are potential partners for patient organizations. A dialogue with them initiated by the organization may positively contribute to the situation of patients with certain diseases.

Federal Health Commission

In Austria, one of the key elements influencing the shape of law and decisions in healthcare is the concept of health goals (*Gesundheitsziele*). Their implementation remains the responsibility of the federal government, the federal states, and public insurers. The implementation of these established healthcare goals is supervised by the Federal Goals Control Agency *(Die Bundes-Zielsteuerungskommission*).

The Act on Goals in Healthcare (*Gesamte Rechtsvorschrift für Gesundheits-Zielsteuerungsgesetz*) grants the authority to create these goals to the *Bundes-gesundheitsagentur* (BGA), another institution legally related to BMASGK (as mentioned earlier in this report). Similar to drug reimbursement in the LKF system, this task is entrusted to members of the Federal Health Commission (*Bundesgesundheits-kommission*, BGK). Members of the BGK are, among others, a representative of the umbrella patient organization BVSHOE (as described in the section below) and a representative of *Patientenanwälten*.

As a result, patients are effectively represented both directly through the participation of a representative from the umbrella organization and indirectly through the involvement of a representative of *Patientenanwälten* in this body, which plays a role in the development of the Austrian healthcare system.

17. § 30 p. (2) leg. cit.

1.5.2. General administrative framework

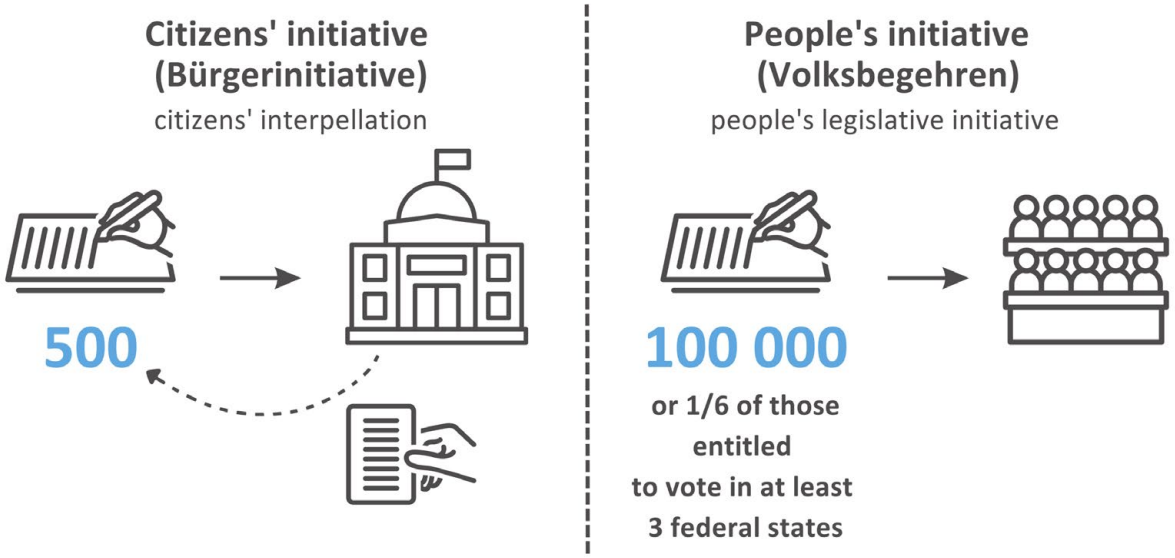
Patient organizations in Austria, in their advocacy activities, can use several tools available to all citizens.

Citizens' interpellation

Citizens' Initiative (*Bürgerinitiative*) gives a group of citizens the opportunity to submit an interpellation – like question to the National Council[18]. To submit such a request, 500 signatures from citizens are needed. Its scope is limited to matters falling within the executive competences of the federal government, including health care issues. Most importantly, the National Council processes such an inquiry in the same way as questions submitted by members of the Council. As a result, citizens are guaranteed to receive an answer to their question. These replies are usually prepared by the relevant ministries and forwarded to the Parliamentary Directorate (*Parlamentsdirektion*), which informs the representative of the signatories about how the matter has been concluded. This tool appears to be available to almost all patient organizations. Collecting 500 signatures with approximately 100 people subscribed to the newsletter or having the status of a member of the organization does not seem to be a problem, and in return patient representatives get a guarantee that they will receive the position of the federal government on a given issue.

People's legislative initiative

People's initiative (*Volksbegehren*) is one of the constitutional ways of submitting bills to the Austrian parliament. Similarly to citizens' legislative initiatives, it is required to collect an appropriate number of signatures. In Austria, it is 100,000 signatures or signatures of at least 1/6 of those entitled to vote in at least 3 federal states. This is a tool that requires an extremely efficient organization that will promote the idea among the public and organize the logistics of the collection. However, taking into account the success of similar initiatives in various European Union countries, it seems that this tool may be used by the largest patient organizations in media matters regarding



Comparison of citizens' initiative (Bürgerinitiative) and People's initiative (Volksbegehren) in Austria.

18. §100 to 100d Bundesgesetzes über die Geschäftsordnung des Nationalrats (Geschäftsordnungsgesetz 1975).

treatment and social care services that affect a large part of society, e.g. people with disabilities. The mere registration of the initiative and the resulting media response may have a positive impact on the case.

Public consultations

Austrian citizens have the opportunity to submit comments on draft laws processed by parliament. Importantly, this option is also available to legal persons, i.e. companies and non-governmental organizations (such as patient organizations). Written comments may be submitted to all draft laws processed in parliament (including selected pre-parliamentary drafts). This possibility exists until the parliament closes the proceedings on the act. Opinions are published, but the legislator is not obliged to respond the comments.

Importantly, however, the Patient Charter also mentions the need to listen to the opinions of umbrella patient organizations in the legislative process: *Umbrella organizations of patient self-help groups should be given the opportunity to be heard in the assessment process on patient-relevant draft laws and regulations*[19].

Therefore, when commenting on draft legal acts, it may be worth also referring to this specific although not a completely clear provision.

Access to public information

In Austria, there is a federal act on access to information (*Informationsweiterver-wendungsgesetz*), which regulates the obligations of public administration bodies in the field. Thanks to this, every citizen can request access to information held by public administration offices (both at the federal and local levels). This is the implementation of the provisions of the European Union directive.

Patient organizations may be primarily interested in statistical issues: the number of patients with a given diagnosis or the amounts spent on treatment or to cover the costs of sick leave. Such data is usually necessary to prepare a convincing letter to the relevant ministry, taking into account the issues of social costs, or to prepare a substantive social campaign regarding access to treatment. Administrative authorities are obliged to respond; however, there are certain restrictions on the data that can be obtained.

Ombudsman Office

Equal access to health care is a right of every Austrian citizen. As a result, health care matters fall under the purview of the Ombudsman Office (*Volksanwaltschaft*). Only natural persons have the right to assert their rights, meaning patient organizations cannot file complaints. However, the complaints procedure enables the resolution of local issues such as access to treatment or delays in administrative proceedings related to benefits for disabled individuals. Additionally, the office can provide assistance to patients facing discrimination based on illness when dealing with government agencies.

19. § 30 p (2) Vereinbarung zur Sicherstellung der Patientenrechte (Patientencharta).

1.5.3. Alternative routes

In Austria, patient organizations have various tools to indirectly influence healthcare legislation and decision-making. This is primarily achieved through collaboration with larger entities, which may not be exclusively focused on healthcare.

Austrian Chamber of Commerce (*Wirtschaftskammer Österreich, WKÖ*)

Members of the Austrian Chamber of Commerce are legally authorized members of both the inpatient (LKF) and outpatient (DVSV) medical procedure evaluation committees. Obviously, they will primarily represent the interests of their members, but it is worth considering each time whether the interests of the patient organization in a given case are consistent with the interests of the Chamber. In such a situation, you may consider joining forces while maintaining full transparency of activities.

> **"(...) patient representatives may consider staying in touch with the Association of Entrepreneurs in the Health Industry (Fachverband der Gesundheitsbetriebe) operating within the WKÖ."**

Constant communication between the patient organization and the responsible employee of the Chamber may help for this purpose. In particular, patient representatives may consider staying in touch with the Association of Entrepreneurs in the Health Industry (*Fachverband der Gesundheitsbetriebe*) operating within the WKÖ.

Chamber of Employees (*Arbeiterkammer, AK*)

Similarly to the Chamber of Commerce, members of the Chamber of Employees have seats on both the LKF and DVSV's drug committees. It should also be remembered that the AK has the statutory right to express opinions on draft laws in the law-making process in Austria. It can be assumed that comments submitted by the AK will be analyzed more carefully than comments submitted by an individual citizen or a small organization. Taking into account its area of operation, the AK may also issue opinions on laws related to the health care system. While it is obvious that the interests of employees as an extremely broad social group will be crucial for AK, it should be remembered that they will often coincide with the interests of the patient organization. The introduction of an innovative treatment method for a specific group of people, which significantly increases their quality of life, is also an investment in the employee's well-being. This is particularly important in the case of population diseases such as cardiovascular diseases and cancer.

Members of federal parliament

Cooperation with members of the federal parliament is one of the elements of the strategy of many patient organizations. It is no different in Austria – members of the National Council have, among others, the right to submit parliamentary interpellations, i.e. questions addressed to the federal government. There is a Health Committee in the Austrian National Council (*Gesundheitsausschuss*), where draft laws relating to health care are discussed. Both the composition and meetings of the committee are, of course, fully public.

Members of the National Council may receive guests at their offices in the constituencies, but also at the parliamentary seat in Vienna, after prior arrangement with the staff of the office of a given MP. It should be remembered that legislative initiative in Austria is not only the domain of the government or the Federal Council, but also of a group of 1/3 of the members of the National Council. Therefore, submitting a non-partisan, politically neutral and pro-social project has a chance to

become a grass-roots initiative. Patient organizations may consider maintaining transparent relations with MPs sitting on the Health Committee (and the staff of their offices), as these people have a significant influence on the final shape of legal acts in the area of health care.

From the point of view of patient advocacy, the second chamber of the Austrian parliament, the Federal Chamber, is much less important.

Pro Rare Austria

The non-profit organization (association) mentioned earlier in this chapter, which brings together 97 Austrian organizations representing various rare diseases. This is a very dynamic association (organization of organizations) that effectively promotes the interests of patients with rare diseases.

Importantly, *Pro Rare Austria* has a formalized position within the Austrian National Plan for Rare Diseases. It is indicated there as a partner of public administration bodies in the implementation of some of the plan's assumptions. In addition, *Pro Rare Austria* may delegate a member to the meetings of the Rare Diseases Advisory Council (*Beirat für seltene Erkrankungen*), which coordinates and supervises the implementation of the Plan.

"(...) Pro Rare Austria may be considered as an ally in the fight for the rights of people with rare diseases in Austria (...)."

The National Plan for Rare Diseases is a roadmap used in European Union countries, which contains regulations regarding the health care system. It includes, among others: about access to treatment, social care services, patient registers and the way of organizing the system of hospital expert centers. Therefore, the fact that the patient organization has an influence on the content and method of implementing the plan's assumptions is extremely important.

Therefore, *Pro Rare Austria* may be considered as an ally in the fight for the rights of people with rare diseases in Austria, and other organizations can gain a lot by exchanging knowledge with the association's authorities.

Bundesverband Selbsthilfe Österreich (BVSHOE)

It is an independent non-profit organization (association) that brings together various patient organizations operating in Austria. In practice, it is a pre-sole organization that tries to represent the interests of all patients in the country; both at federal and regional levels. The members who, according to the statute, have an influence on the decisions of the general meeting are patient organizations with legal personality – so it is a classic organizational structure. Importantly, representatives of other federal umbrella organizations with a broad therapeutic scope (including the previously discussed *Pro Rare Austria*, which, however, remains a partner of BVSHOE) cannot sit on the organization's management board.

The financial organization comes from state sources - it is supported by the ministry (BMASGK) and the umbrella organization of insurers (DVSV). As of the date of completion of this report, the association consisted of 25 organizations, including umbrella organizations, the vast majority representing non-rare diseases (like obesity, epilepsy or kidney diseases).

Importantly, this organization is the only patient organization that has a representative in the Federal Health Commission, the public administration body discussed earlier, which has an impact on the situation of patients in Austria. It seems that the mediation of BVSHOE is of particular importance in cases of diseases that do not meet the definition of a rare disease.

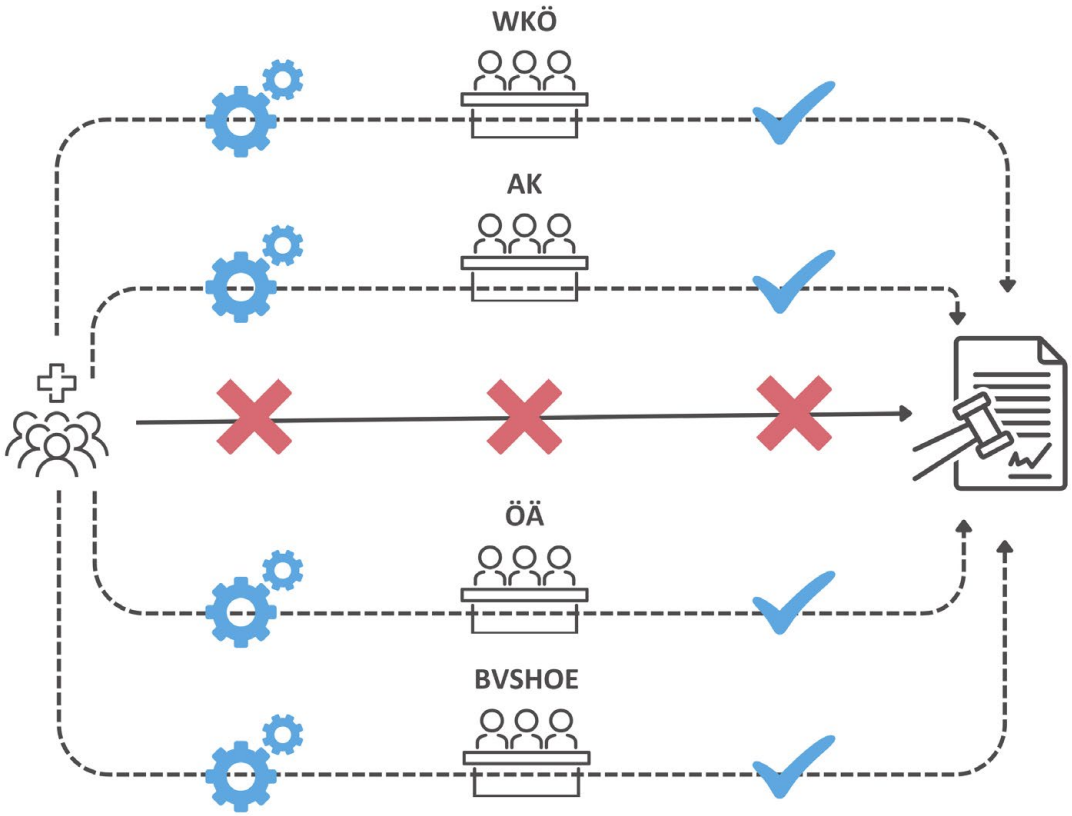
Austrian Medical Association *(Österreichische Ärztekammer, ÖÄ)*

The Austrian Medical Association is an institution of a mandatory self-governing association of doctors. And although its tasks include primarily self-regulation of the medical community, ensuring standards and representing the interests of doctors as an community, it is included in the decision-making processes of some importance for patients. This concerns primarily the process of determining the valuation of medical procedures by individually practicing physicians and participation in the work of the Committee for the Evaluation of Therapeutic Products (HEK).

However they also negotiate the rates for medical services of individually practicing physicians with the public insurers. It does not concern medicines, but e.g. reimbursement estimates for visits or outpatient procedures – while this has an impact on the financial condition of the system, for advocates representing specific communities it is not an important area for activity. Nevertheless, patients are in no way formally present in this process.

ÖÄ's participation in the drug reimbursement process at DVSV, where this organization has the right to vote on the HEK committee, is undoubtedly more important. The representative of ÖÄ in the committee takes into account primarily the interests of doctors as a community, however, it seems likely that doctors will understand arguments of a medical nature and those related to patients' experiences, hence close cooperation with the medical community, including ÖÄ, may have positive impact on achieving the goals of patient organizations.

The situation is similar with the Austrian Chamber of Pharmacists (*Österreichische Apothekerkammer*), whose representative is also present in the HEK and BGK.



Indirect influence of patient organizations on healthcare legislation and decision-making in Austria.

1.6. Summary

Although patient organizations in Austria are not embedded in the national legal system in a coherent and orderly way, they have some opportunities to operate at the federal level. According to the authors of the report, this is mainly due to the maturity of Austrian civil society and the changing awareness of decision-makers who are beginning to notice that the patient's voice is crucial in the context of organizing the health care system.

Unfortunately, however, there are areas where the voice of patients is basically absent. First of all, his is the area of health technology assessment, where only recently, and mostly indirectly, patient representatives can have an advisory voice. However, there are examples of inviting patient organizations to formal advisory bodies, like the Oncology Council, or positioning their representatives *ex lege* in the steering committees, like in the area of rare diseases or in the *Bundesgesunsheits-kommission*.

Nevertheless, the catalog of available measures that can be used by patient organizations is quite wide. Cooperation with other entities seems to be important. In terms of the specific framework, patient representatives may take into consideration cooperation with the state patient ombudsmen and large umbrella organizations such as Pro Rare Austria or BVSHOE.

The key difference between the Austrian *Patientenanwälten* institution and the legal position of patient ombudsmen in other countries in the region is that the ombudsman is legally obliged to seek agreement with umbrella patient organizations. Moreover, it is also unusual that state ombudsmen are encouraged by the legislator to submit comments on draft health care bills and participate in meetings of decision-making bodies regarding the reimbursement of drugs and medical procedures.

In the general administrative area, it is worth noting the relatively small number of signatures that are necessary for a group of citizens to submit an interpellation to the Parliament. This allows for an official, formal dialogue with the government. It is worth noting the existing regulations regarding the transparency of public data – by accessing public information, organizations can obtain a lot of extremely valuable data, especially regarding the social costs of diseases.

When it comes to the alternative routes, the Chamber of Labor and the Chamber of Commerce have a strong position, resulting from both law and tradition. From the point of view of the patient organization, they may be interested in looking for common points in the activities of these chambers in the area of health care – undoubtedly, some initiatives, especially those positively affecting public health, can be supported by the Chambers. Similar situations occur in various European countries, where Chambers support access to innovative therapies, and on the other hand, employee associations promote solutions that improve the quality of life of working people, especially in the context of treatment of lifestyle diseases. Cooperation with physicians is always important, but the Austrian Medical Association has a certain legal position in the area of medicine reimbursement; the same situation is with the Chamber of Pharmacists. Multi-channel advocacy, aimed at those who have a real influence on the decision making processes, seems to be the key to success.

Austria lacks many specific legal tools for patient advocacy, but existing laws allow patient representatives to reach out with their voice both to parliamentarians creating laws and to bodies making decisions regarding treatment. These possibilities are limited, but it seems that each year there are a little more of them and there is a slow change in the awareness of decision-makers and a drift towards a patient-centric system.

Czech Republic

2. Czech Republic

2.1. The healthcare system in Czech Republic

According to the Charter of Fundamental Rights and Freedoms[20], which is a component of the Czech constitutional order, every citizen has the right to health care. Additionally, under social insurance, Czech citizens are entitled to free health care and medical assistance, subject to conditions established by law.[21]

The Ministry of Health serves as the central administrative body responsible for managing the Czech healthcare system. It establishes and supervises health policy, develops draft laws, and formulates other legal provisions in this area. Additionally, the Ministry oversees health care entities, including public hospitals and the State Institute for Drug Control (*Státní ústav pro kontrolu léčiv, SÚKL*).

SÚKL's responsibilities include ensuring the safety and quality of pharmaceutical products and medical devices. Among its duties are the registration of medicines, medical devices and aids, setting maximum prices and reimbursements for medicines covered by statutory health insurance, and managing reimbursement procedures for medical devices and aids.

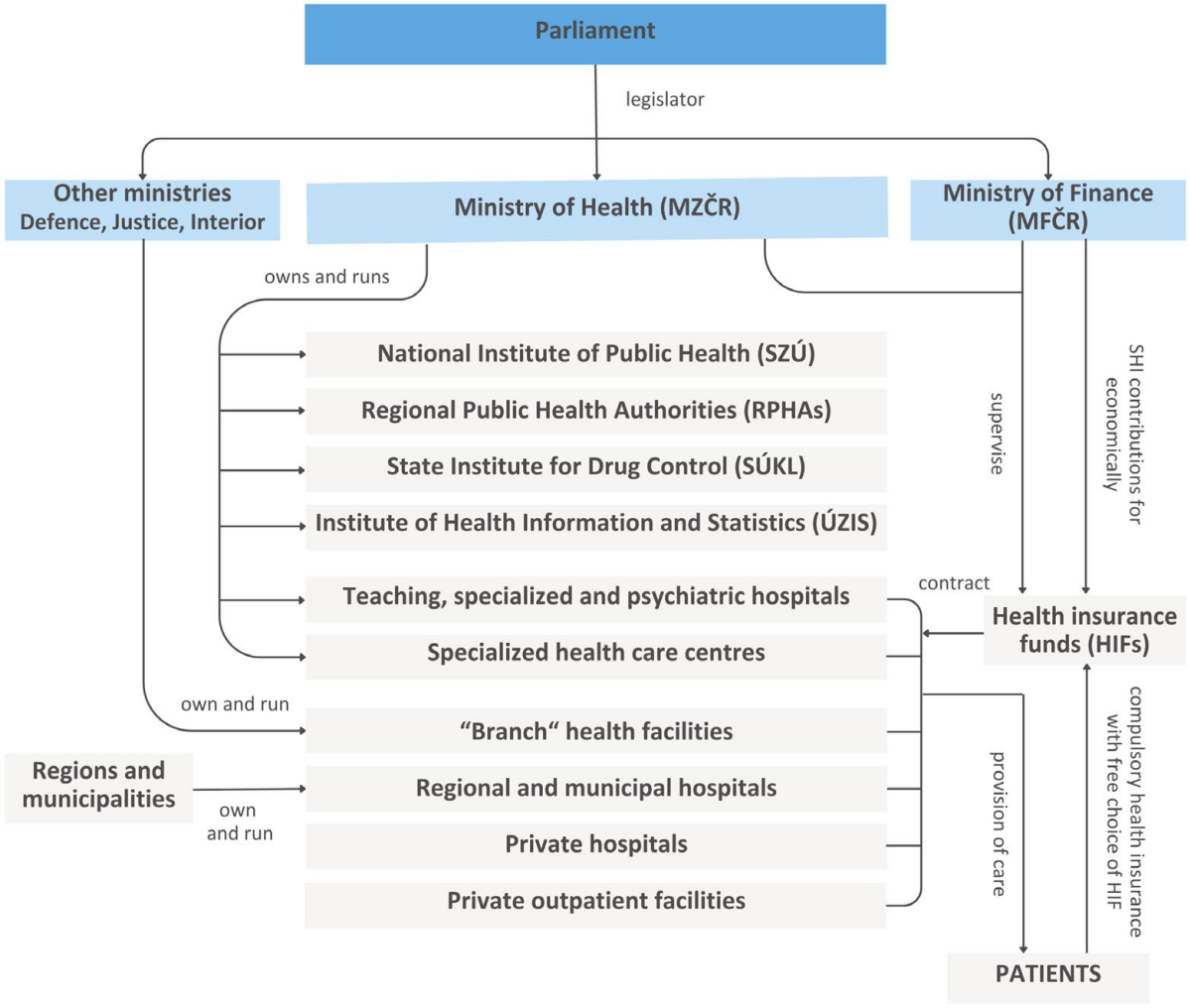
Regional authorities also play a significant role in the healthcare system. They manage their own healthcare facilities, register private facilities, coordinate emergency care, and develop regional healthcare concepts.

The Czech healthcare system is financed through a universal health insurance scheme, mandating compulsory membership in one of the health insurance institutions (*Zdravotní pojišťovna*). This applies to all Czech citizens residing in the country, including the self-employed. It also includes permanent residents and most foreign temporary residents. A significant portion of society, such as students, retirees, or the unemployed, are exempt from paying compulsory social security contributions. For these 'economically inactive' groups, the state covers their contributions.

20. Listina základních práv a svobod.
21. Art. 31 Listina základních práv a svobod.

There are seven health insurance companies in the Czech Republic, which are quasi-public, self-governing bodies that, on the one hand, collect health insurance premiums from payers and, on the other hand, pay health services to healthcare providers. They operate on a non-profit basis and are obligated to provide health services to every public health insurance policyholder. Individuals have the freedom to choose their health insurance companies and healthcare providers. The use of risk assessment mechanisms and the refusal of insurance based on these assessments are prohibited. The largest of these institutions is the General Health Insurance Company (*Všeobecná Zdravotní Pojišťovna, VZP*).

In the Czech Republic, there is also a system of voluntary health insurance. However, its role is relatively minor due to the extensive range of services covered by the general health insurance (which covers both inpatient and outpatient care, prescription drugs, selected dental procedures, rehabilitation, spa treatments, over-the-counter drugs and long-term care timely services provided in hospitals).[22,23]



The healthcare system in Czech Republic.
[source: Bryndová et al., 2023]

22. Vostalová, L., Mazelová, J., Samek, J., Vocelka, M., Health Technology Assessment in Evaluation of Pharmaceuticals in The Czech Republic, International Journal of Technology Assessment in Health Care, 33:3 (2017), 339–344.
23. Bryndová, .L, Šlegerová, L., Votápková, J., Hrobon, P., Shuftan, N., Spranger, A., Czechia: Health system review. Health Systems in Transition, 2023; 25(1): i–183.

2.2. Creation of the healthcare law

In the Czech Republic, legislative power is vested in a bicameral parliament, which consists of the *Poslanecká sněmovna* (the lower house) and the *Senát* (the upper house), while executive power is held by the president and the government. According to the Constitution, the right to submit a bill may be exercised by a member of parliament, a group of deputies, the Senate as a whole, the government, or a representative of a higher local government unit, such as the capital city of Prague or a region.[24]

The President of the Czech Republic appoints the Prime Minister and, upon his request, the other cabinet members, whom he entrusts with the management of specific ministries and offices. These ministries are responsible for preparing draft laws and other legal provisions related to matters within their jurisdiction. They also prepare drafts commissioned by the government.[25]

The hierarchy of legal acts is determined by the status of the bodies authorized to issue them. At the top are the constitutional laws (*ústavní zákony*) issued by the parliament, followed by standard laws (*zákony*) and legal measures (*zákonná opatření*). Next in this hierarchy are government regulations (*nařízení vlády*), which are implementing regulations for laws, issued without direct authorization in the law itself. Below these are decrees (*vyhlášky*) issued by ministries and other central administrative authorities as executive acts to laws, enacted after being directly authorized by law.[26,27]

2.3. The place of patient organizations in the legal system

The Czech legal system is unique in the context of patient organizations in that it defines a patient organization within a legal act, thereby recognizing the distinct and expert status of both the organization itself and its representatives. This definition is found in § 113f of the Act on Health Services and the Conditions for their Provision (*Zákon č. 372/2011 Sb. o zdravotních službách a podmínkách jejich poskytování*). According to this Act, a patient organization is defined as a registered association (*spolek*), an institution (*ústav*), or a public benefit society (*obecně prospěšná společnost*), primarily engaged in assisting patients and protecting their rights and interests. Its members typically include individuals with a specific disease or disability, their relatives, or their representatives as defined in the Czech Civil Code. These members have a decisive (in the case of *spolky*) or a clearly decisive (in the case of *ústav* and *obecně prospěšná společnost*) influence on the organization's management. Furthermore, a patient organization can also be an association (*spolek*) whose members are other associations (*spolky*) that meet these criteria and elect members of its statutory body.

The Ministry of Health maintains a List of Patient Organizations (*Seznam pacientských organizací*) comprising those that have applied for inclusion and meet the conditions. These organizations are required to publish their

24. Art. 15 (1), art. 54 (1), art. 67 (1) and art. 41 (2) Ústava České republiky.
25. § 24 Zákon č. 2/1969 o zřízení ministerstev a jiných ústředních orgánů státní správy České socialistické republiky.
26. N-Lex, About the national database: Czech Republic [online] Available at: https://n-lex.europa.eu/n-lex/info/info-cz/index?lang=cs [30.01.2024].
27. Information system of Masaryk University, Teaching material for the subject AEB_34 [online] Available at: https://is.muni.cz/el/1421/podzim2013/AEB_34/Uvod_do_prava.pdf [23.01.2024].

financial reports and sources of financing on their website. Additionally, they must have been actively involved in assisting patients and protecting their rights and interests for at least 12 months immediately preceding the date of their application submission. The List of Patient Organizations is published on the website of the Ministry of Health. As of the date of this report's preparation, there were 41 organizations on the list that met the statutory definition.[28]

> **"The Czech legal system is unique in the context of patient organizations in that it defines a patient organization within a legal act, thereby recognizing the distinct and expert status of both the organization itself and its representatives."**

Being included on the aforementioned list may be an opportunity for patient organizations, particularly in terms of their representatives' participation in processes such as the reimbursement procedure for drugs for rare diseases. Inclusion on this list is a necessary prerequisite for being recognized by the State Institute for Drug Control (SÚKL) as a participant in the first stage of the reimbursement procedure for medicines for rare diseases. Additionally, it qualifies an organization to potentially become a member of the advisory body of the Minister of Health. This body assesses the reimbursement of medicines for rare diseases at the second stage (further details on the reimbursement procedure for drugs for rare diseases will be provided later in the report).

At the same time, it should be emphasized that, in addition to the List of Patient Organizations (*Seznam pacientských organizací*), there is also a Catalog of Patient Organizations (*Rozcestník organizací pro pacienty*)[29], and these are two distinct databases.

Being included in the Catalog of patient organizations does not guarantee an organization's inclusion on the List of patient organizations. To be added to the List, an organization must submit an application for registration and fulfill the legal requirements stipulated in the act. The Catalog primarily serves to inform the public about organizations that assist patients, and currently, there are no specific conditions for entry into this database. Similar systems are in place in other countries within the region; for example, the inclusion of a patient organization in the Polish directory does not confer any special privileges. Therefore, the distinction between the Czech List and the Catalog, and the statutory regulation of the List, are of significant importance.

2.4. Patient advocacy opportunities in Czech Republic

In the Czech Republic, over the last 10 years, there has been a noticeable increase in activities aimed at strengthening the involvement of patient organizations and patients in decision-making processes. The Ministry of Health plays an active role in this effort by creating special bodies that include patient representatives. Significant changes in legal regulations have been made, enabling patient representatives to gain a strong legal position with voting rights. One of the objectives outlined in the Strategic Framework for Healthcare Development in the Czech Republic until

28. Seznam pacientských organizací [online] Available at: https://pacientskeorganizace.mzcr.cz/index.php?pg=pacientske-organizace--seznam-pacientskych-organizaci [23.01.2024].
29. Rozcestník organizací pro pacienty [online] Available at: https://pacientskeorganizace.mzcr.cz/index.php?pg=hledam-organizaci--databaze [23.01.2024].

2030, created by the Ministry of Health, is "Strengthening the segment of patient organizations and patient aid organizations".[30] Patient advocates in the Czech Republic have access to a number of tools that enable them to effectively influence – directly or indirectly – law and decision-making processes.

2.4.1. Specific framework

Decision-making process regarding the reimbursement of drugs

Until the end of 2007, the Minister of Health was the authority responsible for issuing decisions on drug reimbursement, while the Minister of Finance was responsible for setting their maximum prices. However, from January 2008, these responsibilities were taken over by the State Institute for Drug Control (SÚKL). SÚKL is now responsible for setting maximum drug prices and making reimbursement decisions, acting under the Act on Universal Health Insurance and amending certain related acts (*Zákon č. 48/1997 Sb., o veřejném zdravotním pojištění a o změně a doplnění některých souvisejících zákonů*, hereinafter referred to as the Health Insurance Act). SÚKL's responsibility is limited to the reimbursement of outpatient drugs. It is not authorized to make decisions in this respect regarding inpatient drugs, because inpatient drugs only require price regulation, and the amount of reimbursement is agreed individually with the insurance funds. Regarding the setting of maximum drug prices, SÚKL's competencies cover drugs intended for both outpatients and inpatients.

The Health Insurance Act stipulates separate requirements for applications concerning the setting of a maximum price and/or reimbursement, depending on whether the drug is generic or original. Pricing and reimbursement proceedings are treated as individual administrative processes. The entity authorized to apply for price determination or reimbursement is either the marketing authorization holder (who is obliged to pay a fee for the application) or the health insurance institution. They must provide the required documentation, including clinical documentation that describes the effectiveness and safety of the drug, as well as economic documentation, which analyzes cost-effectiveness and the budgetary impact. Decisions on price or reimbursement are made within 75 days (or 165 days for joint applications). Since 2012, a shorter, 30-day procedure has been available for generic and biosimilar medicines. SÚKL issues an evaluation report based on which the applicant can submit comments. Then, if the comments are considered significant, SÚKL issues another evaluation report or a final decision. After the decision is issued, the applicant may appeal to the Ministry of Health.[31,32]

30. ZDRAVÍ 2030. The Strategic Framework for Healthcare Development in the Czech Republic until 2030 [online] Available at: https://www.dataplan.info/img_upload/7bdb1584e3b8a53d337518d988763f8d/strategic-framework-for-health-care-development-in-the-czech-republic-until-2030.pdf [23.01.2024].
31. SÚKL – Regulation of prices and reimbursements for pharmaceuticals. Pricing and reimbursement - general information 2018.
32. Skoupá, J., Drug Policy in the Czech Republic, Value in Health Regional Issues, Volume 13, September 2017, p. 55-58.

"What makes this regulation unique, and a potential role model for other countries, is the strong involvement of patient organization representatives throughout the entire process. For orphan drugs, this new approach allows patient organizations to have a say in the administrative procedure aimed at setting prices and reimbursement rates."

Until 2022, there were no separate legal regulations specifically for orphan drugs in the Czech Republic. However, as of January 2022, changes in this area have come into effect. These changes define a specific process for assessing and approving the reimbursement of medicinal products intended for the treatment of rare diseases from public health insurance. What makes this regulation unique, and a potential role model for other countries, is the strong involvement of patient organization representatives throughout the entire process. For orphan drugs, this new approach allows patient organizations to have a say in the administrative procedure aimed at setting prices and reimbursement rates[33].

The decision-making process in the Czech Republic for the reimbursement of drugs for rare diseases consists of two stages: the first is conducted by SÚKL, and the second by the Ministry of Health. At both stages, representatives of patient organizations are strongly involved.

The first stage of proceedings, conducted by SÚKL, is initiated upon the request of marketing authorization holders or insurance companies. Upon receiving such a request, SÚKL begins administrative proceedings. The participants in these proceedings include the requesting insurance company or marketing authorization holder, a professional association of experts (doctors) specializing in the treatment of the specific rare disease that could be affected by the assessed product, and patient organizations that meet the statutory definition and represent patients suffering from diseases that may be impacted by the medicine under evaluation.

Participants in the proceedings, including patient organizations, have the opportunity to submit evidence and make other statements within 30 days from the initiation of the proceedings. At this stage, patient organizations act as the voice of patients suffering from rare diseases for whom the orphan drug is intended. They usually maintain direct contact with individuals affected by a given disease, understand their needs, and are familiar with their experiences. Their participation contributes valuable insights on the drug's effectiveness, side effects, and impact on patients' quality of life.

Subsequently, within 110 days from the commencement of the proceedings, SÚKL issues an evaluation report. This report includes information on, among other things, the effectiveness and safety of the evaluated medicinal product, the rare disease it is intended to treat, the current methods of treating this disease, and the impact of treatment with the evaluated product on the quality of life of patients.

Participants, which again include patient organizations, have the right to submit comments on the evaluation report within 15 days. SÚKL may then revise the report based on these comments. Following this, the evaluation report is submitted to the Minister of Health, who is responsible for the second stage of the procedure regarding the reimbursement of drugs for rare diseases.

The Minister of Health evaluates the evaluation report and issues an opinion that is binding on SÚKL. For this purpose, the Ministry of Health has established an advisory body for the reimbursement of medicines intended for the treatment of rare diseases

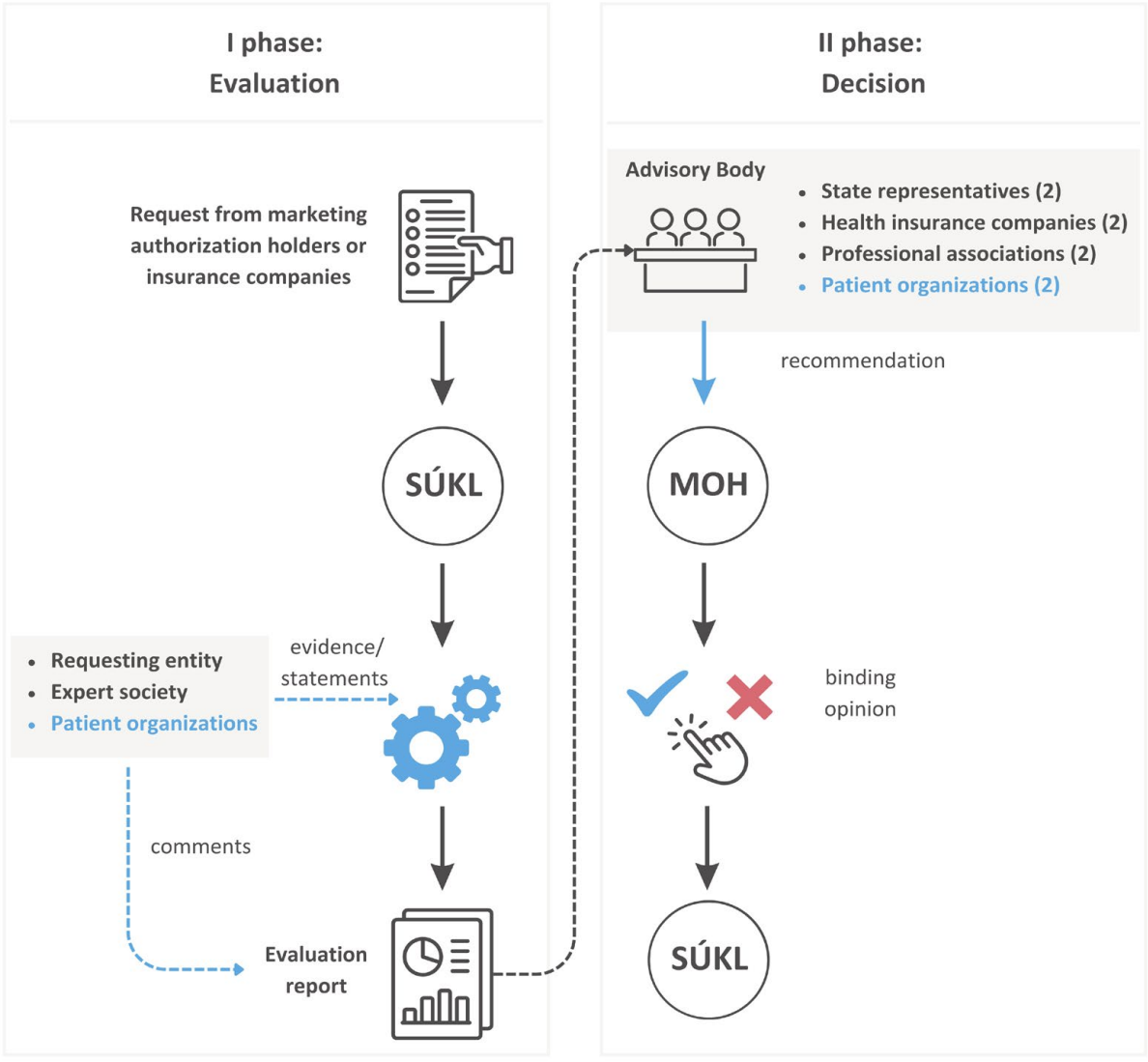
33. § 39da Zákon č. 48/1997 Sb., o veřejném zdravotním pojištění a o změně a doplnění některých souvisejících zákonů.

(*Poradní orgán pro úhradu léčiv určených k léčbě vzácných onemocnění*). Members of this advisory body are appointed and dismissed by the Minister of Health, and their term of office lasts for three years.

"(...) in the Czech Republic, patient organizations not only have a place in the reimbursement process for drugs for rare diseases but also hold a strong legal position with voting rights."

The advisory body includes state representatives (such as employees of the Ministry of Health or the Ministry of Labor and Social Affairs), representatives of health insurance companies, representatives of professional associations, and representatives of patient organizations as defined by the Act (like those meeting the statutory definition of a patient organization).

For each meeting, 8 people from among the members are always invited – 2 people from each of the four groups. This ensures the absence of conflicts of interest. In practice, this means that, for example, representatives of patients suffering from the disease for which a given medicinal product is intended cannot be invited to discuss a report assessing that specific medicine. This is to ensure that the assessment remains objective.



Decision-making process regarding the reimbursement of drugs in Czech Republic.

The members then vote on the decision and, depending on the results of the vote, the Ministry of Health prepares a binding opinion for SÚKL. This is where a crucial legal distinction compared to regulations in other countries should be noted. For instance, in Poland or Romania, representatives of patient organizations may be invited to participate in some stages of the drug reimbursement process, but they do not have voting rights, and their opinions are not binding on the recommendations of the HTA agency or the ministry. In contrast, in the Czech Republic, patient organizations not only have a place in the reimbursement process for drugs for rare diseases but also hold a strong legal position with voting rights.

As previously mentioned in the section on the legal definition of patient organizations, a priority for Czech patient organizations should be to register on the List of patient organizations (*Seznam pacientských organizací*). This registration is necessary for those who wish to join the advisory body. They must be registered on the List to contact The Patients' Rights Support Department (*Oddělení podpory práv pacientů*) via email. The selection of these individuals is approved by the Patients' Council (*Pacientská rada*), following consultation with the Rare Diseases Czech Republic (*Česká asociace pro vzácná onemocnění*) (both of which are described in detail later in the report). Additionally, individuals who wish to provide evidence or make statements during the creation of an evaluation report by SÚKL must also be included on this List.

When it comes to the participation of patient organizations in Health Technology Assessment (HTA) processes in Central and Eastern Europe (CEE), the situation is not favorable. However, the fact that we can look to the Czech Republic as a role model in this respect should be seen as a significant advantage. Patient advocates from other CEE countries, who are striving for changes in legal regulations within their national systems regarding patient involvement in HTA, may now refer to a relatable example from their region. They can cite the Czech experience instead of examples from countries like the Netherlands or Great Britain, which differ significantly in GDP per capita and political history.

Additionally, this precedent may serve as an example of good practice for Czech patient organizations in fields other than rare diseases, as they advocate for changes in the regulations concerning drug reimbursement for their respective diseases.

The Patients' Council (*Pacientská rada*)

The Ministry of Health actively supports the continuous involvement of patient organizations in decision-making processes. In 2014, the Deputy Minister of Health confirmed that patient organizations are one of the pillars of the healthcare system.[34] In 2015, quarterly meetings for representatives of patient organizations began to be organized. During these meetings, the ministry provided information about current plans and invited representatives from various areas of the healthcare system. Approximately 80 patient representatives participated in each meeting.[35] These events enabled patient organizations to engage in dialogue not only among themselves but also with other interested parties, such as representatives of SÚKL, health insurance companies, and medical associations.

For the sustainability and development of patient participation, it was necessary to create a specialized organizational unit in cooperation with the ministry. Therefore, the Patients' Rights Support Department (*Oddělení podpory práv pacientů*) was first

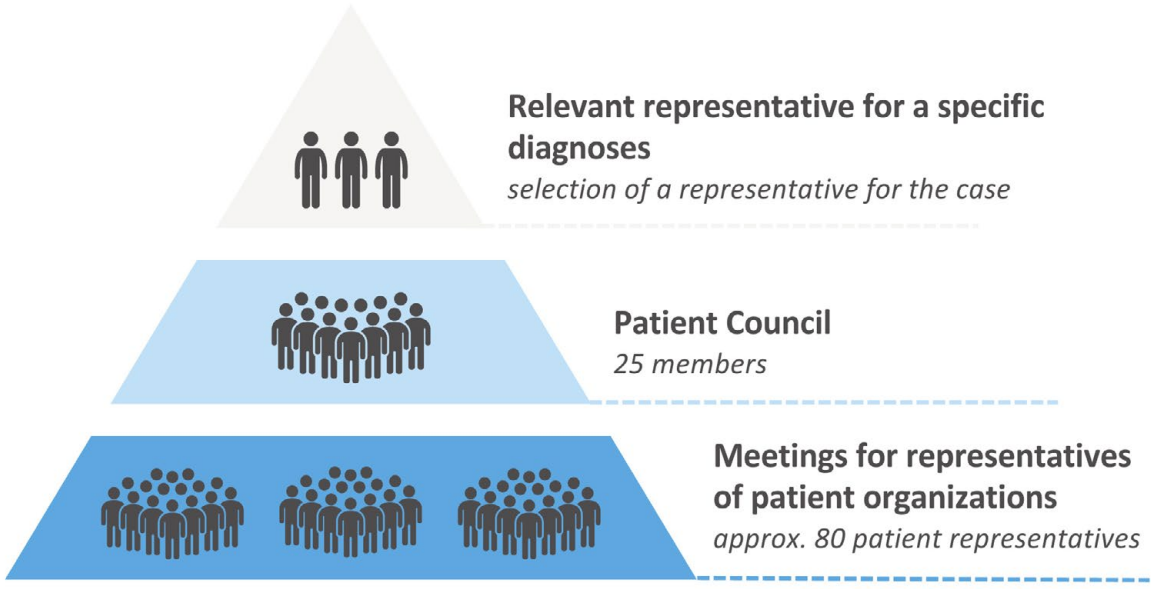
34. Arellanesová, A., Uhlíková, K., Břečťan, R., Národní plán pro vzácná onemocnění na období 2015–2017, ČAVO Zpravodaj 2/2014.
35. Patient organizations in the Czech Republic, Poster Number: #24 [online] Available at: https://pacientskeorganizace.mzcr.cz/res/file/dokumenty/media-poster_aj_final.pdf [23.01.2024].

established within the Law and Legislation Section of the Ministry of Health in July 2017. Subsequently, in October 2017, pursuant to Minister's Decree No. 15/2017 (*Příkaz ministra č. 15/2017*), the Patients' Council (*Pacientská rada*) was established. This body structured patients' activities and strengthened their involvement.

The Patients' Council serves as a permanent advisory body to the Minister of Health. Members are appointed from among patient representatives nominated by patient organizations. The Council is composed of up to 25 members (as at the date of preparation of this report, it includes 24 members). These members are required to meet stringent criteria, with a particular focus on representativeness and achieving a balance among patients with varying diagnoses. The term of office for the members is four years, and the Council convenes at least four times annually.

"(...) the Patients' Council plays an important role in representing patients' interests and influencing the development of health policy. Its ability to comment on draft legislative and non-legislative materials ensures that the patient perspective is considered in the law-making process, which directly impacts patients' health and lives."

The Council aims to "increase the protection of patients' rights". It serves as a mediator between patients and the Ministry of Health, representing the patients' voice within the ministry. Its primary statutory tasks include commenting on draft legal provisions and non-legislative documents relevant to its areas of expertise. Through



Search for the eligible patient representative in Czech Republic.
[source: Portál pro pacienty a pacientské organizace, Patient organisations in the Czech Republic: Poster Number: #24]

the Patients' Rights Support Department, The Patients' Council participates in the Minister of Health's internal arrangement procedures and in inter-ministerial arrangement processes. It also proposes the development, modification, or revision of legal provisions and other non-legislative materials, particularly in areas concerning the implementation of patient rights. The Patients' Council suggests the inclusion, modification, or removal of treatments, medical devices, or medicinal products from public health insurance reimbursement. Additionally, it initiates and engages in discussions on topics related to healthcare provision, patient needs, prevention, and actively participates in activities that promote health education.

The Council acts as a collegial body and expresses its opinions through resolutions adopted in accordance with the Patients' Council Regulations. Its resolutions are recommendatory in nature.

The Patient Council may establish its own working groups on various topics, which include not only its members but also members of patient organizations who are not represented on the Council. This approach aims to enhance the representativeness of patients' voices and the objectivity of the opinions formed.

Another form of patient representatives' involvement is their participation in working groups, advisory bodies, and commissions of the Minister of Health, as well as in inter-ministerial working groups. For instance, the vice-chairman of the Patients' Council is a member of the Interdisciplinary Commission for Rare Diseases (*Mezioborová Komise Pro Vzácná Onemocnění, MEKOVO*), established by the Ministry of Health to coordinate activities in the field of rare diseases.[36]

The Patients' Rights Support Department provides administrative support for the activities of the Patients' Council and its working groups.

In the Czech Republic, the Patients' Council plays an important role in representing patients' interests and influencing the development of health policy. Its ability to comment on draft legislative and non-legislative materials ensures that the patient perspective is considered in the law-making process, which directly impacts patients' health and lives. The work of its various working groups, covering different areas of healthcare, allows for the formulation of specific patient priorities, contributing to more targeted and tailored healthcare. Its existence serves as a form of social control and a means of protecting patients' interests.

Patients may consider engaging in the activities of the Patients' Council, as active participation enables them to influence health policy development, protect their rights, and contribute to improving the quality and accessibility of healthcare. This Council represents an important platform for dialogue. Practice has shown that the Council is very active[37], and its stance on many issues is often taken into account by the Ministry of Health.

However, it is important to recognize that the nature of this Council is still purely consultative. The opinions it formulates in resolutions are recommendatory and not binding – they may, but are not obliged to, be taken into account by the Ministry of Health. Additionally, the Council was established based on the *příkaz,* which means a decree, a legal act of a lower level than a law or regulation, which can be independently amended or revoked by the minister.

36. Interdisciplinary Commission for Rare Diseases, Portal of advisory bodies, working groups and expert committees of the Minister of Health [online] Available at: https://ppo.mzcr.cz/workGroup/159 [23.01.2024].
37. List of materials on which the Patient Council submitted comments in 2017-2021 available at https://pacientske-organizace.mzcr.cz/index.php?pg=pacientska-rada--pacientska-rada-2017-2021--vpr [23.01.2024].

Advisory bodies, working groups, expert committees

There are many advisory bodies, working groups, and expert committees operating within the Ministry of Health.[38] These bodies typically bring together various stakeholders in the healthcare sector, including representatives from ministries, SÚKL, health insurance companies, professional organizations, physicians, and commercial entities. Participants also include patient representatives, whose role is to defend their interests and present specific issues from the perspective of the person receiving care. These may be representatives of the Patients' Council, as mentioned in the section describing this body, but they can also represent specific patient organizations. An example is the Working Group on a Conceptual Solution for the Provision of Home Care in the Czech Republic (*Pracovní skupina pro koncepční řešení poskytování domácí péče v ČR*). This group, which discusses problems and proposals for systemic changes to ensure the effective provision of home care in the Czech Republic[39], includes a member from the Czech Association of Paraplegics – CZEPA (*Česká asociace paraplegiků CZEPA*).

Bodies of health insurance funds

As we already mentioned at the beginning of the chapter, *Všeobecná zdravotní pojišťovna* (*VZP*) remains the largest insurance company in the Czech Republic. Despite this, there are no patient representatives in the 30-member Board of Directors (*Správní rada*) or the 13-member Supervisory Board (*Dozorčí rada*).

"The presence of patient representatives on the boards of health insurance funds enables representation of patients' interests."

Other health insurance funds (HIFs) include patient representatives on their boards because they use a tripartite system. One third of the board members are appointed by the government, another third are elected from among the employers contributing the largest share of the HIF's collected contributions, and the remaining third are elected representatives of the insured members of the HIF, usually from trade unions in companies where employers make significant contributions to a given HIF[40].

The presence of patient representatives on the boards of health insurance funds enables representation of patients' interests. Pursuant to the Health Insurance Act, this includes, among other things, the ability of health insurance companies to propose the inclusion, modification, or exclusion of certain benefits from the list of health services (*Seznam zdravotních výkonů*), with their representatives being part of the working group at the Ministry of Health that addresses this issue. Moreover, the participation of patient representatives in bodies contributes to increasing the transparency of the activities of health insurance companies. Patients gain insight into the decision-making processes, which builds social trust and confidence in the fair representation of the interests of all parties.

38. Full list of advisory bodies, working groups and expert committees available at: https://ppo.mzcr.cz/ [23.01.2024]
39. Working group for a conceptual solution for the provision of home care in the Czech Republic, Portal of advisory bodies, working groups and expert committees of the Minister of Health [online] Available at: https://ppo.mzcr.cz/workGroup/103 [23.01.2024].
40. § 10a Zákon č. 280/1992 Sb. o resortních, oborových, podnikových a dalších zdravotních pojišťovnách.

Patient councils in hospitals

Generally, there are no patient councils in Czech hospitals with which the hospital management could consult, but there are some exceptions.[41,42]

Since 2017, the Masaryk Memorial Cancer Institute (*Masarykova onkologického ústavu*), the largest oncology center in the Czech Republic, managed directly by the Ministry of Health, has had the Patient Council (*Pacientská rada*). Its aim is to provide support in solving problems encountered by people using the facility's services. The Council responds to patients' suggestions that may contribute to improving both the conditions in the facility and the way patients are treated. In addition, it acts as an intermediary, facilitating contact between patients and management. Importantly, the patients' council includes representatives not only of hospital and outpatient departments but also representatives of patient organizations and patients themselves.[43]

In December 2023, members of the new Patient Council of the Central Military Hospital – Military Faculty Hospital in Prague (*Pacientská rada Ústřední vojenské nemocnice – Vojenské fakultní nemocnice Praha*) were appointed. The Council is an advisory body to the hospital director, and in addition to hospital employees, it also includes patients and representatives of patient organizations (e.g., ČAKO or NAPO described below). The goal is to involve patients in hospital life, which will improve communication between patients and management and contribute to improved health care and patient satisfaction.

2.4.2. General administrative framework

Czech legislation currently does not include forms of civic participation such as referendum initiatives, legislative initiatives, or public consultations, which can be found (all or selected) in the countries discussed in the report, such as Austria, Poland, Hungary and Slovakia.[44]

However, there are regulations in place that can be highly beneficial for the advocacy activities of patient organizations.

Access to public information

Similar to Austria, the Czech Republic has an Act on Free Access to Information (*Zákon č. 106/1999 Sb. o svobodném přístupu k informacím*). Under this law, every natural or legal person has the right to request information from state bodies, local government units and their bodies, and public institutions. These entities are obliged to provide information within the scope of their competences, although the right to information is subject to certain limitations. Information must be provided no later than 15 days from the date of the request submission, although this deadline may be extended by 10 days in certain cases.

As observed in Austria, this law serves as an extremely useful tool for patient organizations in the Czech Republic. These organizations often need to access specific

41. Bryndová, L., Šlegerová, L., Votápková, J., Hrobon, P., Shuftan, N., Spranger, A., Czechia: Health system review. Health Systems in Transition, 2023; 25(1): i–183.
42. ČAKO Česká aliance pro kardiovaskulární onemocnění. ČAKO Členem Pacientské Rady Úvn Praha [online] Available at: https://ca-ko.cz/cako-clenem-pacientske-rady-uvn-praha/ [23.01.2024].
43. Masarykův onkologický ústav, Pacientská rada [online] Available at: https://www.mou.cz/pacientska-rada/t1463 [23.01.2024].
44. Marczewska-Rytko, M., Aksiuto, K., Maj, D., Pomarański, M., Partycypacja obywatelska w państwach Grupy Wyszehradzkiej po 1989 roku. Przewodnik dobrych praktyk [online] Available at: https://phavi.umcs.pl/at/attachments/2018/0623/182103-guideline-pl.pdf [23.01.2024].

data, figures, and statistics held by public authorities to support their positions.

Public Defender of Rights (*Veřejný ochránce práv*). The Ombudsman

As we already noted at the beginning of the chapter, in accordance with the Charter of Fundamental Rights and Freedoms, everyone has the right to health care, and under social insurance, citizens have the right to free health care and medical assistance under the conditions specified by law. As a result, health care issues fall under the competence of the Czech Ombudsman, the Public Defender of Rights (*Veřejný ochránce práv*). In accordance with the Act of December 8, 1999, on the Public Defender of Rights (*Zákon č. 349/1999 Sb. o Veřejném ochránci práv*), the Ombudsman acts "in order to protect persons against the actions of bodies and other institutions specified in this Act, if it is contrary to law, does not comply with the principles of the democratic rule of law and good administration, as well as against their passivity, thus contributing to the protection of fundamental rights and freedoms". His competences apply to ministries and other administrative bodies in the Czech Republic, but also to public health insurance institutions.

> **"(...) health care issues fall under the competence of the Czech Ombudsman, the Public Defender of Rights (Veřejný ochránce práv)."**

The Public Defender of Rights takes action based on, among others, initiatives of a natural or legal person addressed to it, which means that patient organizations can also submit such initiatives. This type of action can help solve problems such as delays in administrative proceedings related to benefits for disabled people. Additionally, the Ombudsman works on matters of the right to equal treatment and protection against discrimination, and as such, can provide assistance to patients who experience discrimination due to illness in their interactions with government agencies.

2.4.3. Alternative routes

Czech patient organizations also have an indirect opportunity to influence legislation and the decision-making process in healthcare, particularly through collaboration with larger entities.

National Association of Patient Organizations (*Národní asociace pacientských organizací, NAPO*)

In 2021, the National Association of Patient Organizations (*Národní asociace pacientských organizací, NAPO*) was established, which brings together patient organizations operating in the Czech Republic that deal with all types of diseases and disabilities. The main goal of the association is to engage in advocacy activities, aiming to promote the collective interests of patients and their participation in decision-making processes, especially in the field of health policy. It represents the interests of its members in negotiations with state and local government bodies, other non-governmental organizations, and other legal entities both in the country and abroad. NAPO aims to become an important partner of the Ministry of Health, SÚKL, the National Institute of Health (*Státní zdravotní ústav*), and other institutions that promote health or consult with patients.

Practice shows that NAPO has an increasingly stronger position. The association places great emphasis on patient participation in decision-making processes in health care. This includes involving patients in setting prices and reimbursement for drugs, as is the case with drugs for rare diseases. It also recognizes the need for patient presence

on the management boards of health insurance companies and in ethical committees operating in clinical hospitals, as well as joining the work of advisory bodies of the Government Chancellery.[45]

NAPO may be considered an ally in the fight for patients' rights in the Czech Republic, and other organizations can benefit greatly from joining the association. As of the date of completion of this report, 42 patient organizations are members of NAPO.

Czech Alliance for Cardiovascular Diseases (*Česká aliance pro kardiovaskulární onemocnění, ČAKO*)

One of the founding members of NAPO is the Czech Alliance for Cardiovascular Diseases (*Česká aliance pro kardiovaskulární onemocnění, ČAKO*), which includes patients with heart and vascular diseases, as well as those with risk factors for these conditions.

ČAKO was invited to participate in the creation of the new National Cardiovascular Plan for 2023 – 2033 (*Národní Kardio-vaskulární Plán*). This initiative, led by the Czech Cardiological Society (*Česká kardiologická společnost, ČKS*), is being developed in cooperation with the Ministry of Health, SÚKL, the pharmaceutical industry, many medical societies, and other entities.[46] This represents a unique situation in the Czech Republic, as the previous plan was created without the involvement of patient organizations. As of the date of writing the report, the new plan is in the final stage of development.

Additionally, representatives from ČAKO are members of the Patient Council of the Central Military Hospital – Military Faculty Hospital in Prague (*Pacientské rad Ústřední vojenské nemocnice-vojenské fakultní nemocnice Praha*), serving as an advisory body to the hospital director.

Rare Diseases Czech Republic (*Česká asociace pro vzácná onemocnění, ČAVO*)

Founded in 2012, the Rare Diseases Czech Republic (*Česká asociace pro vzácná onemocnění, ČAVO*) brings together patient organizations representing patients with rare diseases and individual patients. It aims to represent their interests and raise awareness of rare diseases among the public, health care professionals, representatives of state authorities, and international institutions.

The president of ČAVO was elected as the vice-president of The Patients' Council (*Pacientská rada*) for 2021-2025 and leads the working group on innovative treatment, which also addresses the issue of reimbursement of drugs for rare diseases.

ČAVO representatives are members of the Interdisciplinary Commission for Rare Diseases (*Mezioborová Komise Pro Vzácná Onemocnění, MEKOVO*), established by the Ministry of Health to coordinate activities in the field of rare diseases. This committee is responsible for the preparation of strategic documents (*Národní strategie pro vzácná onemocnění, Národní akční plán pro oblast vzácných onemocnění*) and for assessing the tasks resulting from them.

As already mentioned in the chapter describing Austrian regulations, it may be worth for the organizations to periodically review the content and method of implementing the assumptions of the national plan. This plan is a roadmap used in European Union countries, containing regulations regarding the health care system. Similar to Pro Rare

45. NAPO. Including patients in decision-making processes [online] Available at: https://silapacientu.cz/2022/02/11/zapojovani-pacientu-do-rozhodovacich-procesu/ [23.01.2024].
46. ČAKO Česká aliance pro kardiovaskulární onemocnění , ČAKO se Zúčastnila Diskuze k Národnímu Kardiovaskulárnímu Plánu [online] Available at: https://ca-ko.cz/cako-se-zucastnila-diskuze-k-narodnimu-kardiovaskularnimu-planu/ [23.01.2024].

Austria in Austria, ČAVO may be considered a key ally in the fight for the rights of people with rare diseases in the Czech Republic. Exchanging knowledge and experience with the association's authorities should be a priority for other patient organizations in the field of rare diseases.

Significantly, ČAVO played a crucial role in the amendment of the law concerning the reimbursement of drugs for rare diseases, including the introduction of patient representatives with voting rights in the reimbursement process.

An essential strategic element for every patient organization should be cooperation with other patient organizations, especially with the larger ones. In terms of specific frameworks, it is worth considering to us the opportunities offered by large umbrella organizations such as ČAVO.

"An essential strategic element for every patient organization should be cooperation with other patient organizations, especially with the larger ones. In terms of specific frameworks, it is worth considering to us the opportunities offered by large umbrella organizations (...)."

The cooperation with organizations whose strong position stems not only from legal regulations but also from the recognition of the organization itself, as in the case of ČAKO or NAPO. Patient organizations that have earned the trust of the community often gain strength. This trust results from their activities, transparency, effectiveness, and positive impact on the well-being of patients. An organization widely recognized as reliable and effective automatically gains a stronger position in conversations about patients' rights. Participating in alliances, coalitions, and partnerships with other organizations increases the impact.

Via parliamentarians / senators

Czech legislation does not currently provide for forms of civic participation such as the referendum initiative, legislative initiative, or public consultations, which can be found (all or selected) in the countries discussed in the report, such as Austria, Poland, Hungary, and Slovakia. Therefore, fully transparent cooperation with members of parliament should may be a strategy worth considering by Czech patient organizations, similar to practices in other countries.

As we know, the right to submit draft laws and changes to existing laws belongs not only to a group of members of parliament, the Senate, the government, and regional state administration bodies but also to individual members of parliament.[47] This is why initiating a grassroots movement by patient organizations to propose an impartial and socially beneficial project may be important.

In addition, each member of parliament has the right to submit interpellations – oral or written – i.e., questions addressed to the government or its members on matters within their competence.[48] There is also a Health Committee (*Výbor pro zdravotnictví*), which discusses, in particular, draft laws on issues related to health care, medicines, health insurance, and financing of medical facilities, and whose composition is, of course, fully public.

From the standpoint of advocacy, maintaining relationships with parliamentarians, who significantly influence the final shape of legal acts in health care, may be considered as a part of the organization's activity.

Professional organizations

There are three professional health care organizations in the Czech Republic: the Czech Medical Chamber (*Česká lékařská komora*), the Czech Dental Chamber (*Česká stomatologická komora*), and the Czech

47. Art. 41 Ústava České republiky.
48. § 110 Zákon č. 90/1995 Sb. o jednacím řádu Poslanecké sněmovny.

Chamber of Pharmacists (*Česká lékárnická komora*), in which membership is obligatory for practicing physicians, dentists, and pharmacists, respectively. These chambers primarily aim to represent the interests of their members.

Additionally, there are several associations with voluntary membership, such as the Association of General Practitioners (*Sdružení praktických lékařů*) and the Association of Ambulatory Care Specialists (*Sdružení ambulantních specialistů*). They participate in annual negotiations with health insurance companies regarding reimbursement rates.

The Czech Medical Association of Jan Evangelista Purkyně (*Česká lékařská společnost Jana Evangelisty Purkyně, ČLS JEP*), which includes doctors, pharmacists, and other healthcare professionals, works closely with the Ministry of Health on various projects.

The Minister of Health may nominate professional organizations to participate in the working group of the Ministry of Health, which negotiates the fee schedule called the List of Health Services (*Seznam zdravotních výkonů. LHS*)[49] and includes several stakeholders, such as professional chambers, representatives of hospitals, health insurance companies, and others, including a representative from The Patients' Council (*Pacientská rada*).[50]

Cooperation between patient organizations and health sector professional organizations is worth initiating. It enables effective communication of patients' opinions, needs, and expectations. By remaining in contact with doctors who are members of committees and working groups of the Ministry of Health or other key entities, patients can indirectly influence decisions, such as those regarding the reimbursement of medical procedures.

"Cooperation between patient organizations and health sector professional organizations is worth initiating. It enables effective communication of patients' opinions, needs, and expectations."

At this point, it is also necessary to mention the organizations of pharmaceutical industry companies, which often play an important role in initiating changes in health policy. An example is the Association of Innovative Pharmaceutical Industry (*Asociace inovativního farmaceutického průmyslu, AIFP*). This association brings together companies dedicated to developing and introducing new drugs to the market that are more effective and safer.

MZČR's National Patient Satisfaction Assessment (*Národní hodnocení spokojenosti pacientů*)

One of the mandatory standards for the internal quality and safety system of care provided by medical service providers is monitoring patient satisfaction. Due to the high inconsistency of this procedure, which led to its results having practically no systemic impact, the Ministry of Health initiated the National Patient Satisfaction Assessment project (*Národní hodnocení spokojenosti pacientů, NHSP*)[51]. This project aims to create a uniform monitoring and evaluation system for patient satisfaction across the country, thereby strengthening the patient's voice in the hospital healthcare delivery system. A patient satisfaction questionnaire, comprising a total of 35 questions, has been developed to enable patients to assess their level of satisfaction

49. Working group on the list of health performances with point values, Portal of advisory bodies, working groups and expert committees of the Minister of Health [online] Available at: https://ppo.mzcr.cz/workGroup/4 [23.01.2024].
50. Bryndová, L., Šlegerová, L., Votápková, J., Hrobon, P., Shuftan, N., Spranger, A., Czechia: Health system review. Health Systems in Transition, 2023; 25(1): i–183.
51. Národní hodnocení spokojenosti pacientů (NHSP) [online] Available at: https://spokojenost.mzcr.cz/ [23.01.2024].

with the care provided during hospitalization. These questionnaires are distributed to all patients hospitalized for at least one night. At the time of writing this report, 39 hospitals were participating in the project.

Patients are encouraged to share their opinions whenever they have the opportunity to participate in this project. The data from the questionnaires will be analyzed and are expected to have a real impact on the functioning of the Czech health care system. Patient assessments contribute to improving the quality of health care and enhancing patient safety.

2.5. Summary

The healthcare system in the Czech Republic is based on universal access to medical care for citizens and residents. Patient treatment is funded through contributions to both public and private health insurance funds, but the determination of the scope of available services is primarily the responsibility of the state, specifically the Ministry of Health and the State Institute for Drug Control (SUKL). Citizens' contributions, whether to public or private insurers, are treated de facto as public funds.

In practice, this system is not significantly different from other solutions employed in Central and Eastern European countries. A key aspect is the presence of a well-developed Health Technology Assessment (HTA) procedure in the Czech Republic, overseen by SUKL. Reimbursement decisions are based on a standardized and transparent process evaluating the value of a given medical intervention, drug, or equipment.

From a patient advocate perspective, a notable development is the incorporation of patient voices into the decision-making process. Representatives of patients with rare diseases are allowed to participate in procedures related to the reimbursement of orphan drugs. The fact that Czech lawmakers see the patient's voice and the potential for genuine patient experiences as an added value rather than a liability is highly encouraging. Although the entire process is formalized and state interests are protected by constitutional "checks and balances" mechanisms (verification of organizations within the registry, the principle of *nemo iudex in causa sua* when voting), patient representatives participate in proceedings on equal terms with other stakeholders.

Undoubtedly, Czech patients now anticipate the introduction of a similar mechanism for reimbursement procedures related to non-rare diseases. The Czech approach to rare diseases can unquestionably serve as a role model for other countries in the region.

In the Czech Republic, patient organizations outside the realm of rare diseases have the opportunity to participate in various consultative bodies. The Patient Council serves as a forum for discussions, and organizations can apply to become partners within the Catalog and List of patient organizations. They also have the chance to participate in the work of insurer teams or advisory boards in certain hospitals. The role of large and recognized patient organizations, such as the umbrella organizations mentioned in the text, NAPO and ČAVO, is significant.

In summary, while the legal options within *alternative routes* in the Czech Republic are relatively limited, they are more than compensated by the opportunities within the *specific framework*. Opening the HTA system to the voices of patients with rare diseases is a breakthrough not only in Central and Eastern Europe but also on a global scale.

3 Hungary

3. Hungary

3.1. The healthcare system in Hungary

According to the Fundamental Law of Hungary[52], everyone has the right to physical health, and the implementation of this right is ensured by the state through, among others, providing health care.[53] The state is responsible for the health of the population, its protection, and improvement.[54]

Hungary has a universal health care system, financed mainly by wage contributions, taxes, and subsidies for ancillary services, with the National Health Insurance Fund (*Nemzeti Egészségbiztosítási Alapkezelő, NEAK*) as the main managing body of the Single Health Insurance Fund. This system offers almost universal access to health services, providing protection for approximately 95% of the population[55], with exceptions for people without permanent residence and citizens working abroad.

In 2019, legislation was introduced that requires uninsured patients to pay for treatment out of pocket, except in emergency cases. The uninsured can purchase insurance from NEAK, but the benefits package is limited compared to the package offered to insured people under general health insurance. Universal health insurance is completely free for children (under 16 years of age), mothers or fathers with children, students, pensioners (all over 64 years of age), people on low incomes, people with disabilities (including those with physical and mental disorders), priests, and other church workers.

Hungarian citizens benefit from a wide range of health services under universal health insurance, but public financing does not fully cover the costs of outpatient medical care or medicines.

It is also possible to benefit from private healthcare and additional private health insurance in addition to the compulsory health insurance offered by the state.

In 2022, management of the healthcare system was transferred from the Ministry of Human Resources to the Ministry of Interior. It is the Minister of the Interior, as a member of the government, who manages, coordinates, and organizes the national healthcare system. The ministerial areas in the Ministry of Interior are headed by secretaries of state, including the head of the Secretariat of State for Health, who exercises professional and political leadership in relation to tasks related to the functioning, development of the national and EU health sector, health insurance, strategic planning of the health sector, providing medicines and medical aids, or public health.

52. Magyarország Alaptörvénye.
53. Art. XX Magyarország Alaptörvénye.
54. 141. § (1) 1997. évi CLIV. törvény az egészségügyről.
55. OECD/European Observatory on Health Systems and Policies (2023), Hungary: Country Health Profile 2023, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.

3.2. Creation of the healthcare law

In Hungary, legislative power is vested in a unicameral parliament, the National Assembly (*Országgyűlés*)[56]. The government is the main body of executive power in Hungary.[57] Executive power also rests with the President, elected by the National Assembly, but this office is largely ceremonial.[58]

Legislative initiative is vested in the President, the Government, the parliamentary committee, and each of the deputies.[59]

The Prime Minister is elected by the National Assembly on the proposal of the President.[60] In turn, ministers are appointed by the President on the proposal of the Prime Minister.[61] As we have already mentioned, there is no independent ministry of health in Hungary. Health issues were taken over in 2022 by the Ministry of Interior. The Minister of the Interior prepares legislation in the area of tasks related to public health or health protection, as well as in the area of organization and operation of the health care sector.

The Fundamental Law of Hungary is the basis of the Hungarian legal system; all other legal acts must comply with it.[62] The remaining normative acts are: organic law (*sarkalatos törvény*), laws (*törvény*), regulations (*rendeletek*) issued by the Government, the Prime Minister, ministers, the President of the Hungarian National Bank, heads of autonomous regulatory bodies, and local government regulations. The regulation of the National Defense Council issued during a state of emergency and the regulation of the President issued during a state of emergency are also normative acts.[63]

3.3. The place of patient organization in the legal system

There is no legal definition of a patient organization in Hungarian law. However, these entities often fall into the broader category of civic organizations, which includes associations and foundations. The basic legal framework for civic organizations is provided by the Hungarian Civil Code (*2013. évi V. törvény a Polgári Törvénykönyvről*). This Act comprehensively regulates the creation, operation, and liquidation of civic organizations, both associations and foundations. Moreover, Act CLXXV of 2011 on freedom of association, public benefit status and the operation and support of civil organizations (*2011. évi CLXXV. törvény az egyesülési jogról, a közhasznú jogállásról, valamint a civil szervezetek működéséről és támogatásáról*) contains detailed regulations regarding operation, registration, and financial management of non-profit organizations.

Although official legal acts do not contain the concept of "patient organization" and its definition, it should be noted that in several places the legislator uses the statutory definition of a civil organization in relation to patient organizations, specifying them more precisely, e.g. in the National Patient Forum (*Nemzeti Betegfórum*), that they must "act in the field of health care" or "represent

56. Art. 1 Magyarország Alaptörvénye.
57. Art. 15 (1) leg. cit.
58. Art. 9 and 10 leg. cit.
59. Art. 6 (1) leg. cit.
60. Art. 16 (3) leg. cit.
61. Art. 16 (7) leg. cit.
62. Art. R (1) leg. cit.
63. Art. T (2) leg. cit.

people suffering from a given disease".[64] The decree regarding the National Patient Forum also states that the possibility of joining the organization is open to all organizations "that meet the requirements of CLXXV of 2011 on freedom of association, public benefit status and the operation and support of civil organizations, operate in accordance with the law, and conduct health care activities."[65] When regulating the functioning of hospital supervisory boards, it was also stipulated that their members are primarily "representatives of civic organizations operating in the field of health care in the area served by the facility".[66]

3.4. Making decisions regarding drug reimbursement

Only drugs for which the National Center for Public Health and Pharmacy (*Nemzeti Népegészségügyi és Gyógyszerészeti Központ, NNGYK*) or the European Medicines Agency have issued marketing authorization can apply for a refund. The National Center for Public Health and Pharmacy (*NNGYK*) was created in 2023 from the merger of Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (*OGYÉI*), which was a public body responsible, among others, for the supervision and assessment of medical and medicinal products, the pharmaceutical market, and the functioning of pharmacies and genetic engineering in health with the National Public Health Center responsible for coordinating all tasks related to public health in the country. The newly created body is headed by the country's chief medical officer.[67]

Procedures related to the reimbursement of medicines are carried out by Nemzeti Egészségbiztosítási Alapkezelő (NEAK), which plays a decisive role in the Hungarian health care system – it establishes the list of medicines subject to reimbursement and also decides to exclude certain categories from the reimbursement list. Reimbursement procedures for medicines are initiated at the request (*kérelemre*) or notification (*bejelentésre*) of the holder of the marketing authorization for the medicine or *ex officio* (*hivatalból*) by NEAK.

Making reimbursement decisions includes two basic procedures: simplified (*egyszerűsített eljárás*) and ordinary (*normál eljárásrend*). The simplified method applies to generic drugs, drugs already reimbursed but in new packaging, as well as in the case of combinations of two or more substances that are already reimbursed separately. However, the normal procedure concerns new active substances, price increases requested by the manufacturer, new indications, and new routes of administration.

"Due to the fact that no form of participation of patient representatives is foreseen in the drug reimbursement process, patient organizations may carefully consider fully transparent contacts with the bodies cooperating with NEAK (...)."

The inclusion of individual medicines in social security and the scope and basis of support in the case of the usual procedure are decided by NEAK, after consulting the NNGYK and the College of Health Professionals (*Egészségügyi Szakmai Kollégium*), which acts as a professional body proposing, commenting on, and advising the minister responsible for health care. The Director-General of NEAK also appoints the

64. 151. § 1997. évi CLIV. törvény az egészségügyről.
65. 1. § 50/2012. (XII. 19.) EMMI rendelet a Nemzeti Betegfórumról.
66. 156. § (4) 1997. évi CLIV. törvény az egészségügyről.
67. 333/2023. (VII. 20.) Korm. rendelet a Nemzeti Népegészségügyi és Gyógyszerészeti Központról.

Commission for Health Technology Assessment (*Egészségügyi Technológiaértékelô Bizottságdo*), which is an application and opinion-forming commission.

However, if a positive reimbursement decision is associated with a change in regulations, NEAK is obliged to send its proposal regarding reimbursed drugs to the minister responsible for health insurance. Then, a commission is appointed, consisting of 2 experts appointed by the minister responsible for health insurance, 1 person appointed by the minister responsible for public finances, 2 experts appointed by the Director-General of NEAK, and 2 experts appointed by the Director-General of NNGYK.[68,69,70]

Due to the fact that no form of participation of patient representatives is foreseen in the drug reimbursement process, patient organizations may carefully consider fully transparent contacts with the bodies cooperating with NEAK, i.e. NNGYK, the Commission for Health Technology Assessment (*Egészségügyi Technológiaértékelô Bizottságdo*), and in particular the College of Health Professionals (*Egészségügyi Szakmai Kollégium*), which consists of doctors of particular specializations. The following persons may be invited to meetings of the presidium and departments of the College, with the right to consult, among others: civic organizations or representatives of organizations concerned with the subject of the meeting. Maintaining relationships with members of the College of Health Professionals (*Egészségügyi Szakmai Kollégium*), who are doctors, so people to whom the well-being of the patient should be particularly close to them and actions in this area should be a priority, may result in an invitation to a meeting of the presidium, during which representatives of the patient organization will be able to present their position on the matter.[71]

However, it should be remembered that the opinions of NNGYK, the Commission for Health Technology Assessment, or the College of Health Professionals are not binding on the decision-making NEAK or the minister.

3.5. Patient advocacy opportunities in Hungary

Patient organizations in Hungary can be involved by the authorities in several ways within specific frameworks in decision-making or law-making processes, but mainly at the local level. Consultative bodies may lack significant legal authority, yet they serve as vital forums for discussion. These committees convene regularly, with government representatives participating in the meetings. Furthermore, there are various tools accessible beyond those specifically designated for patient organizations.

68. 452/2017. (XII. 27.) Korm. rendelet a gyógyszerek társadalombiztosítási támogatásba történő befogadásának, a befogadás és a támogatás mértéke megállapításának, valamint a támogatás megváltoztatásának részletes szabályairól.
69. Nemzeti Egészségbiztosítási Alapkezelő. Gyógyszerek és tápszerek társadalombiztosítási támogatásba történő befogadása, és a támogatás megállapítása [online] Available at: https://www.neak.gov.hu/felso_menu/rolunk/kozerdeku_adatok/tevekenysegre_mukodesre_vonatkozo_adatok/a_hatosagi_ugyek_intezesenek_rendjevel_kapcsolatos/gyogyszer_tb_tamogatas_befogadas [14.03.2024].
70. Inotai, A., Csanádi, M., Harsányi, A., Németh, B. Drug Policy in Hungary. Value Health Reg Issues. 2017 Sep;13:16-22. doi: 10.1016/j.vhri.2017.06.003. Epub 2017 Aug 2. PMID: 29073982.
71. 26/2020. (VIII. 4.) EMMI rendelet az egészségügyi szakmai kollégium működéséről.

3.5.1. Specific framework

The National Patient Forum (*Nemzeti Betegfórum*)

In 2013, a new advisory body was established – The National Patient Forum (*Nemzeti Betegfórum*), which is composed of civil organizations representing people suffering from a given disease. Through the National Patient Forum, the minister responsible for health maintains contact with civic organizations operating in the field of health care.[72]

The National Patient Forum may submit proposals to the minister and, at his request, issue opinions and prepare analyses and assessments. It represents interests related to a given disease or group of diseases, and also maintains contact with vocational universities, organizations representing civic interests, relevant professional chambers of health care workers, and foundations.

> **"The National Patient Forum may submit proposals to the minister and, at his request, issue opinions and prepare analyses and assessments."**

Patient organizations that are part of the National Patient Forum work in 15 thematic sections, within which they create proposals for the government and express their views on health-related laws. They participate in the development of public health programs and in the creation of professional standards.[73] As of the date of writing the report, over 100 patient organizations from Hungary belonged to the National Patient Forum.[74]

Patients should engage in the activities of the National Patient Forum because in this way they can influence health policy, protect their rights, and contribute to improving the quality and availability of health care. However, it should be remembered that this is a purely consultative body – applications, opinions, analyses, and assessments are of a recommendatory and non-binding nature – they may, but do not have to, be taken into account by the minister responsible for health.

Regional Health Council (*Térségi Egészségügyi Tanács*)

According to the Health Service Act (*1997. évi CLIV. törvény az egészségügyről*), the Regional Health Council is an organization that contributes to shaping health policy in the area of health specified in the Act on the Development of Specialized Health Care. Its tasks include, among others: supporting the work of the regional health organization center, providing professional support in establishing regional care responsibilities, advising on the definition of regional goals.[75]

What may be interesting from the point of view of patient organizations, a member of the Council is a common representative of patient organizations operating in the region.[76] It ensures that patients' voices are heard when local health policies are formulated. Especially it is helpful when decisions regarding creation of a new hospital ward (or closing one) are made locally – patient association can support a position that is beneficial for the patient community.

Social and Health Committee (*Egészségügyi és Szociális Bizottság*)

Social and Health Committees (*Egészségügyi és Szociális Bizottság*) in Hungary operate mainly at the local government level, being

72. 151. § 1997. évi CLIV. törvény az egészségügyről.
73. 50/2012. (XII. 19.) EMMI rendelet a Nemzeti Betegfórumról.
74. List of patient organizations belonging to the National Patient Forum: http://www.nemzetibetegforum.hu/betegszervezetek/ [14.03.2024].
75. 148. § (1) and (2) 1997. évi CLIV. törvény az egészségügyről.
76. 148. § (3)m 1997. évi CLIV. törvény az egészségügyről.

subsidiary bodies of local authorities such as city or municipal councils. Their activities are linked to local policies and health and social care systems.

Their activities may include giving opinions on local plans and programs in the field of health and social care, monitoring the implementation of local health and social strategies, supporting activities for health promotion and prevention in the local community, giving opinions on budget projects in the part concerning expenditure on health and social assistance, cooperation with local health institutions, non-governmental organizations, and other entities operating in the field of health and social assistance.[77]

The composition of Social and Health Committees usually includes councilors elected by the city or commune council, representatives of local health care and social welfare institutions, as well as experts and representatives of non-governmental organizations operating in the field of health and social assistance.

These committees play an important role in shaping local health and social policy, serving as a forum for the exchange of opinions and coordination of activities between the various entities involved in these areas; therefore, patient organizations may consider using Social and Health Committees as a platform to advocate for specific changes in local health and social care systems. As members of such committees, they can present their positions, reports, and recommendations and have a real impact on decision-making related to health care and social care.

Hospital Supervisory Board (*Kórház felügyelő bizottsága*)

The Health Service Act (*1997. évi CLIV. törvény az egészségügyről*) also regulates the activities of the hospital supervisory board in medical facilities providing hospital-based specialist care.

The hospital supervisory board, within the scope of its duties related to the provision of health services by a given facility, expresses opinions and submits proposals on matters related to its operation, maintenance, and development. It is an intermediary in contacts between the facility's management and patients. The hospital's supervisory board also represents the interests of patients in the operation of the medical facility and monitors its activities.

The hospital's supervisory board is a body consisting primarily of members elected from among representatives of civic organizations operating in the field of health care in the area served by the facility. The remaining members are representatives of a given medical facility and members delegated by the facility's operator. The chairman of the council must be elected from among representatives of civic organizations.

National Plan for Rare Diseases (*Ritka Betegségek Nemzeti Terve*) and Expert Committee on Rare Diseases (*Ritka Betegségek Szakértői Bizottság*)

In Hungary, the first national plan for rare diseases covered the period 2014-2020 (*Ritka Betegségek Nemzeti Terve*).[78] The Committee of Experts on Rare Diseases (*Ritka Betegségek Szakértői Bizottság*) was established as an advisory group, whose members include, among others, patient organizations. The Committee of Experts on Rare Diseases participated

77. Based on information available on selected websites of city and commune offices in tabs describing the activities of Social and Health Committees.
78. National Plan For Rare Diseases. Healthcare policy strategy for rare diseases until 2020 [online] Available at: https://health.ec.europa.eu/document/download/81fcea56-adad-4f8d-a5f0-c358ace15171_en?filename=national_hungary_en.pdf.

in the preparation of the National Plan for Rare Diseases. It reviews the actions taken to achieve its goals and examines the results of implementing its assumptions and considers and approves annual and final implementation reports.[79]

The National Organization for Rare Disorders (*Ritka és Veleszületett Rendellenességgel élők Országos Szövetsége, RIROSZ*), which is an umbrella organization of Hungarian civil organizations dealing with patients with rare diseases and representing their problems, played a key role in creating the national plan and then in implementing its assumptions at the national and European level. Importantly, RIROSZ was mentioned by name in the National Plan, which indicates the areas in which cooperation with it is necessary to implement its assumptions.

Work is underway on the second National Plan covering actions until 2030, in which RIROSZ is also actively involved.

3.5.2. General administrative framework

Patient organizations in Hungary can use several tools available to all citizens in their advocacy activities.

Public consultations

The 2010 Act on public participation in the creation of legislation[80] provides for public consultations, i.e. seeking the opinions of individuals and non-state and local government bodies on projects prepared by ministers. Draft laws (*törvény*), government regulations (*kormányrendelet*), and ministerial regulations (*miniszteri rendelet*) together with justifications must be submitted for public consultation. It is also possible to submit the project concept itself for public consultation. However, the Act provides for a number of exceptions that specify when a draft act does not have to or cannot be subject to such public consultations.

Hungarian regulations provide for two forms of public consultations: general consultations (*általános egyeztetés*) and direct consultations (*közvetlen egyeztetés*).

Conducting general consultations is mandatory in every case and consists in the fact that the draft legal act together with a summary of the preliminary impact assessment is published on the website of the ministry responsible for preparing the project, and citizens can comment on them via a dedicated e-mail. The deadline for submitting an opinion cannot be shorter than 8 days. The Minister considers the opinions received and prepares their written summary. In the case of rejected opinions, it prepares a justification for such rejection and publishes it on the website along with a list of persons giving opinions. He is not obliged to respond individually.

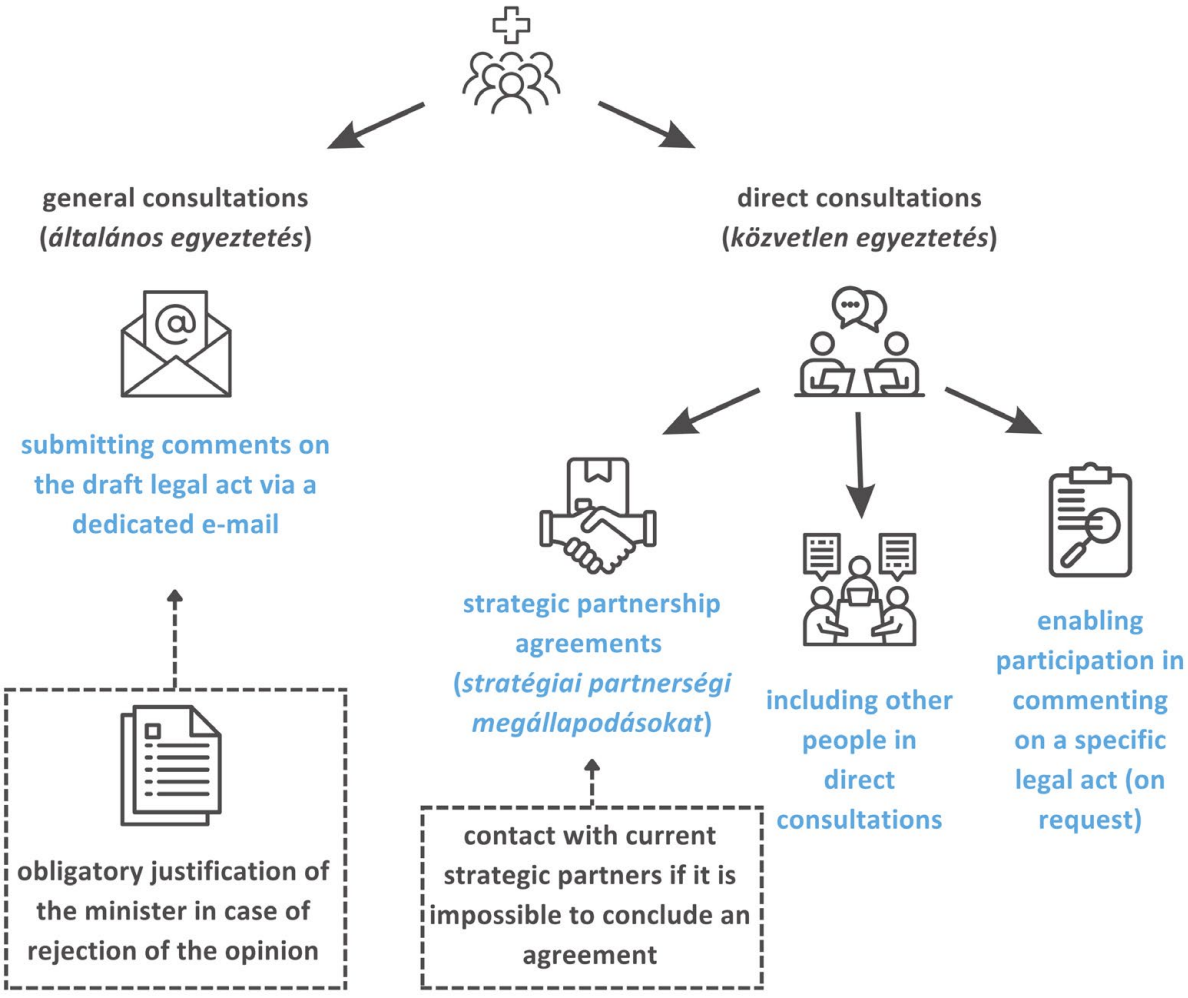
However, as part of direct consultations, the competent minister may conclude strategic partnership agreements (*stratégiai partnerségi megállapodásokat*) with organizations, the so-called strategic partners that represent broad social interest or conduct scientific activities in a specific field, in particular, among others with civic organizations, professional and scientific organizations, and organizations representing interests. The minister responsible for preparing the project may include, in addition to strategic partners, other persons in direct consultations. It may also, upon request, provide the opportunity to participate in commenting on a specific legal act. The strategic partner's

79. Vrony Munkájának Szakértői Támogatása. Nemzeti Népegészségügyi Központ [online] Available at: https://www.nnk.gov.hu/index.php/nepegeszsegugyi-strategiai-egeszsegfejlesztesi-es-egeszsegmonitorozasi-foosztaly/egeszsegmonitorozasi-osztaly/veleszuletett-rendellenessegek-felugyelete-es-ritka-betegsegek-orszagos-kozpontja/szakertoi-tamogatas/ritka-betegsegek-szakertoi-bizottsag [02.04.2024].
80. 2010. évi CXXXI. törvény a jogszabályok előkészítésében való társadalmi részvételről.

written opinions must be made available to the parliamentary committee considering the draft bill at its request, and a summary of the consultations with personal participation along with a justification of the strategic partner's position must be published on the website.

Hungarian patient organizations have several ways to take advantage of the described public consultation regulations and influence legislation, especially in the field of health and patient protection. First of all, they may actively participate in general consultations – regularly follow the websites of ministries involved in public health and others important for health care to stay up to date with new draft laws or government and ministerial regulations. It is important that opinions submitted via dedicated e-mail are comprehensive, contain specific proposals for changes, are based on data and evidence and are well justified, preferably also supported by other health experts.

Patient organizations, especially umbrella organizations, as those bringing together a larger number of organizations may consider taking efforts to obtain the status of a strategic partner by building relationships with ministries and proving their value as experts in the field of health care. If it is impossible to obtain such status, one should try to be included by the minister in consultations or take part in commenting on the project. But also to establish contact with current strategic partners, trying to find common interests and goals.



Public consultations in Hungary.

Patient Ombudsman (*A betegjogi képviselő*)

In Hungary, there is an institution of patient ombudsmen who are employed by the ministry, headed by the minister responsible for health matters. Their task is to protect patients' rights specified by law.

The activities of the patient's rights ombudsman include, among others: helping the patient learn about his rights, gaining access to and understanding medical records, and helping the patient formulate a complaint. They may initiate explanatory proceedings and, based on the patient's written authorization – in matters related to the patient's treatment – submit a complaint to the competent authority and represent the patient during the proceedings. They maintain contact – in the area of their operation – including: with healthcare providers, public health administration bodies, and health insurance funds. In their activities, they strive to peacefully resolve disputes between the parties, assuming the role of a mediator.

The network of patient rights representatives is run by the Integrated Legal Protection Service (*Integrált Jogvédelmi Szolgálat, IJSZ*), which is an independent organizational unit of the Ministry of the Interior.

Right of petition

The Fundamental Law of Hungary guarantees everyone the right to address any public authority with written requests, complaints, or demands, which may be submitted individually or jointly with others.[81] In turn, the Act on complaints, reports in the public interest, and rules for reporting abuses (*2023. évi XXV. törvény a panaszokról, a közérdekű bejelentésekről, valamint a visszaélések bejelentésével összefüggő szabályokról*) obliges state authorities and local government bodies to consider complaints and reports of interest to the public, whereby a complaint is considered to be a request to remove a violation of an individual right or interest, while a notification in the public interest is considered to be drawing attention to a circumstance the removal of which is in the interest of the community or society as a whole. Both forms may also include a proposal.

Complaints and public interest notifications should be considered within 30 days of their receipt by the authority authorized to proceed, but if the procedure is expected to take longer, the deadline may be extended to 6 months.

Patient organizations often identify systemic problems in access to health care or in the quality of health services. This regulation allows them to raise such issues as matters of public interest that may affect a larger group of patients or the entire healthcare system.

Access to public information

In Hungary, the right to access public information is regulated by Act CXII of 2011 on the right to information, self-determination, and freedom (*2011. évi CXII. törvény az információs önrendelkezési jogról és az információszabadságról*). Anyone may submit a request for public information in oral, written, or electronic form, but the Act provides for a number of exceptions. The request for information must be considered as soon as possible, but no later than 15 days, which may be extended once by 15 days in specific cases specified in the Act.

As in other countries, in Hungary, access to public information may be useful for the activities undertaken by patient organizations because they will be supported by reliable, hard data obtained as part of access to public information.

81. Art. XXV Magyarország Alaptörvénye.

3.5.3. Alternative routes

Cooperation Agreement (*Együttműködési megállapodás*)

Ministries may sign cooperation agreements with various entities. An example of such an agreement is the cooperation agreement between the Secretariat of State for Health of the Ministry of the Interior and the Hungarian Alliance of Patient Organizations (*Betegszervezetek Magyarországi Szövetsége, BEMOSZ*), signed on February 26, 2024, which aims to improve the health of society and reduce the burden of diseases. The parties also jointly agreed on the purpose for which the aid budget of the Ministry of the Interior will be used. The Hungarian Alliance of Patient Organizations is to be responsible for announcing a tender for the use of budget funds, to which legally registered non-profit organizations will be able to apply.[82]

Another example may be the cooperation agreement concluded on November 14, 2020, by the government with organizations representing patients with diabetes, under which the parties agreed to cooperate to prevent diabetes and improve the quality of life of people already suffering from diabetes.[83] Thanks to the cooperation, among others, access to medical supplies used by diabetic patients was improved, public nutrition was reformed, special supervision was provided in educational institutions, and tax relief for diabetic patients was provided. The next step in this cooperation is for the Government to develop a National Strategy for Combating Diabetes in cooperation with civic organizations representing people with diabetes.[84]

Patient organizations, thanks to direct cooperation with ministries under cooperation agreements, can have a real impact on shaping health policy. They can provide information about patients' needs and expectations, which helps create more targeted and effective solutions. Collaborative agreements can give patient organizations a seat at the table where public health decisions are made. This is an opportunity to represent patients' interests at the highest levels of administration. And if it is not possible to sign such an agreement directly with the ministry, contact may be made with patient organizations that already cooperate with the ministry under such agreements.

"Patient organizations, thanks to direct cooperation with ministries under cooperation agreements, can have a real impact on shaping health policy."

Cooperation with other entities

In a situation where the patient organization does not have a direct opportunity to influence decisions or changes in the law, cooperation with other entities whose position is stronger may be important. These will primarily be umbrella organizations bringing together patient organizations. An example is the already mentioned National Organization for Rare Disorders (*Ritka és Veleszületett Rendellenességgel élők Országos Szövetsége, RIROSZ*), which is an umbrella organization of Hungarian civic organizations dealing with patients with rare diseases, or the Hungarian Alliance of Patient Organizations (*Betegszervezetek Magyarországi Szövetsége, BEMOSZ*), which, as a nationwide coalition of patient organizations, cooperates with the Secretariat of State for Health of the Ministry of Interior under a cooperation agreement.

82. Magyar Hírlap. Együttműködési megállapodást kötött az egészségügyi államtitkárság és a Betegszervezetek Magyarországi Szövetsége [online] Available at: https://www.magyarhirlap.hu/belfold/20240226-egyuttmukodesi-megallapodast-kotott-az-egeszsegugyi-allamtitkarsag-es-a-betegszervezetek-magyarorszagi-szovetsege [20.03.2024].
83. Magyarország Kormánya. Cukorbetegek szervezeteivel kötött együttműködési megállapodást a kormány [online] Available at: https://kormany.hu/hirek/egyuttmukodesi-megallapodas-cukorbetegek-szervezeteivel [21.03.2024].
84. Magyarország Kormánya. Elkezdődött a nemzeti diabétesz stratégia kidolgozása [online] Available at: https://kormany.hu/hirek/elkezdodott-a-nemzeti-diabetesz-strategia-kidolgozasa [21.03.2024].

The College of Health Professionals (*Egészségügyi Szakmai Kollégium*), mentioned in this discussion, may also prove crucial for patient organizations. It consists of a presidium and departments corresponding to individual branches of medicine. The presidium, among others, takes a position on health policy issues, prepares, and submits proposals in this regard to the minister, or submits proposals regarding the financing and allocation of funds of institutions providing public services. The following persons may be invited to meetings of the Presidium with the right to consultations, among others: civic organizations or representatives of organizations concerned with the subject of the meeting. Faculties express their opinions, among others: on the health care financing system, and representatives of professional organizations and other organizations concerned with the discussed topic may also be invited to their meetings, with the right to consult.[85]

The Association of Innovative Pharmaceutical Manufacturers (*Innovatív Gyógyszergyártók Egyesülete*)

The association represents 26 pharmaceutical companies present in the Hungarian market. In matters where patient organizations have common interests with industry representatives, it is worthwhile to engage with IGE. This organization has documented successes in shaping the policy, also in the area of treatment protocols. Its insights are often considered by authorities, and representatives of the organization are also in constant contact with medical community representatives. Obviously, however, care must be taken to ensure that joint initiatives respect the independence of the patient organization and are maximally transparent.

3.6. Summary

The situation in Hungary does not significantly differ from that in other countries in the region. Patient organizations do not have a permanent place in the country's legal system. Nevertheless, they have a documented history of success in influencing legislation. Similarly to Romania, social organizations often sign bilateral agreements between the organization and the ministry responsible for health, which is an ingenious and effective method of creating their own legal frameworks (contracts) in situations where there are no statutory regulations.

From our conversations with representatives of patient organizations, it also appears that they are consulted by authorities regarding the creation of treatment protocols, which are crucial guidelines for the use of drugs in specific disease entities.

A notable exception is the realm of rare diseases, where a plan for rare diseases has been implemented, with legally regulated rights and obligations of patient organizations. It is worth noting here that the European Union did not require – in legal terms – the creation of such mechanisms from its member states, but only recommended such action. Nevertheless, all member countries have implemented plans where patient organizations play a significant role. This demonstrates the strength of EU recommendations and directives.

Collaboration with representatives of medical communities, who have a real influence on decisions regarding the reimbursement of new drugs, seems to be beneficial for the patient community. Combining forces and creating a common position undoubtedly can aid the cause.

However, it seems that the first step towards change should be formalizing the cooperation between the Ministry responsible for health and patient organizations. A good practice in the form of agreements or consultations already exists, so it seems that the time has come for specific legal frameworks.

85. 26/2020. (VIII. 4.) EMMI rendelet az egészségügyi szakmai kollégium működéséről.

4 Poland

4. Poland

4.1. The healthcare system in Poland

According to the Constitution of the Republic of Poland[86], the supreme law in Poland, everyone has the right to health protection. Public authorities must ensure equal access to healthcare services financed from public funds for all citizens, regardless of their financial situation[87]. However, this obviously does not equate to the obligation to treat every disease under any conditions.

The healthcare system in Poland is based on universal health insurance. The Social Insurance Institution (*Zakład Ubezpieczeń Społecznych*, ZUS) deducts a mandatory health insurance contribution of 9% of the earnings from employment for the health insurance institution, which is the National Health Fund (*Narodowy Fundusz Zdrowia*, NFZ). The NFZ finances healthcare services provided to the insured and reimburses medications. A portion of health contributions comes from taxes, like for students and registered unemployed persons. Certain healthcare procedures within the framework of universal public healthcare, including emergency medical services, are funded directly from the state budget, not from the NFZ[88]. Individuals insured with the NFZ generally do not bear other treatment costs beyond the insurance premium. An exception to this includes medications, of which some are available for a lump sum fee or partial payment, sanatorium care, and adult dental care available for a lump sum fee.

In Poland, one can also make use of voluntary private health insurance. It is becoming more popular every year, however, the scope of available treatment under these insurances is limited and focused primarily on access to appointments with specialists and medical procedures that does not need expensive drugs. It does not cover, for example, high-cost and specialized procedures such as chemotherapy, cardio-surgical operations, or treatment for with orphan drugs. Such specialized procedures are sometimes performed in private facilities, but only within the framework of agreements between the private entity and the NFZ, where NFZ cover the costs of the procedures.

4.2. Creation of the healthcare law

In Poland, legislative power is exercised by the *Sejm* (the lower house of Parliament) and the *Senat* (the upper house of Parliament), while executive power is held by the President of the Republic of Poland and the Council of Ministers (commonly referred to as the

86. Konstytucja Rzeczypospolitej Polskiej.
87. Art. 68 leg. cit.
88. Art. 48 Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych.

government). The right to legislative initiative belongs to deputies, the Senate, the President, and the Council of Ministers. The legislative initiative also belongs to a group of at least 100,000 citizens who have the right to elect members of the Sejm. The exclusive right to create acts (*ustawa*) is held by the Parliament.

The Prime Minister (head of government) proposes the composition of the Council of Ministers to the President, who then appoints its members, including the minister responsible for health. The healthcare sector falls under the Ministry of Health. The minister responsible for health is obliged to initiate and develop the health policy of the Council of Ministers. The minister issues universally applicable regulations (*rozporządzenie*), which cannot contradict the law or the Constitution as well as orders (*zarządzenie*), acts of internal range of influence only.

4.3. The place of patient organizations in the legal system

Patient organizations in Poland do not have a separate place in the legal system at the level of the Constitution, acts, and regulations. They operate on general principles common to specific types of non-governmental organizations; most often, these are associations and foundations.

The formal supervisory body for patient foundations and associations is usually the Ministry of Health (due to organizations' legal form and scope of activities). However, the control of their activities is limited to ensuring that the organizations' activities comply with the law. In certain cases, the Ministry has the right to intervene by establishing a provisional administration over the entity, but in practice, this happens extremely rarely.

There is also no definition of a patient organization in the Polish legal system. Nevertheless, the term *patient organizations* appears in several low-ranking legal acts (orders), and thus they formally operate within the legal system. We discuss these cases in the subsequent subsections.

4.4. Reimbursement of medical procedures (guaranteed benefits)

In the Polish law the term *guaranteed benefits* means all kinds of medical services and healthcare procedures funded or co-funded from public funds. These are provided by service providers (hospitals, clinics) to patients insured in the universal health insurance system. A guaranteed benefit can be, for example, a visit to a family doctor, surgical operation, or chemotherapy for cancer. However, it's important to note that in most cases, whether a particular drug can be used as part of a specific procedure is subject to additional regulations, which are described in the following subsections.

The management of the so-called *basket of guaranteed benefits* in Poland is primarily regulated in the Act on healthcare services funded from the public funds (*Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych*, hereinafter referred as to the *Act on healthcare services*). The process of managing the basket of healthcare services, which are not drugs, can be divided into two areas:

1. Qualifying medical procedures as guaranteed benefits,
2. Removing a given procedure from the list of guaranteed benefits or changing the conditions.

The qualification of the procedure as a *guaranteed benefit* is made by the Minister of Health[89]. They delegate to the President of the Agency for Health Technology Assessment and Tariff System (Polish: *Agencja Oceny Technologii Medycznych* i Taryfikacji, *AOTMiT* or *the Agency*) the preparation of recommendations on this issue. AOTMiT is a Polish national agency responsible for HTA and issuing recommendations on reimbursement. This agency operates within the Ministry of Health and performs advisory and opinion-forming functions towards the Minister of Health.

Upon receiving an assignment from the Ministry, the AOTMiT seeks the opinion of the President of the National Health Fund (NFZ) and national consultants in the field of medicine relevant to the given procedure. National consultants are recognized physicians specialized in various fields of medicine appointed by the Minister of Health.

The opinions obtained are presented by the Minister of Health to the Transparency Council (*Rada Przejrzystości*), which operates under the AOTMiT and serves an advisory and opinion-forming role. Members of the Transparency Council are appointed and dismissed by the Minister of Health, and its composition includes: 10 individuals with relevant experience, recognized achievements, and at least a doctoral degree in medical sciences or other fields specified in the law, 4 representatives of the Minister of Health, 2 representatives of the NFZ, and 2 representatives of the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products[90] and 2 representatives of the Patient Ombudsman.

Its responsibilities include preparing and presenting positions on not only the qualification or non-qualification of a procedure as a guaranteed service, but also on the removal of a given healthcare service from the list of guaranteed services, covering it with reimbursement and establishing the official sale price of a drug, as well as the justification for granting approvals for drug reimbursement within the framework of targeted import, which will be discussed later in the report. The Council also issues opinions on health program projects and medical technologies[91]. The essence of the Council's activity, and the positions and opinions it issues, is to ensure that the state spends money on medicine rationally, financing technologies that are proven and bring objective health benefits.

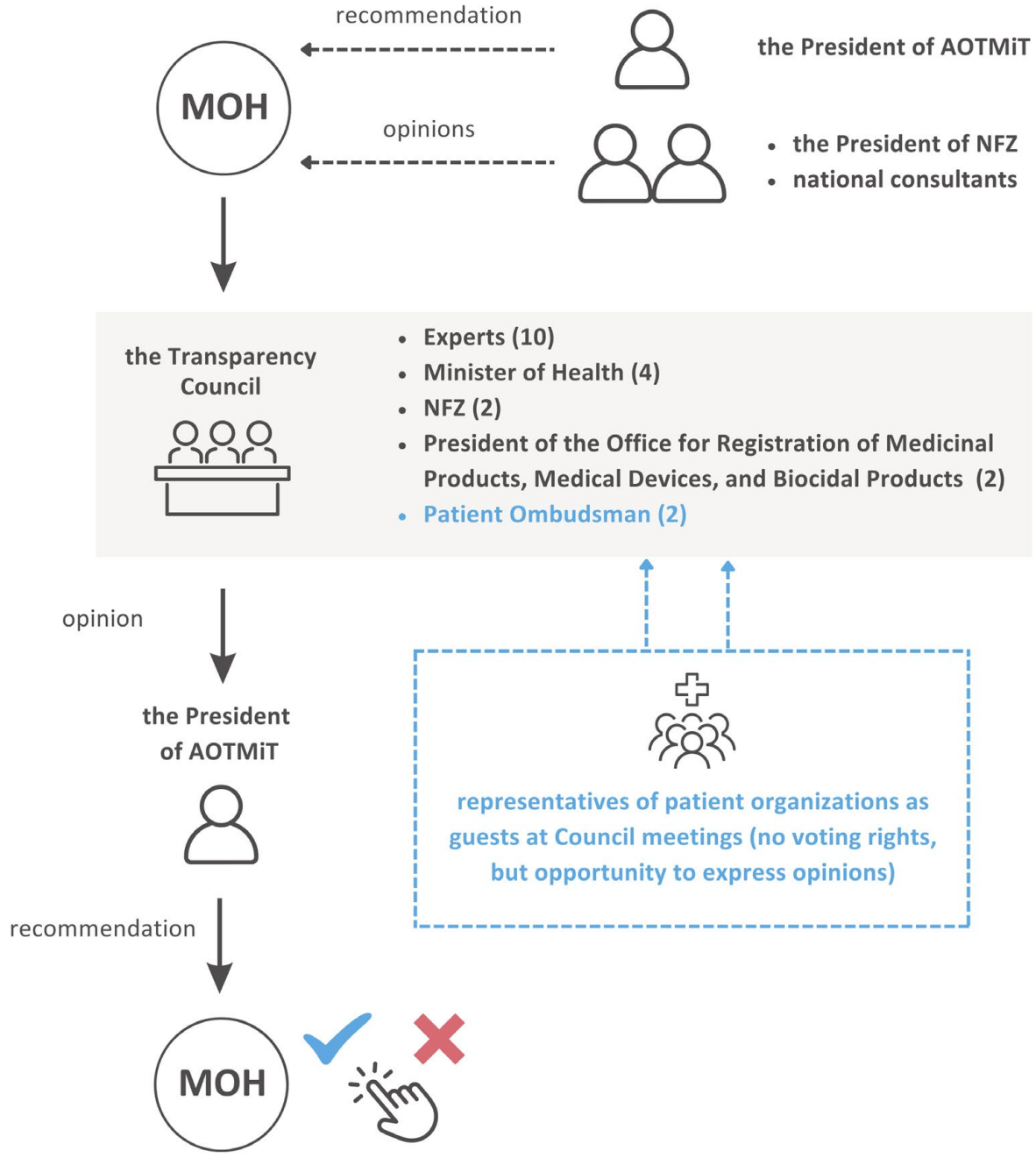
"(...) greater legal possibilities are provided in the area of removing a given procedure from the list of guaranteed services or making changes to the level or method of financing or conditions for the provision of the service."

Other individuals invited by the chairman of the Transparency Council can also participate in the meetings of the Council as guests.

89. Art. 31b sec. 1 leg. cit.
90. The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products is the central government administration body competent in matters related to the authorization of medicinal products for marketing.
91. Art. 31s sec. 1-3 and 6 Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych.

Sometimes those guests are representatives of patient organizations. They must submit a declaration of no conflict of interest and they have no voting right in any matter, but they can express their opinion during the meeting. In the agendas published by the Agency, information about the dates of the next meetings of the Transparency Council and the topics to be discussed is provided.

The Transparency Council issues an opinion on the matter, and the President of the Agency, taking it into account, issues recommendations on the qualification or non-qualification of a given procedure as a guaranteed service, which is then forwarded to the Minister of Health. The Minister, in turn, makes a final decision by regulation[92].



The qualification of the procedure as a guaranteed benefit in Poland.

92. Art. 31a-31d leg. cit.

However, greater legal possibilities are provided in the area of removing a given procedure from the list of guaranteed services or making changes to the level or method of financing or conditions for the provision of the service. Besides the Minister of Health (acting *ex officio*), national consultants, scientific associations, and the NFZ, also associations and foundations whose statutory objective is to protect patient rights can also, through a national consultant, submit applications in this procedure[93].

In the area of qualifying procedures as guaranteed services, where the Minister of Health is the sole applicant, patient organizations and patients may consider seeking meetings at the Ministry of Health or to engage in other activities that initiate actions by the Minister. Additionally, it is advisable to undertake indirect actions through the national consultant and the two representatives of the Patient Ombudsman on the Transparency Council, who can represent the patient's voice in these decisions.

"(...) associations and foundations whose statutory objective is to protect patient rights can also, through a national consultant, submit applications in this procedure."

Meanwhile, in the area of removing a given procedure from the list of guaranteed services or changing the conditions of the service, it is possible to submit applications through the national consultant in a given field of medicine.

4.5. Making decisions regarding drug reimbursement

One of the main duties of the Minister of Health is to ensure that patients have access to effective and safe therapies, while simultaneously optimizing expenditures on patient healthcare. A key instrument that influences the shaping of the country's drug policy is the reimbursement of medicines (as well as foodstuffs for particular nutritional uses and medical devices).

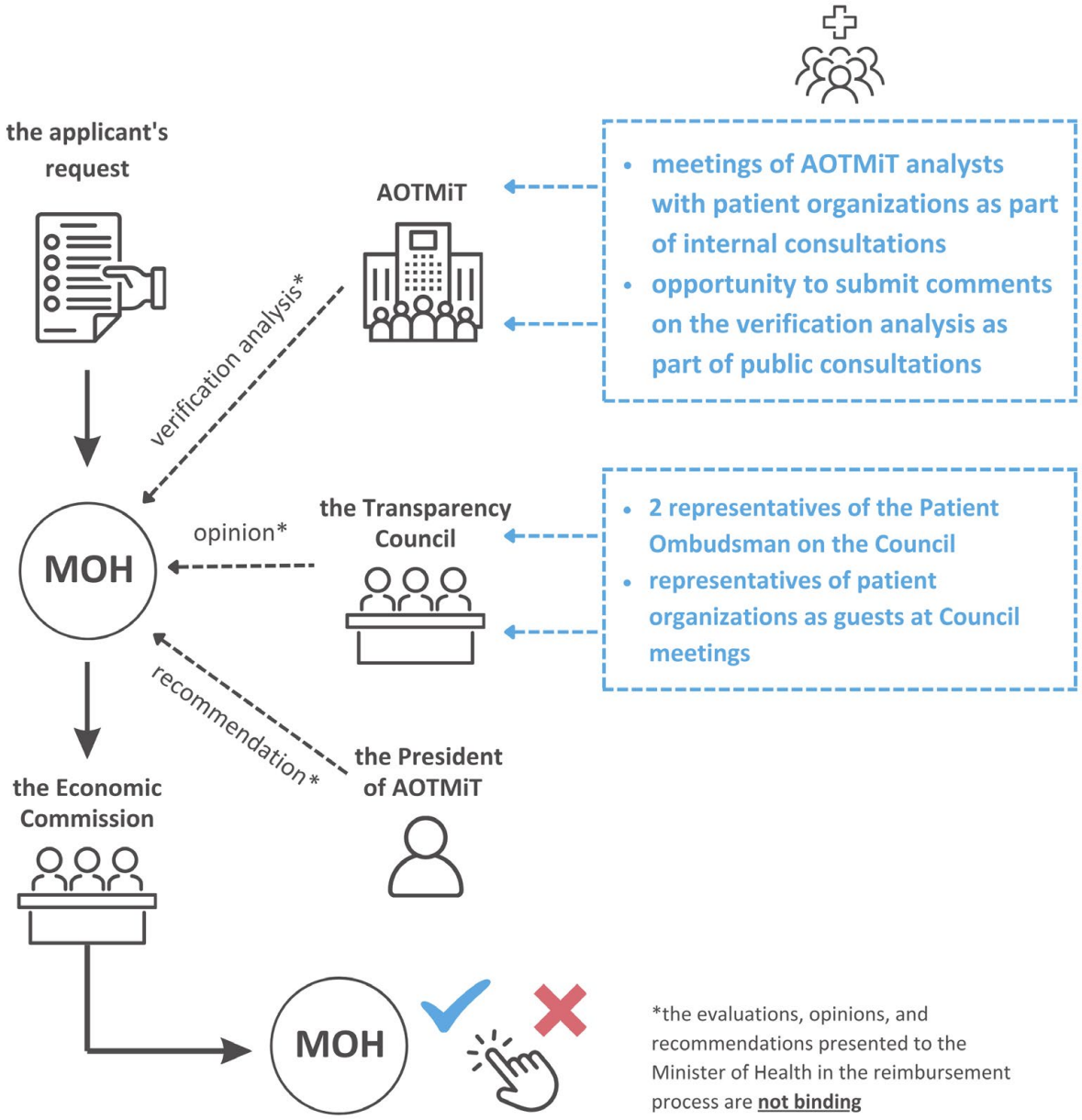
The process of drug reimbursement in Poland is primarily regulated in the Act on the reimbursement of medicines, foodstuffs for particular nutritional uses, and medical devices (*Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych*, hereinafter referred to as *the Reimbursement act*). According to this act, the inclusion of a drug in the reimbursement scheme occurs through an administrative decision of the Minister of Health[94].

In general, only a drug that is registered and marketed can be reimbursed. As in other member states of the European Union, this can be a drug authorized for marketing by European Medicines Agency. In the following part, we will focus on the reimbursement procedure with respect to drugs meeting these criteria, where the reimbursement procedure is initiated upon application. However, it should be noted that the reimbursement act also provides for the possibility of reimbursement for other drugs, such as a drug not authorized for marketing or not available for sale in the territory of Poland and imported from abroad as part of the so called *targeted import* procedure, a drug used for indications other than those

93. Art. 31e sec. 2 p. 4 leg. cit.
94. Art. 11 sec. 1 Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych.

registered and listed in the Summary of Product Characteristics, so-called *off-label reimbursement* and the Emergency Access to Drug Technologies, which allow to finance therapies for Polish patients with drugs not funded from public funds for a given indication. But the situation of patient representatives in all of those procedures is the same as in the main one.

The reimbursement procedure is initiated, as a rule, upon request of the applicant submitted to the Ministry of Health.[95] The applicant can be a responsible entity or its representative, an entity authorized for parallel import, a manufacturer of a medical device or its authorized representative, a distributor or importer of a medical device, and an entity operating in the food market. When it comes to medicines, usually it is the producer or a distributor. An exception



Making decisions regarding drug reimbursement in Poland.

95. Art. 24 sec. 1 leg. cit.
96. Art. 40 sec. 1 leg. cit.

is the aforementioned inclusion of a drug in reimbursement for off-label indications, which takes place through a decision issued by the Minister of Health *ex officio*[96].

The Minister of Health forwards the application to the AOTMiT in order to prepare the Agency's verification analysis, the Transparency Council's opinion, and the recommendation of the President of AOTMiT[97]. At this stage, there are several possibilities for the involvement of patient organizations or the patients themselves.

Firstly, at the stage of developing the Agency's verification analysis, AOTMiT analysts can organize meetings with patient organizations as part of internal consultations, but this arises solely from AOTMiT's internal procedures and not from statutory regulations[98]. Secondly, after completing the work on the Agency's verification analysis, the President of the Agency publishes the along with the applicant's analyses. For 7 days before the meeting of the Transparency Council, there is an opportunity to submit comments as part of public consultations[99,100].

The next step is the opinion of the Transparency Council, which, as it was mentioned before, serves an advisory role at AOTMiT. Its composition is the same as in the procedure regarding medical procedures described above. So also here, other individuals invited by the chairperson of the Transparency Council can participate in its meetings without voting rights, as guests of the Transparency Council[101].

The next step in the reimbursement process involves the President of the Agency preparing a recommendation on the coverage of a particular drug by reimbursement, based on the position of the Transparency Council. This recommendation is then submitted to the Minister of Health[102].

"Patient organizations usually monitor publications in the AOTMiT communications in order to submit their comments within a 7-day period as part of public consultations."

Subsequently, the Minister of Health forwards the applicant's request, along with the Agency's verification analysis, the Transparency Council's opinion, the recommendation of the Agency's President, and other documents to the Economic Commission, in order to conduct negotiations on the terms of reimbursement coverage (the pricing)[103]. The Economic Commission operates under the Minister of Health and comprises 14 representatives of the Minister and 6 representatives of the President of the National Health Fund (NFZ). Its primary tasks include conducting negotiations with the applicant regarding the determination of the official selling price, the level of patient co-payment, the indications for which the drug is to be reimbursed, and the risk-sharing instruments[104].

The final stage is the issuance of a decision by the Minister of Health regarding the

97. Art. 35 sec. 1 leg. cit.
98. Pacjenci.pro., Barometr zaangażowania organizacji pacjentów w procesy kształtowania systemu opieki zdrowotnej w Polsce w 2021 r. Raport końcowy, 2023 [online]. Available at: https://www.pacjenci.pro/wp-content/uploads/2023/04/Raport_Barometr_PACJENCI.PRO_-2.pdf.
99. Art. 35 sec. 4 Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych.
100. AOTMiT – Agencja Technologii Medycznych I Taryfikacji. Składanie uwag do AWA [online]. Available at: https://www.aotm.gov.pl/informacje-dla-przemyslu/skladanie-uwag-do-awa/ [18.10.2023].
101. AOTMiT – Agencja Technologii Medycznych I Taryfikacji. Udział w posiedzeniach Rady Przejrzystości [online]. Available at: https://www.aotm.gov.pl/o-nas/rada-przejrzystosci/udzial-w-posiedzeniach-rady-przejrzystosci/ [20.10.2023].
102. Art. 35 sec. 6 and 8 Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych.
103. Art. 35 sec. 9 leg. cit.
104. Art. 17 sec. 1 and 2, art. 18 sec. 1 leg. cit.
105. Art. 37 sec. 1 leg. cit.

inclusion of the drug in the reimbursement scheme[105]. This decision can be either positive or negative, as the evaluations, opinions, and recommendations presented to the Minister of Health in the above-described reimbursement process are not binding. Only in the case of drug reimbursement through the *targeted import* procedure, as mentioned earlier, is the Minister of Health bound by the negative recommendation of the President of AOTMiT[106].

There are also several procedures used in specific situations, like the reimbursement of the off-label treatment, the so called *targeted import* (reimbursement of an imported drug not registered in Poland) and Emergency Access to Drug Technologies (RDTL), which allow to finance therapies for Polish patients with drugs not funded from public funds for a given indication. But the situation of patient representatives in all of those procedures is the same as in the main one.

"(...) collaboration with the Patient Ombudsman may be considered important, as two of its representatives are members of the Transparency Council."

Patient organizations usually monitor publications in the AOTMiT communications in order to submit their comments within a 7-day period as part of public consultations. The dates and agendas of meetings are published at the AOTMiT's website. Keeping track of this information will enable patient organizations to timely submit a request to participate in a specific meeting as a guest. Additionally, collaboration with the Patient Ombudsman may be considered important, as two of its representatives are members of the Transparency Council.

4.6. Patient advocacy opportunities in Poland

In Poland, there has been an ongoing process for several years now of opening up the central government authorities to systematic dialogue with patients. As a result, several consultative committees have been established, but none of them have a strong legal position. The success of a patient organization's activities usually depends on its potential, rather than on existing legal regulations. Nevertheless, these are significant platforms for dialogue – these committees meet regularly, and state officials appear at the meetings. Moreover, a wide range of means other than those exclusively intended for patient advocacy groups remains available.

4.6.1. Specific framework

Reimbursement of medicines and medical procedures

As described in the subsection on the reimbursement of medical procedures and drugs, patient organizations have certain limited opportunities in this area. The presence of a patient organization representative as an invited guest, thus at the initiative and with the consent of AOTMiT, is possible at the meetings of the Transparency Council. Of course, patient organizations can apply for such participation themselves, but there is no specific formalized procedure for this. Nevertheless, being present at the council meeting provides an opportunity to present one's own position, and the evidence

106. Art. 39 sec. 3e p. 1 and 2 leg. cit.

submitted at the meeting can be used to formulate the Council's position.

Interestingly, patient organizations can submit applications to change the reimbursement conditions of a medical procedure (or to remove it from the registry). This is done through the national consultant. This is significant because in some areas of medicine it allows modifying existing treatments or even treatment procedures (still in accordance with the characteristics of the drugs and the method of their application as determined by separate regulations). In practice, however, this regulation is not widely used, as – like in other countries – the issue of medical procedures and their pricing is the subject of work by medical communities and hospital managers. To some extent, medical procedures are also subordinate to the available drugs.

"(...) patient organizations can submit applications to change the reimbursement conditions of a medical procedure (or to remove it from the registry). This is done through the national consultant."

Rare Diseases Council

In 2021, Poland adopted the National Plan for Rare Diseases for the years 2021-2023. Polish patient organizations dealing with rare diseases also participated in the activities aimed at developing and leading to the adoption of this document. The plan aims to improve the diagnosis of rare diseases and medical care for people who suffer from these diseases.

In May 2022, by order (*zarządzenie*) of the Minister of Health, the Council for Rare Diseases (*Rada ds. Chorób Rzadkich*) was established[107], which serves as an advisory body to the Minister. The purpose of establishing the Council is to provide expert support to the Minister in the implementation of the Plan for Rare Diseases through opinions and advice.

Patients in the Council are currently represented by one member in the person of the President of the Polish Patients' Federation (*Federacja Pacjentów Polskich*), a nationwide umbrella organizations aiming to represent all the therapeutic areas (described in one of the subsequent chapters). Besides him, the Council consists of 16 doctors, including 6 national consultants, a representative of the National Chamber of Physiotherapists (*Krajowa Izba Fizjoterapeutów*), and a representative of the e-Health Center (*Centrum e-Zdrowia*, an agency subordinate to the Ministry of Health, responsible for managing IT systems)[108], a representative of the NFZ, a representative of the Medical Research Agency (*Agencja Badań Medycznych*, a state agency responsible for the development of research in the field of medical sciences and health sciences), and 5 representatives from departments within the Ministry of Health.

In the Council's proceedings, individuals who are not members of the Council, including external experts and representatives of other organizational units of the Ministry of Health and entities, may participate with an advisory vote (if invited). In practice, this provides patient organizations for rare diseases, through contact and agreement with a member of the Council, the opportunity to submit their own remarks for the implementation of the Plan for Rare Diseases.

The Patient Organizations Council at the Minister of Health

In March 2022, based on the order (*zarządzenie*) of the Minister of Health, the Patient Organizations Council was established[109], and it serves as an auxiliary and advisory body to the Ministry of Health in Poland. Its primary role is to facilitate dialogue on

107. Zarządzenie Ministra Zdrowia z dnia 26 maja 2022 r. w sprawie powołania Rady do spraw Chorób Rzadkich.
108. Zarządzenie Ministra Zdrowia z dnia 4 czerwca 2020 r. w sprawie Centrum e-Zdrowia.
109. Zarządzenie Ministra Zdrowia z dnia 16 marca 2022 r. w sprawie powołania Rady Organizacji Pacjentów przy ministrze właściwym do spraw zdrowia.

systemic issues in healthcare. The Council's responsibilities include:

1. Coordinating patient organizations' efforts in pre-consultations and public consultations of legislative drafts and other government documents conducted by the Ministry of Health.
2. Reviewing and providing opinions on legislative proposals.
3. Initiating changes in health care legislation.
4. Collaborating with other councils that represent patient organizations, particularly those associated with the Patient Rights Ombudsman and the NFZ.
5. The Council comprises no more than 15 members, appointed for a five-year term by the Minister of Health. These members are selected from candidates nominated by patient organizations that operate in the healthcare sector, have a nationwide impact, and have been registered for at least five years.

Besides the Council members and its secretary, the meetings are attended by a secretary or undersecretary of state in the Ministry of Health, appointed by the Minister. Experts invited by the Council's Chairperson may also participate in the meetings.

This context reveals several opportunities for patient organizations in relation to the Patient Organizations Council in Poland. First of all, patient organizations have the opportunity to nominate a representative for membership on the Council when there's a call for candidate applications. This allows these organizations to have a direct voice and presence within the Council. Moreover, POs can submit their positions and opinions to the Council regarding legislative drafts or changes in health care regulations. This provides an indirect pathway for patient organizations to influence the legislative process and ensure that their viewpoints are considered in the later stages of legislative changes. POs also have the opportunity to suggest to the Council Chairperson to invite experts to the meetings. These experts can support and reinforce the stance of the patient organization on specific issues.

Overall, these opportunities enable patient organizations to play a significant and active role in shaping health policy and legislation, ensuring that the interests and needs of patients are adequately represented and addressed. Nevertheless, the legal position of the council remains weak, and it can be dissolved by a single personal decision of the minister. Additionally, it is still merely a consultative body, though quite impactful.

> **"(...) patient organizations have the opportunity to nominate a representative for membership on the Council (...). Moreover, POs can submit their positions and opinions to the Council regarding legislative drafts or changes in health care regulations. (...) POs also have the opportunity to suggest to the Council Chairperson to invite experts to the meetings."**

Council of Patient Organizations at the Patient Ombudsman

In February 2020, the Council of Patient Organizations was established under the Patient Ombudsman, which serves as an advisory and opinion-forming body for the

110. Zarządzenie Rzecznika Praw Pacjenta nr 1/2020 z dnia 5 lutego 2020 r. w sprawie powołania i funkcjonowania Rady Organizacji Pacjentów przy Rzeczniku Praw Pacjenta.

Ombudsman[110]. The primary tasks of the Council of Patient Organizations include identifying areas of risk in the functioning of the healthcare system, expressing opinions on matters presented by the Patient Ombudsman, including in the field of legal act projects, and supporting the Patient Ombudsman in activities related to education and promotion in the field of patient rights.

The Council is composed of non-governmental organizations whose statutory goals include undertaking activities related to the protection of patient rights or education in these rights. The membership of a non-governmental organization in the Council requires the submission of an application and its acceptance by the Patient Ombudsman. Each selected non-governmental organization delegates one representative to participate in the Council's work. The Council primarily carries out its tasks through thematic teams (like for specific therapeutic areas) and the number of members in a given team is unlimited.

According to a report on the results of a study on the engagement of patient organizations in the processes of shaping the healthcare system in Poland in 2021, cooperation with at least one central institution operating in the field of health protection in 2021 was declared by 47.0% of the surveyed representatives of patient organizations. The most frequent collaboration was with the Office of the Patient Ombudsman (38.0% of the respondents) and involved participation in the meetings of the Council of Patient Organizations (65.8% of those, who collaborate with the Ombudsman)[111].

Patient organizations can consider applying for membership in this Council as another avenue to present their proposals on issues that may be taken into account at later stages. It also provides an opportunity to reach the Patient Ombudsman directly and inform them more quickly about irregularities.

4.6.2. General administrative framework

Polish legal regulations offer the general public several tools that can also be effectively utilized by patient organizations

Participation of social organizations as entities with the rights of a party in administrative proceedings

As we mentioned earlier, in Poland, the procedure for including a drug in the reimbursement system is regulated by the provisions of the Reimbursement Act. According to this Act, the inclusion of a drug in the reimbursement system occurs through an administrative decision of the Minister of Health. As indicated in jurisprudence and literature, the procedure for reimbursement inclusion has the character of an administrative proceeding, as a result of which the provisions of the Administrative Procedure Code (*Kodeks Postępowania Administracyjnego*, KPA) should be applied in areas not regulated by the Reimbursement Act. The reimbursement procedure is generally initiated upon the request of the applicant submitted to the Minister of Health. The Reimbursement Act does not mention any other participants in this procedure. Thus, we have the applicant and the Minister of Health.

However, according to the provisions of the KPA, alongside the parties in administrative

111. Pacjenci.pro., Barometr zaangażowania organizacji pacjentów w procesy kształtowania systemu opieki zdrowotnej w Polsce w 2021 r. Raport końcowy, 2023 [online]. Available at: https://www.pacjenci.pro/wp-content/uploads/2023/04/Raport_Barometr_PACJENCI.PRO_-2.pdf.

proceedings, there can also be other entities, known as participants in the proceedings with the rights of a party. One of these entities is a social organization, to which patient organizations can undoubtedly be classified. According to the KPA, a social organization may request the initiation of proceedings or permission to participate in them. However, it must meet two conditions: such a request must be justified by the statutory objectives of the organization, and the initiation or admission of the organization to the proceedings must be in the public interest. If these conditions are met, the public administration authority issues a decision to initiate proceedings or to admit the organization to participate in the proceedings.

"(...) the procedure for reimbursement inclusion has the character of an administrative proceeding (...). (...) alongside the parties in administrative proceedings, there can also be other entities, known as participants in the proceedings with the rights of a party. One of these entities is a social organization, to which patient organizations can undoubtedly be classified."

According to jurisprudence, the actions of a social organization on behalf of patients also include more general initiatives aimed at improving the patient care system. Such actions undoubtedly include efforts to include a drug in the reimbursement system, as this ultimately results in a optimization of drug price and greater patient access to treatment[112]. Secondly, the knowledge and experience gained in connection with the conducted statutory activities can be of significant importance when making a decision about including a drug in the reimbursement system[113]. Thirdly, the lack of proper treatment for a given disease has far-reaching consequences and burdens the state budget with the costs of additional treatment, therefore the participation of a social organization in making reimbursement decisions may contribute to better expenditure of public funds.

By meeting the above conditions, patient organizations can appear in the proceedings as a third party alongside the Minister of Health and the applicant, and have the opportunity to participate in all actions of the proceedings. It should be remembered that as a participant with the rights of a party, they do not have the right to dispose of the subject matter, so for example, when participating in negotiating the price of a drug, as a material element of the case, the voice of patient organizations will only have the character of an opinion[114].

But this opinion can be conveyed, and they can present evidence such as case studies of other patients, opinions of key doctors, their own cost calculations, etc. Importantly, a participant with the rights of a party has full access to the case files and is served a copy of the decision. This ensures that they are aware of all the information.

Unfortunately, patient organizations very rarely take advantage of the opportunities provided by Polish administrative regulations. And it is an useful regulation. Therefore, patient organizations may consider using this route of participation in decision-making by the authorities.

Social legislative initiative

According to the Constitution of the Republic of Poland, the legislative initiative also belongs to a group of at least 100,000 citizens who have the right to elect to the

112. Wyrok Naczelnego Sądu Administracyjnego z dnia 6 października 2016 r., sygn. akt II GSK 3491/15.
113. Ibidem.
114. Siwiec, A., Komentarz do wyroku Naczelnego Sądu Administracyjnego z dnia 6 października 2016 r., sygn. akt II GSK 3491/15, Studia Prawnicze KUL, nr 3 (71), 2017, p. 140-150.

Sejm. Similar to the people's initiative (*Volksbegehren*) existing in Austria, this is a tool that requires extremely efficient organization. In the case of this solution, the focus should be on large and high-profile issues in the field of treatment and medical care that affect a significant part of society.

Public (social) consultations

Public consultations, also interchangeably referred to as *social*, can be conducted at both the local and central government levels and they must be subjected to specific legal procedures. This influences the transparency of the consultation process itself and the entire legislative process. In Poland, the rules for conducting public consultations have been defined in the 'Guidelines for conducting impact assessments and public consultations in the government legislative process'[115].

As for the legal basis of public (social) consultations, due to the variety of possible forms of conducting consultations, there is no single legal act describing this form of public participation. For the purposes of this report, let's focus primarily on public consultations of government draft laws. Their basis is the Regulations for the Operation of the Council of Ministers. It clearly specifies that the procedure with government document projects, such as laws, normative acts of the Council of Ministers, regulations of the Prime Minister or a minister, and orders of the Prime Minister, includes among others, public consultations.[116]

All documents related to the work on projects are made available in the Public Information Bulletin of the Government Legislation Center under the Government Legislative Process (RPL) tab. Every citizen can review the draft legal acts and submit comments. Moreover, each ministry on its website posts information about ongoing legislative work on a given project, along with a mention of the possibility of submitting comments by interested entities. How much time is allocated for comments, responses, and taking a position depends on the decision of the proposing body. The proposing body may also direct the project to social organizations or other interested entities or institutions to present their position.

Importantly, after the consultations are conducted, a report summarizing them is published, which should include: a discussion of the consultation results and their impact on the final shape of the project, identification of the consultation participants, response to the opinions submitted in the consultations, and an annex to the report in the form of a table summarizing all submitted opinions, ways of considering them, and justification for any rejection.

Therefore, it seems important to continuously monitor information about legislative work in order to participate in social consultations at the right time. On the other hand, sending letters with the position of the organization to government bodies in a situation where the proposing body did not direct the project to it for such a purpose may make the government side see an active partner and decide to involve the organization in future projects.

115. Wytyczne do przeprowadzania oceny wpływu oraz konsultacji publicznych w ramach rządowego procesu legislacyjnego.
116. § 21 sec. 2 Uchwała nr 190 Rady Ministrów z dnia 29 października 2013 r. Regulamin pracy Rady Ministrów.

Citizens can also participate in the work on legislative projects in the parliament. Both the Sejm's Regulations and the Senate's Regulations provide for the possibility of organizing a public hearing in the case of parliamentary draft laws, which serves an advisory and informational function. This is one of the forms of direct citizen participation in law-making, as it gives them the opportunity to have a say in the creation of laws that, in their opinion, will affect them or assert that their voice can contribute significantly to the debate.

Here an opportunity is created for representatives of patient organizations to participate in a public hearing. Therefore, they may consider expressing their interest in participating in the public hearing on the form provided to the Marshal of the Sejm. In the Senate, social consultations can also be conducted.

"Both the Sejm's Regulations and the Senate's Regulations provide for the possibility of organizing a public hearing in the case of parliamentary draft laws, which serves an advisory and informational function. This is one of the forms of direct citizen participation in law-making (...)."

Access to public information

In Poland, the Act on Access to Public Information[117] is in force, according to which everyone has the right to access public information, and the person exercising the right to public information cannot be required to demonstrate a legal or factual interest. Public authorities (and other entities performing public tasks, listed in the Act) are obligated to provide public information. Of course, the right to public information is subject to certain limitations. Importantly, the provision of public information upon request takes place no later than within 14 days from the date of submission of the request. If the public information cannot be provided within this period, the entity obligated to provide it informs about the reasons for the delay and the deadline by which it will provide the information, which, however, should not be longer than 2 months from the date of submission of the request.

"(...) although the 'journalistic right to public information' arises from the Act on Access to Public Information, the status of the journalism profession is of great importance. (...) Formally, a journalist does not possess special privileges, but in practice, applications submitted by journalists are often considered with special care and thoroughness."

This is a very useful tool for patient organizations to support their positions with hard data, numbers, and statistics obtained through access to public information. Of course, in practice, adhering to the 14-day deadline is rare. However, it is worth keeping in mind that "although the 'journalistic right to public information' arises from the Act on Access to Public Information, the status of the journalism profession is of great importance. (...) Formally, a journalist does not possess special privileges, but in practice, applications submitted by journalists are often considered with special care and thoroughness."[118] Therefore, a way to obtain the requested information more quickly and efficiently might be to request it through a journalist.

An example of such action is the initiative of the Polish Association of Persons with Immune Deficiencies *Immunoprotect*, which in 2015 registered its own press title (a quarterly magazine for patients printed in an

117. Ustawa z dnia 6 września 2001 r. o dostępie do informacji publicznej.
118. Sitniewski, P., Dostęp do informacji publicznej. Pytania i odpowiedzi. Wzory pism, Wolters Kluwer, 2020.

edition of 1,000 copies), opening up the association to fast communication with the press offices of both the Ministry of Health and the NFZ.

4.6.3. Alternative routes

Patient Ombudsman

The patient's rights have been defined in the Act of on patient rights and the Patient Ombudsman (*Ustawa z dnia 6 listopada 2008 r. o prawach pacjenta i Rzeczniku Praw Pacjenta*). Under this act, the Patient Ombudsman was established, who is the central government administration body competent in matters of protecting the rights of patients defined in this act and in separate regulations.

The patient's rights include the right to healthcare services, to information, to report adverse effects of medicinal products, to confidentiality of information related to them, to consent to the provision of healthcare services, to respect for the patient's intimacy and dignity, to medical documentation, to object to the opinion or decision of a doctor, to respect for private and family life, to pastoral care, and to the safekeeping of valuables in a deposit.

In terms of the competencies of the Patient Ombudsman, the most important fact is that they have a wide range of possibilities to act in support of patients and the protection of their rights.

First and foremost, there is the possibility of submitting a request to the Ombudsman to initiate an explanatory proceeding in the case of a violation of patient's rights. Thus, a patient or a patient organization can use this route, remembering to designate the applicant, the patient whom the case concerns, and a concise description of the facts. Patient organizations may be particularly interested in cases of violation of the patient's right to health care services meeting the requirements of current medical knowledge or violation of the right to demand that the doctor providing health care services seeks the opinion of another doctor or convenes a medical council, which in the case of rare diseases, for example, can be crucial for making the correct diagnosis.

"(...) there is the possibility of submitting a request to the Ombudsman to initiate an explanatory proceeding in the case of a violation of patient's rights. Thus, a patient or a patient organization can use this route (...)."

The Ombudsman may also initiate such proceedings on their own initiative – if the information obtained at least suggests such a violation. Therefore, these can be both information resulting from their own findings, as well as information provided to them in writing or resulting from notifications by third parties, politicians, institutions and organizations, legal persons, etc. Media information can also initiate such proceedings. Therefore, patient have a right to organizations to publicize cases where patients' rights have been violated in the media, and inform politicians, doctors, and other organizations, as these channels can also bring signals to the Ombudsman that may lead to the initiation of proceedings on their own initiative.

Another extremely important competency of the Ombudsman is the ability given by the law to act in civil cases concerning the violation of patient's rights. The Ombudsman can, *ex officio* or at the request of a party, demand the initiation of proceedings and participate in ongoing proceedings with the rights granted to a prosecutor.

Public authorities also make normative acts available to the Ombudsman for consultation during the legislative process. Patient organizations have the opportunity for direct contact with the Ombudsman's Office to convey their position on specific changes in the processed legislative acts.

Member of Parliament

In Poland, a Member of Parliament has the right to submit an interpellation on matters of fundamental nature and related to problems associated with state policy. It is a written question to the Prime Minister or a specific minister, through the Marshal of the Sejm of the Republic of Poland. Importantly, a response to the interpellation is provided in writing no later than within 21 days from the date of receiving the letter[119].

From the citizen's perspective, parliamentary questions also play an important role, which are submitted in matters of an individual nature, related to the domestic and foreign policy conducted by the Council of Ministers, and public tasks carried out by the government administration. Questions on current issues are asked orally at each Sejm session and require direct answers from the ministers to whom the questions are directed, or in exceptional situations, their authorized representatives. The posing of a question cannot last longer than 2 minutes, and the provision of an answer – no longer than 6 minutes. There is no discussion over the question and the answer provided.

These are additional indirect opportunities for patient organizations, and therefore fully transparent cooperation with parliament members may be considered as one of the elements of the strategy of patient organizations. Moreover, Sejm and Senate committees can invite guests to their meetings, who can be experts or representatives of social partners, and thus obtain opinions or information about specific legislative proposals.

It seems worth considering to maintain relationships with MPs sitting on Health Committees (and the staff of their parliamentary offices). These politicians have a significant influence on the final shape of legal acts in the healthcare sector, and staying in contact with them increases the chances of at least receiving an invitation to such a meeting, during which representatives of patient organizations will have the opportunity to present their position. Among the MPs, there are often individuals with medical education, for whom health-related topics are, or at least should be, especially close, and acting in this area should be a priority.

"It seems worth considering to maintain relationships with MPs sitting on Health Committees (and the staff of their parliamentary offices). These politicians have a significant influence on the final shape of legal acts in the healthcare sector (...)."

It must not be forgotten that, in addition to the Senate, the President of the Republic of Poland, and the Council of Ministers, the legislative initiative in Poland also belongs to the deputies – it is required that a draft bill be submitted by a group of at least 15 deputies or a permanent Sejm committee.

Members of Parliament and Senators also create parliamentary, senatorial, or joint parliamentary-senatorial offices to support their field activities. Representatives of patient organizations can visit these offices to present their opinions, demands, and proposals.

Catholic Church

One of the most influential organizations in Poland is still the Catholic Church. Despite the progressing secularization of society, church hierarchs have a significant impact

119. Uchwała Sejmu Rzeczypospolitej Polskiej z dnia 30 lipca 1992 r. Regulamin Sejmu Rzeczypospolitej Polskiej.
120. Silbey, A., Health care's ills: A Catholic diagnosis, Lincare, 2016, p. 420.

on the actions of certain political options; both on the side of the government and the opposition. Importantly, activities for the access to treatment for chronically ill patients are in line with the church's social teachings in this area, especially in terms of respecting life[120]. Support from church hierarchs can have a positive impact on resolving the issue, both due to their political connections and social authority.

Trade unions and employers organizations

Trade unions in Poland have a relatively strong position, stemming both from legal conditions and tradition. This is especially true for the largest trade union in Poland, the famous "Solidarity," widely known for its struggle against the communist system in the 1980s. Trade unions are strongly linked with political parties, and their representatives have a real impact on the legal solutions created. Trade unions also participate in the works of a statutory body, namely the Social Dialogue Council, where key legislative projects in the social sphere are discussed. Similar to other countries, patient organizations may be able to interest trade unions in issues that affect the quality of life of workers, i.e., a broad group of society, primarily in the area of common and lifestyle diseases.

Employers' associations hold a strong position in the political system, largely due to their substantial budget and the many experts and lobbyists working for them. Beyond participating in the Social Dialogue Council, they organize numerous meetings and conferences, including those related to health topics. Moreover, like trade union representatives, they are interested in regulations that can affect large social groups. Recently, they have actively engaged in drafting legal acts on topics such as blood donation.

Umbrella patient organizations

In Poland, several umbrella organizations represent patients. In the field of rare diseases, the primary one is the National Forum *Orphan* (*Krajowe Forum Orphan*) which brings together patient organizations for rare diseases. Its president is a person who has been active in this therapeutic area for many years. They also lead the organization named the Federation of Polish Patients (*Federacja Pacjentów Polskich*), which brings together various patient organizations regardless of the therapeutic area and acts as a kind of main umbrella organization in the country.

As mentioned earlier, the Federation of Polish Patients holds a seat in the committee for rare diseases. Interestingly, this seat was not formally assigned to the "Orphan" forum, but both organizations are managed by one person, who represents patients on the committee.

Umbrella organizations also operate in other specific areas of medicine, such as in oncology, where the Polish Coalition of Oncology Patients operates. It is also worth mentioning the foundation *My Pacjenci*, which works in Poland for systemic changes without being linked to a specific disease entity. The president of this organization is the chairperson of the advisory council at the Ministry of Health.

In principle, patient organizations in Poland dealing with common diseases are usually strong and well-organized. Nevertheless, cooperation with umbrella organizations can be considered important, as their representatives have the best contacts with politicians and state administration officials, even if they do not have a strong position in the legal system.

Pharmaceutical industry organizations

The Employers' Association of Innovative Pharmaceutical Companies INFARMA is a Polish organization that brings together representatives of innovative pharmaceutical companies (exclusively foreign entities). Contrary to what the name might suggest,

it is not merely an organization representing the interests of companies as employers, but also the broadly understood innovative pharmaceutical industry. It support also many activities related to patient advocacy, like organizing trainings, conferences and issuing reports.

Other significant organizations in this ecosystem include the Farmacja Polska an organization with the longest tradition and widest reach, and the National Association of Medicines Producers, grouping Polish pharmaceutical companies.

4.7. Summary

Patient advocacy in Poland benefits from systematic dialogue with central government authorities, though consultative committees lack strong legal positions. The engagement of patient organizations in shaping healthcare policy is possible, with opportunities to participate in public consultations, legislative processes, and collaborations with entities like the Patient Ombudsman.

Patient organizations can also leverage their influence through interactions with parliament members and committees. Participation in public hearings and consultations in both the Sejm and Senate is a viable pathway for these organizations to contribute to healthcare discussions. Additionally, engaging with influential entities like the Catholic Church, trade unions, and umbrella organizations can amplify their impact on healthcare policy and patient rights.

The establishment of several committees in recent years, where patients can engage in open dialogue with government representatives, gives hope that patient organizations will soon also find their place in the Polish HTA system.

In summary, patient organizations in Poland have several ways to influence healthcare policy, from participating in the legislative process and decision making procedures. These activities, although sometimes limited by the existing legal framework, contribute significantly to shaping healthcare services and policies in Poland.

5

Romania

5. Romania

5.1. The healthcare system in Romania

According to the Constitution of Romania[121], the country's supreme law, everyone has the right to health care. The state is obliged to take measures to ensure public health, and citizens have the right to medical care in state healthcare facilities.

When it comes to the organization of healthcare in Romania, it is a social health insurance system financed by compulsory social security contributions collected from wages. Those exempt from paying contributions include: the unemployed, pensioners, and people receiving social benefits. Their contributions are paid by the state budget. In the case of pregnant women, disabled and chronically ill people, children, and students up to 26 years of age, their insurance is financed from contributions paid by employees.

Under this insurance scheme, patients are entitled to primary health care services and most outpatient medications. This includes medicines for children and pregnant women, treatments for certain serious diseases, and conditions covered by national health programs. However, patients are required to cover part of the cost for outpatient medications. This also applies to the costs of rehabilitation and hospital care, but in this case over 60% of the population is exempt from paying for hospital care (including children under 18 years of age and adolescents up to 26 years of age if they are studying).[122] In the case of dental care, the benefits package guarantees full coverage only for children, war veterans and people suffering from chronic diseases.

Despite the mandatory social health insurance system, according to data from 2020, 12% of the population remains uninsured.[123] However, uninsured people are entitled to a minimum benefits package covering life-threatening emergencies, infectious diseases and care during pregnancy.

The Ministry of Health is responsible for the overall management of the social health insurance system, while the National Health Insurance House (*Casa Națională de Asigurări de Sănătate, CNAS*) administers the National Health Insurance Fund (*Fondul național unic de asigurări sociale de sănătate*) and regulates its functioning. The Ministry of Health and CNAS are represented at the local level through district public health authorities and district insurance houses, respectively.

121. Constituția României.
122. OECD/European Observatory on Health Systems and Policies (2021), Romania: Country Health Profile 2021, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.
123. OECD/European Observatory on Health Systems and Policies (2023), Romania: Country Health Profile 2023, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.

It is also possible to take advantage of voluntary, complementary or additional health insurance offered by authorized insurance institutions, but it does not exclude the obligation to pay social health insurance contributions.

5.2. Creation of the healthcare law

In Romania, legislative power resides in a bicameral parliament, consisting of the Chamber of Deputies (the lower house) and the Senate (the upper house). Executive power is exercised by the Government and the President of Romania.

The right to legislative initiative is vested in the government, deputies, senators, and at least 100,000 citizens entitled to vote. These citizens must additionally come from at least one-fourth of the country's districts, and in each of these districts, or in the city of Bucharest, at least 5,000 signatures supporting such an initiative are required.

The President of Romania nominates a candidate for the position of Prime Minister. After the parliament passes a vote of confidence in the government, the President appoints the government. This includes the Minister of Health, who, along with the Ministry of Health, is responsible for healthcare in Romania. This responsibility covers its regulatory framework and policies, as well as the general management of the healthcare system. The Minister, in exercising his powers, issues orders (*ordine*) and instructions (*instrucţiuni*) of a normative or individual nature. These are issued solely on the basis of and in execution of laws (*legi*), decisions (*hotărâri*) and government regulations (*ordonanțe*).

5.3. The place of patient organizations in the legal system

Patient organizations in Romania, similarly to those in countries like Poland, do not have a designated place in the legal system at the level of the Constitution, laws, decisions, or government regulations. They operate based on general principles common to specific types of non-governmental organizations. Most often, patient organizations function as associations (or foundations), the operation of which is regulated by Government Regulation No. 26/2000 concerning associations and foundations.[124]

Furthermore, there is no definition of patient organizations within the Romanian legal system. However, this term appears in several lower-ranking legal acts, which will be discussed in the following subsections.

124. Ordonanţa nr. 26/2000 cu privire la asociaţii şi fundaţii.

5.4. Making decisions regarding drug reimbursement

In Romania, the main legal act regulating the use of health technology assessment is Ministerial Order No. 861/2014, which specifies the criteria and methods for assessing medicines with a view to including them on the reimbursement list.[125]

The applicant, who is usually the market authorization holder, submits the application to the special HTA unit operating within the National Agency for Medicines and Medical Devices of Romania (*Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România, ANMDMR*). ANMDMR is a public institution reporting to the Minister of Health, competent in the fields of medicines for human use, medical devices, and health technology assessment.

Within 10 days from the date of submission of the application, ANMDMR requests the opinion of the advisory committees of the Ministry of Health to approve the selection of the comparator.[126] The committees then have 10 days to send their consent to ANMDMR regarding this selection.

Then, within 30 days from the date of submission of the application, a special Health Technology Assessment unit at ANMDMR evaluates the application by analyzing the documents submitted by the applicant and calculating the costs of therapy, comparing the results of these analyses with the results of the analysis of a comparator. Next, it sends the applicant an interim report in which it presents its analysis of the submitted documentation, proposed changes, and possible requests for additional information.

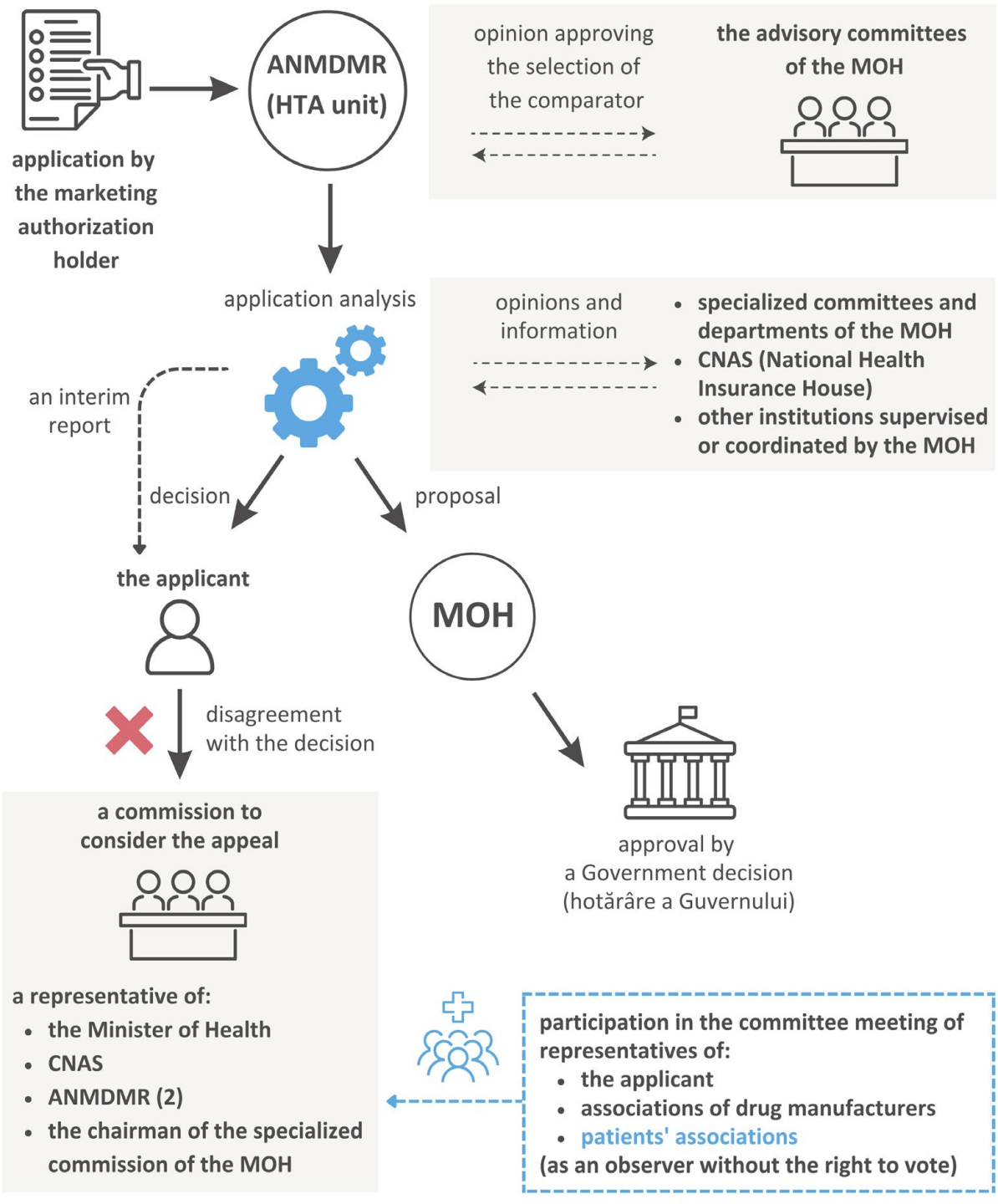
In exercising its powers in the field of HTA, ANMDMR may request opinions and information from specialized committees and departments of the Ministry of Health, CNAS (National Health Insurance House), and other institutions supervised or coordinated by the Minister of Health.

The decision, which may take the form of a recommendation to include the drug on the list with unconditional reimbursement, inclusion with conditional reimbursement, non-inclusion, or exclusion from the list, is communicated to the applicant by ANMDMR within 90 days from the date of submission of the application.

If the applicant does not agree with the decision, he or she has the right to appeal to ANMDMR. A commission to consider the appeal is then established, approved by order of the Minister of Health, and composed of a representative of the Minister of Health, CNAS, two representatives of ANMDMR, as well as the chairman of the specialized commission of the Minister of Health corresponding to the therapeutic area related to the appeal. Representatives of the applicant who filed the appeal, associations of drug manufacturers, and patients' associations may participate in the meetings of the committee resolving the appeal, but their participation is only of an observer nature and does not include the right to vote. Decisions of the dispute settlement committee are taken within 15 days in an open vote by a simple majority of votes. If the applicant still does not agree with the decision, the only further option is

125. Ordin nr. 861 din 23 iulie 2014 pentru aprobarea criteriilor şi metodologiei de evaluare a tehnologiilor medicale, a documentaţiei care trebuie depusă de solicitanţi, a instrumentelor metodologice utilizate în procesul de evaluare privind includerea, extinderea indicaţiilor, neincluderea sau excluderea medicamentelor în/din Lista cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, precum şi denumirile comune internaţionale corespunzătoare medicamentelor care se acordă în cadrul programelor naţionale de sănătate, precum şi a căilor de atac.
126. A comparator, in the context of health technology assessments, refers to a standard or method against which a new health technology (e.g., new drug, medical device, medical procedure) is compared to assess its value.

to approach the competent administrative courts. ANMDMR proposes to the Minister of Health a list of reimbursed drugs, which is approved by a Government decision (*hotărâre a Guvernului*). The list is updated at least once a year, in line with the Government's budgetary policy and national priorities set by the Ministry of Health.



Making decisions regarding drug reimbursement in Romania.

5.5. Patient advocacy opportunities in Romania

Although patient organizations in Romania do not have a strong legal position in the system, they are able to influence decisions and legislation using various available tools.

Interestingly, despite the lack of formal recognition and definition, patient organizations can be engaged by authorities through several options within a specific framework.

5.5.1. Specific framework

HTA appeal committee

As described in the section on drug reimbursement, patient associations have limited options in this area. Representatives of patient associations may participate in the meetings of the committee considering the applicant's appeal against the decision issued by ANMDMR, but only as observers without voting rights.

> **"Representatives of patient associations may participate in the meetings of the committee considering the applicant's appeal against the decision issued by ANMDMR, but only as observers without voting rights."**

Attending a committee meeting, however, allows them access to the materials and information presented. Although they cannot influence the outcome by voting, they can express their position during the debate and present evidence. It should be noted, however, that this evidence does not have to be formally taken into account.

Scientific Council of the National Agency for Medicines and Medical Devices of Romania (ANMDMR)

Within ANMDMR, a Scientific Council has been established by order of the Minister of Health. It is composed of the president of ANMDMR, the vice-president of ANMDMR, two representatives from ANMDMR, as well as representatives from medical faculties, pharmacy faculties, the G6-UMF University Alliance, the Minister of Health, the College of Pharmacists in Romania, the Romanian Medical College, and the National School of Public Health, Management and Improvement in Health.[127]

The Scientific Council is responsible for establishing the scientific policy of ANMDMR. It can make decisions, which are then notified to the Minister of Health and published on ANMDMR website.[128]

In consultation with the Administrative Council of ANMDMR, the Scientific Council aims to develop cooperation between ANMDMR and representatives of patients, consumers, business entities, and academic institutions. This cooperation may include their participation in the activities of ANMDMR, under terms previously established by the Management Board in consultation with the Scientific Council.[129] Therefore, the relationship between patient organizations and the Scientific Council may be considered useful.

Meetings within the National Agency for Medicines and Medical Devices of Romania (ANMDMR)

In the fields of medicines for human use and medical devices, the ANMDMR has the opportunity to organize, among others,

127. Art. 11 (1) Lege nr. 134 din 12 iulie 2019 privind reorganizarea Agenției Naționale a Medicamentului și a Dispozitivelor Medicale, precum și pentru modificarea unor acte normative.
128. Art. 11 (9) leg. cit.
129. Art. 14 leg. cit.

working groups,[130] to which representatives of patient organizations are invited. An example is the meeting of the working group organized in 2017, which was attended by representatives of the Romanian National Alliance for Rare Diseases (*Alianța Națională pentru Boli Rare România, ANBRaRo*). During the meeting, the topics discussed included increasing patient involvement in ANMDMR pharmacovigilance activities and the role of patients in health technology assessment.[131,132]

In accordance with statutory provisions, ANMDMR also organizes meetings with consumer and patient organizations/associations and with the authorities responsible for the application of legislation in Romania to provide public information on activities related to the prevention and application of legislation to combat counterfeit medicines.[133]

Co-payment of medical services under social health insurance

As mentioned earlier, patients covered by social health insurance are required to cover part of the costs for selected medical services. The list of services for which a co-payment (*coplata*) is charged, and the amount of such co-payment, are determined by the framework agreement. Importantly, the areas of medical assistance for which the co-payment and its amount are determined are approved by a Government decision (*hotărâre a Guvernului*) following negotiations with patient associations, specialist associations, associations of employers providing health services, and CNAS.

By engaging in setting the financial parameters of healthcare, patient organizations help promote equity in access to healthcare. They work to ensure that co-payments do not discriminate against certain groups of patients, such as those with chronic diseases or those with low incomes. Participating in these negotiations gives patient organizations the opportunity to represent the interests and needs of patients in front of authorities and healthcare providers. This participation is an opportunity to influence health decisions and policies towards better adaptation to patients' needs.

National Plan for Rare Diseases and the National Committee for Rare Diseases (*Comitetul Național pentru Bolile Rare*)

In Romania, the first national plan for rare diseases covered the period from 2010 to 2014. It was established as a result of a partnership signed in 2008 between the Ministry of Health and the Romanian National Alliance for Rare Diseases (*Alianța Națională pentru Boli Rare România, ANBRaRo*). This association currently unites almost 50 patient organizations dealing with rare diseases in Romania.[134] The agreement clearly defines the obligations of both parties, stipulating, among other responsibilities, that ANBRaRo appoints a person responsible for monitoring the implementation of the National Plan for Rare Diseases and another for cooperating with a representative of the Ministry of Health. ANBRaRo is also responsible for informing and consulting with patient associations on the main operational directions of the National Plan for Rare Diseases and for submitting proposals for legal acts that consider the real needs of patients and aim at managing rare diseases.[135]

Due to political instability and socio-economic challenges, the implementation of

130. Art. 4 (3) p. 17 and (4) p. 6 leg. cit.
131. Agentia Nationala a Medicamentului si a Dispozitivelor Medicale din România, Anunt important 05/08/2017 Attention interested persons [online] Available at: https://www.anm.ro/anunt-important-08-05-2017/ [11.01.2024]
132. Asociația Națională Miastenia Gravis România. Raport de activitate 2016 – 2017 [online] Available at: https://miastenie.ro/wp-content/uploads/2018/01/Raport2016-2017.pdf.
133. Art. 869 Lege nr. 95 din 14 aprilie 2006 privind reforma în domeniul sănătății.
134. List of members of the Romanian National Alliance for Rare Diseases [online] Available at: https://www.bolirare-romania.ro/membri [11.12.2023].
135. Planul Național De Boli Rare România 2010- 2014 [online] Available at: https://www.apwromania.ro/sites/default/files/files/PNBR_2011_11.pdf [11.12.2023].

the national plan for rare diseases was postponed until 2013.[136] By the end of 2013, the Ministry of Health had adopted the National Plan for Rare Diseases, which was included in the National Public Health Strategy for 2014-2020.

Furthermore, by order of the Minister of Health[137] the National Committee for Rare Diseases (*Comitetul Național pentru Bolile Rare*) was established. As an interdisciplinary scientific body consisting of experts in the field of rare diseases, it serves as an advisory body to the Minister of Health.[138] The committee is composed of a total of 20 members, including healthcare professionals, academics, representatives of the Ministry of Health, CNAS, ANMDMR, and patient representatives. It is noteworthy that the ordinance allocates seats for three representatives from Alianţa Naţională pentru Boli Rare România, although, at the time of writing this report, there were only two representatives of the alliance in the Committee.[139] Representatives of patient associations may also attend Committee meetings as guests, without voting rights.[140]

It is important to note that the role of Alianţa Naţională pentru Boli Rare România was clearly defined within the plan itself, with the organization being mentioned by name, similar to the Austrian patient organization Pro Rare Austria in the Austrian National Plan for Rare Diseases. ANBRaRo, an active and professional patient organization operating since 2007, has had a significant impact on state policy regarding patients with rare diseases.

Economic and Social Council (*Consiliul Economic și Social*)

In 2013, the Economic and Social Council (*Consiliul Economic şi Social*), was established by law. As a public institution, it serves as an advisory body to the Romanian Parliament and Government. Its establishment aimed to enable tripartite dialogue at the national level among employers' organizations, trade unions, and representatives of non-governmental associations and civil society foundations.[141]

The Council's main task is to provide opinions on draft normative acts initiated by the Government, as well as legislative drafts from deputies and senators. Consultation on these projects is mandatory in the areas specified by the law, including health policy.[142]

The Council's meetings include 45 members: 15 representatives from employers' confederations, 15 representatives from trade unions, and 15 members representing civil society. This last group includes representatives of associations representing disabled people and other non-governmental organizations operating in fields within the Council's competence. Notably, from 2018 to 2020, a member of the Council was the President of the Romanian National Alliance for Rare Diseases (*Alianța Națională pentru Boli Rare România*)[143]. Currently, the Council includes representatives from organizations such as *Asociația Help Autism* – the largest organization dealing with autism in Romania, and the National Council for Disability in Romania (*Consiliul Național al Dizabilității din România, CNDR*).[144]

136. Rare Disease Day. About Romanian National Alliance For Rare Diseases [online] Available at: https://www.rarediseaseday.org/friends/romanian-national-alliance-for-rare-diseases/.
137. Ordinul nr. 1215/2013 privind aprobarea constituirii Consiliului Naţional pentru Bolile Rare.
138. Art. 1 and 2 (1) leg. cit.
139. Composition of the National Committee for Rare Diseases [online] Available at: https://old.ms.ro/?pag=273.
140. Art. 2 (8) (c) Ordinul nr. 1215/2013 privind aprobarea constituirii Consiliului Naţional pentru Bolile Rare.
141. Art. 1 (1) and (2) Lege nr. 248 din 19 iulie 2013 privind organizarea şi funcţionarea Consiliului Economic şi Social.
142. Art. 2 (1) and (2) leg. cit.
143. Consiliul Economic și Social, Raport de activitate 2017 – 2020 [online] Available at: https://www.ces.ro/newlib/PDF/2021/Raport-activitate-2017-2020.pdf [11.12.2023].
144. Composition of the Economic and Social Council [online] Available at: https://www.ces.ro/plen/ro/3 [10.01.2024].

"The Council's meetings include 45 members: 15 representatives from employers' confederations, 15 representatives from trade unions, and 15 members representing civil society. This last group includes representatives of associations representing disabled people and other non-governmental organizations operating in fields within the Council's competence."

The Economic and Social Council represents another avenue for increasing the participation of patient organizations in creating legal regulations in key areas such as health policy. The importance of this arrangement is not solely due to the representation of civil society. Working alongside employer confederations and trade unions can provide patient organizations with a strategic avenue to advocate for changes that improve patients' quality of life and make the healthcare system more responsive to their needs. Similar to other countries, Romanian patient organizations could potentially interest trade unions in issues that affect the quality of life of employees , like issues of a wide segment of society, especially in the area of common and lifestyle diseases. Employer confederations also have an interest in regulations that may impact large social groups. However, such efforts require effective communication, negotiation skills, and the ability to build coalitions with other partners.

Specialist Committees of the Ministry of Health

By Order No. 2396/2023[145] the Minister of Health established three types of advisory bodies. One of these is the specialist commissions (*comisiile de specialitate*)[146], composed of specialists in a given field of medicine with recognized achievements in their professional, medical, teaching, or scientific research activities. They provide the necessary expertise on the basis of which the Ministry of Health coordinates medical assistance.[147]

"(...) representatives of patients' associations may be invited to participate in meetings of specialist committees. (...) These individuals do not have the right to vote."

The committee's tasks include, among others, justifying decisions of the Minister of Health regarding policies, strategies, and action programs in the field of health; identifying and proposing national priorities to the Minister of Health; developing proposals for packages of medical services provided under the health insurance system; and developing proposals for national health programs implemented under the health insurance system or with the state budget.[148]

Importantly, from the patients' perspective, representatives of patients' associations may be invited to participate in meetings of specialist committees. However, in this case, they must comply with the same confidentiality requirements as those applicable to committee members.[149] These individuals do not have the right to vote.[150] However, attendance at a commission meeting gives them the opportunity to present their own position, and the evidence presented at the meeting may be used to formulate the commission's position.

145. Ordinul nr. 2396/2023 privind înfiinţarea, organizarea şi funcţionarea comisiilor de specialitate ale Ministerului Sănătăţii.
146. Current list of specialist commissions of the Ministry of Health [online] Available at: https://ms.ro/ro/minister/organizare/comisii-de-specialitate/ [20.01.2024].
147. Art. 1 (1), (2) and (3) Ordinul nr. 2396/2023 privind înfiinţarea, organizarea şi funcţionarea comisiilor de specialitate ale Ministerului Sănătăţii .
148. Art. 11 (1) leg. cit.
149. Art. 12 (2) and (3) leg. cit.
150. Art. 13 (8) leg. cit.

5.5.2. General administrative framework

Patient organizations in Romania can use several tools available to all citizens in their advocacy activities.

Transparency of decision-making in public administration

The Romanian Administrative Code[151] lists the principle of transparency as one of the principles applicable to public administration. This means that public bodies and institutions, when preparing draft normative acts, are obliged to provide information and submit these drafts for consultations and public debate. They are also required to grant citizens access to the administrative decision-making process, as well as to data and information that are of public interest (of course, within the limits set by law).[152]

Moreover, an exceptional regulation is Act No. 52 of January 21, 2003, on the transparency of decision-making in public administration (*Lege nr. 52 din 21 ianuarie 2003 privind transparența decizională în administrația publică*). This Act regulates the participation of citizens and legally established associations in the policymaking and law-making processes (with certain exceptions specified in the Act, e.g., in the area of defense). Legally established associations should be understood to include any civic organization, trade union, employer, or other group of civic representation.

The aim of the act is to increase the degree of responsibility of the public administration towards citizens, emphasizing that they are the beneficiaries of administrative decisions; to include active participation of citizens in the process of making administrative decisions and creating normative acts; and to increase transparency at the level of the entire public administration. The bodies obliged to apply these provisions include both central and local public administration bodies, such as ministries.[153]

The first type of rights concerns participation in the process of establishing normative acts. The Act obliges a public administration body to publish an announcement on the preparation of a given normative act at least 30 days before submitting it for approval to public authorities. The notice must be published on the authority's website, posted at its headquarters in a publicly accessible place, and, as the case may be, communicated to the central or local media. The public administration body must also provide draft normative acts to all persons who have submitted an application to receive this information.[154]

After publishing the announcement, the public administration authority sets a deadline of at least 10 calendar days for interested parties to submit written proposals, suggestions, or opinions regarding the draft normative act. The submitted proposals, suggestions, and opinions have only recommendation value.[155]

The competent public authority is obliged to organize a meeting for the purpose of public debate on a draft normative act if a legally established association or another public authority has requested it in writing.[156]

It should be emphasized that in case of an urgent situation, or one which, due to its exceptional circumstances, requires immediate solutions to avoid a serious violation of public interest, draft normative

151. Ordonanță de urgență nr. 57 din 3 iulie 2019 privind Codul administrativ.
152. Art. 8 leg. cit.
153. Art. 1, 2 and 4 Lege nr. 52 din 21 ianuarie 2003 privind transparența decizională în administrația publică.
154. Art. 7 (1) and (2) leg. cit.
155. Art. 7 (2) and (4) leg. cit.
156. Art. 7 (9) leg. cit.

acts must be adopted before the expiry of the previously described 30-day period.[157]

"(...) issuing administrative decisions is the exclusive competence of public authorities, and the views expressed at public meetings by citizens or representatives of legally established associations are only of a recommendation nature."

The second type of right is participation in the decision-making process. A public authority has the ability to organize public meetings. They post an announcement about a public meeting at their headquarters, on their website, and send it to the media at least 3 days before the meeting. In addition, they are also obliged to notify those citizens and legally established associations that have submitted written suggestions and proposals of recommendation value regarding one of the areas of public interest to be discussed at the public meeting. Citizens may participate in public meetings, but their participation is subject to the limits of the available seats, as priority is given to legally established associations.[158]

It should be remembered that issuing administrative decisions is the exclusive competence of public authorities, and the views expressed at public meetings by citizens or representatives of legally established associations are only of a recommendation nature.[159]

The solutions discussed enable patient organizations to actively participate in the law-making process. Patient organizations can use these opportunities to promote changes in the law that are beneficial to patients by submitting written proposals, suggestions, or opinions regarding draft normative acts. They may also request a public debate on the draft normative act. It is important to follow the announcements published by public authorities about the development of normative acts and organized public debates. This will allow for a quick response to these processes. Additionally, the possibility of organizing public meetings by public authorities, where patient organizations can present their opinions and suggestions, is a direct way to communicate with officials. Although opinions expressed in writing or at meetings are of a recommendation nature, they present an opportunity to draw attention to the key problems and needs of patients.

However, research shows that authorities still view the participation of citizens and stakeholders as merely a formality, failing to recognize the value these solutions offer. The analysis carried out by the General Secretariat of the Government in 2021 clearly shows that the initiative to initiate public consultation processes or debates most often rests with public institutions, and their main goal is to fulfill the obligations imposed by the act. Moreover, setting short deadlines for consultations on draft normative acts, which are most often the minimum specified by law (e.g., 10 days for submitting written positions, suggestions, and opinions), is negatively perceived by the public. The inability to conduct public meetings online or in a hybrid mode and space limitations in organizing them mean that only a small number of interested parties can take part in them. As a result, the number of recommendations submitted for projects initiated by public authorities is low.

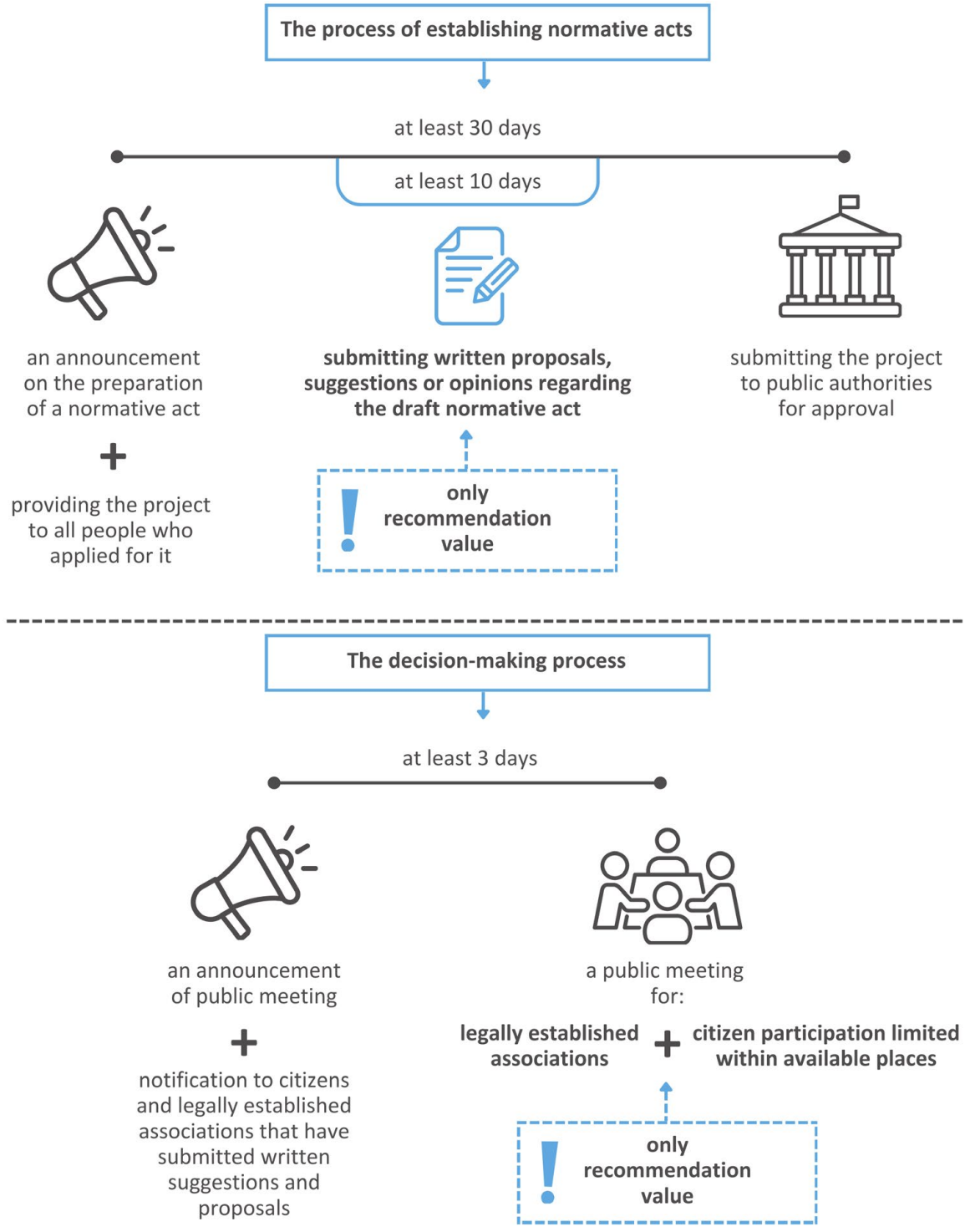
Ultimately, a formalistic approach to legal regulations leads to a situation in which the opportunities arising from interactions with

157. Art. 7 (13) leg. cit.
158. Art. 8 leg. cit.
159. Art. 10 leg. cit.

civil society are not fully exploited. Additionally, the high frequency of use of emergency regulations, which allow normative acts not to be published at the stage of their design, means that interested people and organizations do not have the opportunity to express their point of view.[160]

Regulations of the Act of December 19 on social dialogue (*Lege nr. 367 din 19 decembrie 2022 privind dialogul social*)

An important act from the point of view of citizens' participation in law-making and



Transparency of decision-making in public administration in Romania.

160. Secretariatul General al Guvernului, Analiză privind evaluarea practicilor administrației publice centrale și locale în procesul de luare a deciziei și asigurării accesului la informații de interes public, 2021.

decision-making is the Act of December 19 on social dialogue (*Lege nr. 367 din 19 decembrie 2022 privind dialogul social*), which establishes permanent structures within public authorities and institutions for consultations with legally established civil society organizations:

1) Tripartite National Council for Social Dialogue (Consiliul Național Tripartit pentru Dialog Social)

Pursuant to the aforementioned Act, the Tripartite National Council for Social Dialogue (*Consiliul Național Tripartit pentru Dialog Social*) was established as a national advisory body for social partners, which, according to the Act, include trade unions or trade union organizations, employers or employers' organizations, as well as representatives of public administration bodies. The aim of the Council is to disseminate good practices in the field of tripartite social dialogue among the aforementioned social partners.[161]

The Council consists of the chairpersons of the representative confederations of employers and trade unions at the national level; representatives of the Government appointed by the Prime Minister's decision at least at the level of Secretary of State from each ministry, as well as from other state structures, in accordance with arrangements with social partners; and the chairperson of the Economic and Social Council, along with other members as agreed upon with the social partners.[162] The Council is led by the Prime Minister, with the Minister of Social Dialogue serving as the deputy.[163]

The main tasks of the Council include, among others: analyzing draft programs and strategies developed at the government level; developing and supporting the implementation of strategies, programs, methodologies, and standards in the area of social dialogue; resolving social and economic disputes through tripartite dialogue; negotiating and concluding agreements, social pacts, and other national-level agreements and monitoring their implementation.

Here, as in the case of the Economic and Social Council (*Consiliul Economic și Social*) described earlier, it is worth considering t for patient organizations to cooperate with employers' confederations or trade unions, which may interest patients in issues affecting the quality of life of employees. However, as mentioned earlier, this requires highly effective communication with other social partners and building relationships.

2) Social Dialogue Commissions

Among others, the Ministry of Health has established social dialogue commissions composed of representatives from public administration at the central level, representatives of employers' organizations, and trade unions recognized nationally. These commissions are consultative by nature and are primarily intended to ensure partnership-based social relations between the administration, employers' organizations, and trade unions, and to conduct mandatory consultations with social partners on legislative initiatives or other initiatives of an economic and social nature. At the request of the commission chair, the plenary meeting of the commission may authorize the participation of non-permanent guests.[164] Invited guests may include patient representatives, but the initiative to invite them rests with the permanent members of the commission. Therefore, it may be good idea l to build relationships with the aforementioned organizations.

161. Art. 82 Lege nr. 367 din 19 decembrie 2022 privind dialogul social.
162. Art. 83 leg. cit.
163. Art. 84 leg. cit.
164. Regulament Cadru privind constituirea şi funcţionarea comisiilor de dialog social la nivelul administraţiei publice centrale | Lege 367/2022.

3) The conclusion of agreements with social partners

The Act on Social Dialogue regulates the conclusion of agreements with social partners (i.e., trade unions or trade union organizations, employers or employers' organizations, as well as representatives of public administration bodies) on matters of common interest. These agreements produce effects only between the parties that signed them.[165]

Citizens' initiative

The Constitution of Romania grants the sovereign the right to introduce citizens' legislative initiative, which takes two forms. The first is the possibility of initiating a change (revision) to the Constitution itself.[166] The second is the possibility of initiating the adoption of a law.[167] Both initiatives are only available to Romanian citizens who have the right to vote.[168]

However, the initiatives differ in their quantitative thresholds. For a revision of the Constitution, at least 500,000 signatures are required. An additional condition is that these citizens must come from at least half of the country's districts, and moreover, at least 20,000 signatures must be submitted in each of these districts and in the city of Bucharest in support of this initiative.[169] The Constitution also lists areas in which revision is prohibited.[170]

In the case of initiating the adoption of a law by citizens, this right is granted to a group of at least 100,000 citizens who must come from at least one fourth of the country's districts. In each of these districts and in the city of Bucharest, at least 5,000 signatures supporting such an initiative must be collected.[171] An additional condition is that this initiative cannot concern matters of taxation, international affairs, amnesty, or pardon[172].

"In the case of initiating the adoption of a law by citizens, this right is granted to a group of at least 100,000 citizens who must come from at least one fourth of the country's districts. In each of these districts and in the city of Bucharest, at least 5,000 signatures supporting such an initiative must be collected."

Regarding the initiation the adoption of a law, the number of votes required is five times lower than that for revising the Constitution, but it is still very high. However, as was already emphasized when discussing legislative initiatives in Austria and Poland (where the quantitative requirement is the same), it appears that this tool can be utilized by the largest patient organizations, especially in matters concerning the media. Nevertheless, the initiative itself and the resulting media reaction may serve as a signal to politicians about the need to regulate a given issue.

Right of petition

Pursuant to Article 51 of the Constitution of Romania, citizens, as well as legally established organizations, have the right to address public authorities with petitions. These petitions must be formulated on behalf of the individuals signing the document or the members they represent. However, Government Regulation No. 27 of January 30, 2002, regarding the regulation of activities related to the examination of petitions (*Ordonanța nr. 27 din 30 ianuarie*

165. Art. 1 p. 19 Lege nr. 367 din 19 decembrie 2022 privind dialogul social.
166. Art. 150 (1) Constituția României .
167. Art. 74 (1) leg. cit.
168. Art. 36 leg. cit.
169. Art. 150 leg. cit.
170. Art. 152 (1) and (2) leg. cit.
171. Art. 74 (1) leg. cit.
172. Art. 74 (2) leg. cit.

2002 privind reglementarea activității de soluționare a petițiilor), specifies that a petition refers to an application, complaint, notice, or proposal. Such documents can be directed, in writing or electronically, to various entities, including central and local public authorities and institutions, decentralized public services, ministries, and other central bodies. These entities are obliged to respond to the petitioner within 30 days from the date of registration of the request, regardless of whether the response is favorable or unfavorable.[173] This deadline may be extended by no more than 15 days if the issues raised in the petition require more detailed information and research.[174]

The right of petition is a tool that can be utilized by patient organizations to shape the pro-patient legal environment, report problems, or propose changes to existing legal regulations. It is crucial that petitions are submitted thoughtfully and in accordance with applicable regulations so that they can be effectively considered by the appropriate authorities.

In practice, this means that, at least in theory, public authorities have a 30-day deadline to respond to letters (petitions) also submitted by patient organizations.

Access to public information

The right to access public information in Romania is regulated by Act No. 544 of October 12, 2001, on free access to information of public interest (*Lege nr. 544 din 12 octombrie 2001 privind liberul ccess la informațiile de interes public*). This Act is further elaborated by the Methodological Principles of Application (*Normele metodologice de aplicare a Legii nr. 544/2001, privind liberul acces la informațiile de interes public*).

Any individual or entity, whether Romanian or foreign, may request information that is of public interest. This term refers to any information related to or resulting from the activities of public authorities or institutions[175] (albeit with certain exceptions as provided for by law). The requester is not required to justify their inquiry in any manner.

Public authorities and institutions are obliged to provide a written response to such requests within 10 days or, depending on the request's degree of difficulty, complexity, volume of documentation, and urgency, at the latest within 30 days of the registration of the request. Should the authority decide to refuse the provision of the requested information, it must justify its refusal and inform the requester within 5 days of receiving the request.[176]

It is worth noting the regulation contained in Government Regulation No. 26/2000 on associations and foundations, which mandates that public authorities make information of public interest readily available to associations, foundations, and federations.[177]

As observed in the previously discussed contexts, access to public information in Romania serves as a valuable tool for patient organizations. It enables them to support their positions with concrete data, numbers, and statistics obtained through this means.

People's Advocate (*Avocatul Poporului*). The Ombudsman

The Constitution of Romania guarantees all citizens the right to health protection[178] and medical care in state health care facilities.[179] The People's Advocate (*Avocatul Poporului*), equivalent to the Ombudsman, aims to defend the rights and freedoms of

173. Art. 8 (1) Ordonanța nr. 27 din 30 ianuarie 2002 privind reglementarea activității de soluționare a petițiilor.
174. Art. 9 leg. cit.
175. Art. 1, 2b Lege nr. 544 din 12 octombrie 2001 privind liberul ccess la informațiile de interes public and Art. 20 Normele metodologice de aplicare a Legii nr. 544/2001, privind liberul acces la informațiile de interes public.
176. Art. 7 leg. cit.
177. Art. 50 Ordonanţa nr. 26/2000 cu privire la asociaţii şi fundaţii.
178. Art. 34 (1) Constituția României.
179. Art. 47 (2) leg. cit.

citizens in their interactions with public authorities[180], which includes issues related to health care.

> **"It is important to note that, similar to the Austrian model, only natural persons have the right to assert their rights before the People's Ombudsman; patient organizations cannot submit complaints."**

The People's Advocate performs his duties either ex officio or at the request of the aggrieved party. This party may be any natural person, regardless of citizenship, age, gender, political affiliation, or religious beliefs, whose civil rights or freedoms have been violated as a result of actions by public administration bodies.[181] It is important to note that, similar to the Austrian model, only natural persons have the right to assert their rights before the People's Ombudsman; patient organizations cannot submit complaints. However, as emphasized in the Austrian regulations regarding the Ombudsman Office (*Volksanwaltschaft*), this procedure allows for addressing problems at the local level, including issues related to access to health care or delays in administrative procedures for providing benefits to disabled individuals.

Crucially, the People's Advocate can also take actions ex officio. In performing its duties, it may make recommendations that are not subject to parliamentary or judicial review. By issuing recommendations, it notifies public administration bodies about the illegality of administrative acts they have issued,[182] serving as a form of public criticism. Given that the People's Ombudsman is accountable only to Parliament, this grants him a strong legal position. This accountability is exercised through the obligation to submit reports to Parliament, which may include recommendations for the adoption of laws or other measures to protect citizens' rights and freedoms.[183]

Moreover, the People's Advocate may notify the Constitutional Court about the inconsistency of laws adopted by Parliament with the Constitution before their promulgation and can bring before the Constitutional Court allegations that existing laws and regulations are inconsistent with the Constitution.[184]

Even though patient organizations cannot submit a direct application to the People's Advocate as an aggrieved party, actions they take, such as publicizing certain health protection or patient rights issues in the media, may result in the People's Advocate initiating ex officio actions. This includes conducting inspections regarding the compliance of draft laws with the Constitution and highlighting certain administrative shortcomings in his reports to Parliament, thereby drawing public attention to these issues.

Administrative cases

The Administrative Disputes Act (*Lege no. 554 din 2 decembrie 2004 contenciosului administrativ*) states, "Any person who considers himself or herself to have been affected in his or her right or legitimate interest by a public authority, through an administrative act, or by the failure to process an application within the legal deadline, may apply to the competent administrative court to repeal the act, recognize the asserted right or legitimate interest, and redress the damage caused. A legitimate interest may be both private and public."[185]

180. Art. 58 (1) Constituția României and art. 1 (1) Lege nr. 35 din 13 martie 1997 privind organizarea şi funcţionarea instituţiei Avocatul Poporului.
181. Art. 59 (1) Constituția României and art. 14 Lege nr. 35 din 13 martie 1997 privind organizarea şi funcţionarea instituţiei Avocatul Poporului.
182. Art. 20 Lege nr. 35 din 13 martie 1997 privind organizarea şi funcţionarea instituţiei Avocatul Poporului.
183. Art. 60 Constituția României and art. 5 (1) Lege nr. 35 din 13 martie 1997 privind organizarea şi funcţionarea instituţiei Avocatul Poporului.
184. Art. 146 Constituția României.
185. Own translation.

It is important to note that in defining the concept of an "affected person," the Act indicates that it may also include "interested social entities." This term refers to non-governmental structures, unions, associations, foundations, and the like, whose objective is to protect the rights of various categories of citizens or, alternatively, to ensure the proper functioning of public administration services. Therefore, this group also includes Romanian patient organizations.

This regulation is similar to the Polish regulation, which allows Polish patient organizations to participate in administrative proceedings as a party. Thanks to this provision, they can act as a third party in the procedure for including a drug in reimbursement (which occurs through an administrative decision of the Minister of Health), alongside the Minister of Health and the applicant (as discussed in the chapter on Poland). However, in the case of the Romanian regulation, case law states that in order to initiate such a review of the legality of administrative acts, associations must invoke a legitimate private interest, and a legitimate public interest can only serve as an auxiliary basis.[186] Therefore, unlike Polish patient organizations, it may be challenging for Romanian ones to demonstrate that the interest of the association – and not only the public interest, i.e., the patients – was violated when refusing to reimburse a drug.

5.5.3. Alternative routes

Partnership Agreements

In order to achieve its goals, as specified in Decision No. 144/2010 on the organization and functioning of the Ministry of Health[187], the Ministry cooperates with public administration authorities at both central and local levels, specialized public institutions, and civil society structures, which undoubtedly include non-governmental organizations. Such cooperation may take the form of a partnership agreement.

An example of such an agreement is the partnership titled "Rare Diseases as a Public Health Priority in Romania" *(Bolile rare, o prioritate pentru Sanatatea Publica din Romani*) concluded between the Ministry of Health and the Romanian National Alliance for Rare Diseases (*Alianța Națională pentru Boli Rare România, ANBRaRo*). The purpose of establishing this partnership was to develop and implement the National Plan for Rare Diseases in Romania, which formed the basis for policy activities and resource allocation for the Rare Diseases Program for 2013-2020. The contract details the obligations of both parties.[188]

Entering into such partnership agreements is an out-of-the-box idea. Through these agreements, patient organizations can establish their own legal framework for cooperation with public administration bodies.

Cooperation with other entities

As mentioned in previous sections, there are many cases where patient organizations do not have a direct opportunity to influence decisions made within certain bodies – either because they do not have a seat in them or they can participate in meetings only as observers without voting rights. In such scenarios, cooperation with other members of these bodies becomes crucial. We referenced

186. Decizia Înaltei Curți de Casație și Justiție nr. 8 din 2 martie 2020 referitoare la interpretarea și aplicarea unitară a dispozițiilor art. 1 alin. (1), art. 2 alin. (1) lit. a), r) și s) și art. 8 alin. (1^1) și (1^2) din Legea contenciosului administrativ nr. 554/2004, cu modificările și completările ulterioare.
187. Hotărârea nr. 144/2010 privind organizarea şi funcţionarea Ministerului Sănătăţii.
188. The partnership „Rare Diseases as a Public Health Priority in Romania" („Bolile rare, o prioritate pentru Sanatatea Publica din Romania") [online] Available at: https://www.apwromania.ro/sites/default/files/files/accord_2013.pdf [03.01.2024].
189. Art. 229 Lege Nr. 95/2006 din 14 aprilie 2006 privind reforma în domeniul sănătăţii.

trade unions and employers' organizations in connection with entities such as the Economic and Social Council (*Consiliul Economic și Social*) and the Tripartite National Council for Social Dialogue (*Consiliul Național Tripartit pentru Dialog Social*). However, cooperation with entities that associate medical professionals can also be extremely important in specific cases.

For example, consider the regulations regarding the package of basic services under social health insurance. As indicated at the beginning of this chapter, the insured person is entitled to a specific package of basic services. The scope of such services is determined based on a framework agreement drawn up by CNAS after consultation with entities such as the Romanian College of Physicians (*Colegiul Medicilor din România, CMR*), Romanian College of Dentists (*Colegiul Medicilor Dentiști din România, CMDR*), Romanian College of Pharmacists (*Colegiul Farmaciștilor din România, CFR*), Order of Generalist Medical Assistants, Midwives and Medical Assistants of Romania (*Ordinul Asistenților Medicali Generaliști, Moașelor și Asistenților Medicali din România, OAMGMAMR*), Order of Biochemists, Biologists, and Chemists (*Ordinul Biochimiștilor, Biologilor și Chimiștilor, OBBC*), as well as representative employers' organizations and trade unions in the medical field.[189] Engaging with representatives of these entities offers a method for patient organizations to advocate for patient-centered decisions regarding the package of basic services to be covered by social insurance. It is through these interactions that patient organizations can present their positions and opinions on the matter.

Expert Committees within CNAS

Within the National Health Insurance House (CNAS), there are expert committees. Their responsibilities include: collaborating with the specialized structures of CNAS to develop responses to inquiries and interpellations submitted by institutions, applicants, or associations of patients or service providers, as well as formulating opinions on legislative proposals related to social health insurance.

The members of these expert committees are medical specialists in various fields. It may be beneficial for patient organizations to consider this as another indirect opportunity to present their opinions and positions and to maintain relationships with these members.

The Romanian National Alliance for Rare Diseases (*Alianța Națională pentru Boli Rare România, ANBRaRo*)

Already mentioned several times in this chapter, the alliance brings together almost 50 Romanian organizations representing various rare diseases. It is a very strong organization that effectively promotes the interests of patients with rare diseases in Romania.

Importantly, similar to the Austrian organization Pro Rare Austria, it holds a formalized position within the Romanian National Plan for Rare Diseases. Additionally, pursuant to the order of the Minister of Health, 3 representatives from the Alianța Națională pentru Bolile Rare România are guaranteed seats on the National Committee for Rare Diseases (*Comitetul Național pentru Bolile Rare*), which serves as an advisory body to the Minister of Health in implementing the Plan.

Without a doubt, *Alianța Națională pentru Bolile Rare România* can be considered a key ally in advocating for the rights of people suffering from rare diseases in Romania. Other organizations can greatly benefit from joining the alliance.

5.6. Summary

The Romanian system is based on universal access to healthcare, financed through contributions from citizens and residents. However, what sets it apart from many systems in the region is the requirement for co-payment for certain medical procedures, including hospital stay, which may limit access to treatment for less affluent patients. Therefore, the involvement of patient organizations in activities aimed at increasing access to innovative therapies for patients with rare and chronic diseases is important.

Similarly to many countries in the region, patient organizations in Romania do not have a specific place in the legal system. Romanian legislation also does not allow representatives of patient organizations to participate in the health technology assessment process, except for a consultative role in appeal cases. Nonetheless, a good practice, associated with European Union regulations, is the involvement of patient organizations for rare diseases in the creation and implementation of Rare Disease Plans.

Patient organizations also have the opportunity to participate in the work of some Ministry of Health committees and the agency responsible for drug reimbursement. However, an invitation from the government is usually required for this purpose. Therefore, the activity of patient organizations exists outside existing dedicated legal frameworks. Collaboration with large alliances of organizations, such as Rare Diseases Romania, and with expert communities whose voices are considered by the government (doctors, professional associations, employers' organizations) appears to potentially beneficial. It may be a win-win solution to integrate patient organizations into decision-making processes, especially in the area of drug reimbursement, as in the Czech Republic. Since their voices are considered in the appeals process, a natural step would be to involve patients at an earlier stage, during the assessment of medical technology.

It seems that the Romanian system recognizes the role of patient organizations, gradually incorporating the patient's voice into the legislative and decision-making processes. However, there is a lack of decisive actions in this regard, such as creating definitions or registries for organizations, structuring cooperation, or including patient representatives in HTA processes.

6 Slovakia

6. Slovakia

6.1. The healthcare system in Slovakia

The Constitution of the Slovak Republic[190] grants everyone the right to health care. Moreover, under the health insurance system, citizens are entitled to free health care and medical assistance under the conditions specified by law.[191]

The health care system in Slovakia is characterized by compulsory social health insurance, which is the basis for financing health care in the country. The structure of the system is based on three main entities: the Ministry of Health, health insurance companies, and healthcare providers, with the additional role of the Health Care Surveillance Authority (*Úrad pre dohľad nad zdravotnou starostlivosťou, ÚDZS*) as an independent supervisory body.

The Ministry of Health plays a key role in shaping the country's health policy. It is responsible for developing health legislation, regulating the provision of health care, administering national health programs, and determining the scope of the basic package of health services. It also has the power to regulate prices in the health sector.

There are three main health insurance companies on the market that compete for customers by offering a variety of services. The longest existing and largest institution is the public health insurance institution – *Všeobecná zdravotná poisťovňa*, owned by the State acting through the Ministry of Health, and which in 2023 covered 55.5% of the population with insurance.[192] The others are two private health insurance companies – *Dôvera* and *Union*. These three health insurance companies are obliged to ensure access to health care by contracting services with health care providers. They are responsible for collecting insurance premiums and financing health care. The health insurance companies must operate in the form of joint-stock companies.

The Health Care Surveillance Authority (ÚDZS) serves as an independent regulator, supervising the health insurance market, the purchase of health care services, and its delivery. This office is responsible for ensuring that health insurance companies meet operating conditions, maintain solvency, and adhere to legal regulations. It also has the power to impose sanctions on entities violating the regulations, including exclusion from the market.

The compulsory social insurance system in Slovakia covers nearly 100% of the population,[193] with the exception of people with valid health insurance in another EU country. The state covers contributions for economically inactive people (e.g., students or retirees), while other residents

190. Ústava Slovenskej republiky.
191. Art. 40 leg. cit.
192. OECD/European Observatory on Health Systems and Policies (2023), Slovakia: Country Health Profile 2023, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.
193. OECD/European Observatory on Health Systems and Policies (2023), Slovakia: Country Health Profile 2023, State of Health in the EU, OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.

are obliged to pay monthly insurance premiums. Slovakia provides a wide range of benefits, including payments for some dental services.

There is also voluntary health insurance in Slovakia, but due to the wide range of services covered by general health insurance, its role is minor.

6.2. Creation of the healthcare law

In Slovakia, legislative power is exercised by a unicameral parliament, the National Council (*Národná rada Slovenskej republiky*), while executive power is vested in the President and the Government. The right to submit draft laws is vested in the National Council's committees, Members of Parliament (MPs), and the Government.[194]

The President of the Slovak Republic appoints the chairman of the government (Prime Minister) and, upon his request, other members of the government, entrusting them with the management of ministries.[195]

Ministries and other central government administration bodies prepare draft laws and other generally applicable legal provisions. The competence to do so also extends to the Prime Minister and Deputy Prime Minister, who may not manage a ministry.[196]

At the top of the Slovak hierarchy of legal acts are the constitution (*ústava*), constitutional laws (*ústavné zákony*), and laws (*zákony*) issued by the National Council. Following these are government regulations (*nariadenia vlády*) issued by the Government for the implementation of the law and within its limits. Further down in this hierarchy are implementing decisions (*výnosy*), implementing decrees (*vyhlášky*), and measures (*opatrenia*) issued by ministries and other central state administration bodies, provided they have been authorized to do so by law.[197]

6.3 The place of patient organizations in the legal system

Patient organizations in Slovakia, similar to those in countries such as Poland or Romania, do not have a designated place in the legal system at the level of the constitution, laws, decisions, or government regulations. Therefore, there is no statutory definition of a patient organization in the Slovak legal system. Most often, Slovak patient organizations operate in the form of associations, the activities of which are regulated by the Act of March 27, 1990, on citizens' associations (*Zákon z 27. marca 1990 o združovaní občanov*).

194. Art. 72, art. 87 (1), art. 101 and art. 108 Ústava Slovenskej republiky.
195. Art. 102 (1) g and art. 111 leg. cit.
196. § 37 Zákon z 12. decembra 2001 o organizácii činnosti vlády a organizácii ústrednej štátnej správy.
197. The European e-Justice Portal. Vnútroštátne právne predpisy, Slovensko [online] Available at: https://e-justice.europa.eu/6/SK/national_legislation?SLOVAKIA&init=true&member=1.

6.4. Making decisions regarding drug reimbursement

In order for a pharmaceutical product to be introduced to the Slovak market, it is necessary to obtain permission from the European Medicines Agency (EMA) or the State Institute for Drug Control (*Štátny ústav pre kontrolu liečiv, ŠÚKL*). ŠÚKL is the Slovak state administration body responsible for regulating and supervising pharmaceutical products, including prescription drugs, over-the-counter drugs, and dietary supplements. The main tasks of ŠÚKL include assessing the safety and efficacy of drugs before they are allowed on the Slovak market, monitoring drug side effects, and quality control of pharmaceutical products.[198]

The competences of the Minister of Health include regulating the scope of healthcare services guaranteed under universal health insurance. He decides on the reimbursement – total, partial or no refund – of medicines, medical devices and dietary products, and specifies the list of priority and non-priority diseases, as well as user fees.

The procedure for the reimbursement of medicines is regulated by the Act of September 13, 2011, on the scope and conditions of reimbursement of medicines, medical devices, and dietary food on the basis of general health insurance, and on amending certain acts (*Zákon z 13. septembra 2011 o rozsahu a podmienkach úhrady liekov, zdravotníckych pomôcok a dietetických potravín na základe verejného zdravotného poistenia a o zmene a doplnení niektorých zákonov*).

The marketing authorization holder is obliged to provide the Ministry of Health with comparative data on the drug, as well as information on its effectiveness, safety, and pharmacoeconomics. One of the 22 specialized working groups (*odborné pracovné skupiny*) established by the Minister of Health evaluates the drug in terms of anatomical and therapeutic classification, assessing the aforementioned effectiveness and safety. Each working group consists of three members who are doctors in a given field of medicine.[199] Additionally, a separate Expert working group on pharmacoeconomics, clinical outcomes, and health technology assessment (*Odborná pracovná skupina pre farmakoekonomiku, klinické výstupy a hodnotenie zdravotníckych technológií*) prepares an opinion on the submitted pharmacoeconomic analysis of the drug.[200]

Opinions developed by the specialized working groups and the expert working group on pharmacoeconomics, clinical outcomes, and health technology assessment are forwarded to the Reimbursement Committee for Medicinal Products (*Kategorizačná komisia pre lieky*). The Committee is an advisory body to the Minister of Health and, according to its statute, consists of 11 members, including three representatives from the Ministry of Health, five from health insurance companies, and three from the medical community.[201] Moreover, other persons invited by committee members may also participate in the meeting, after prior consent of the committee chairman or vice-chairman. These persons are obliged to keep confidential all facts learned during the meeting. The Committee submits to the minister a written expert recommendation regarding the inclusion, exclusion, or change of status of a drug in the package of services covered by general health insurance, proposing at the same time the level of reimbursement and co-payment, as well

198. Zákon z 13. septembra 2011 o liekoch a zdravotníckych pomôckach a o zmene a doplnení niektorých zákonov.
199. Composition of specialized working group available at: https://health.gov.sk/?zoznam-odbornych-pracovnych-skupin.
200. Composition of the Expert Working Group on Pharmacoeconomics, Clinical Outcomes and Health Technology Assessment available at: https://health.gov.sk/?clenovia-os-farmakoekonomika-klinickevystupy-hodnotenie-technologii.
201. Štatút Kategorizačnej rady pre lieky [online] Available at: https://health.gov.sk/Zdroje?/kategorizacia/KR_lieky.pdf.

as the terms of reimbursement. Based on these recommendations, the Minister of Health issues final decisions. The process for making reimbursement decisions for medicines is updated and published once a month.[202,203,204]

It should be emphasized that the above-mentioned statute of the Committee[205], published on the website of the Ministry of Health, states that the Committee consists of 11 members. However, according to the Act of September 13, 2011 on the scope and conditions of reimbursement of medicines, medical devices and dietary food under universal health insurance and on amending certain acts (*Zákon z 13. septembra 2011 o rozsahu a podmienkach úhrady liekov, zdravotníckych pomôcok a dietetických potravín na základe verejného zdravotného poistenia a o zmene a doplnení niektorých zákonov*) advisory bodies of the Minister of Health, including *Kategorizačná komisia pre lieky*, should consist of 15 members, with at least one member from two candidates proposed by the umbrella organization associating patient organizations. The actual number of members in the advisory bodies, as published on the Ministry of Health's website, differs from those indicated in the statutes or the act. Notably, in the lists of the 4 advisory bodies,[206] one member is currently the president of the Civic Association SMILE WITH A LINE (*Občianske združenie ÚSMEV S ČIARKOU*) which deals with palates and is part of the umbrella organization Association for the Protection of Patients' Rights of Slovakia (*Asociácia na ochranu práv pacientov*).

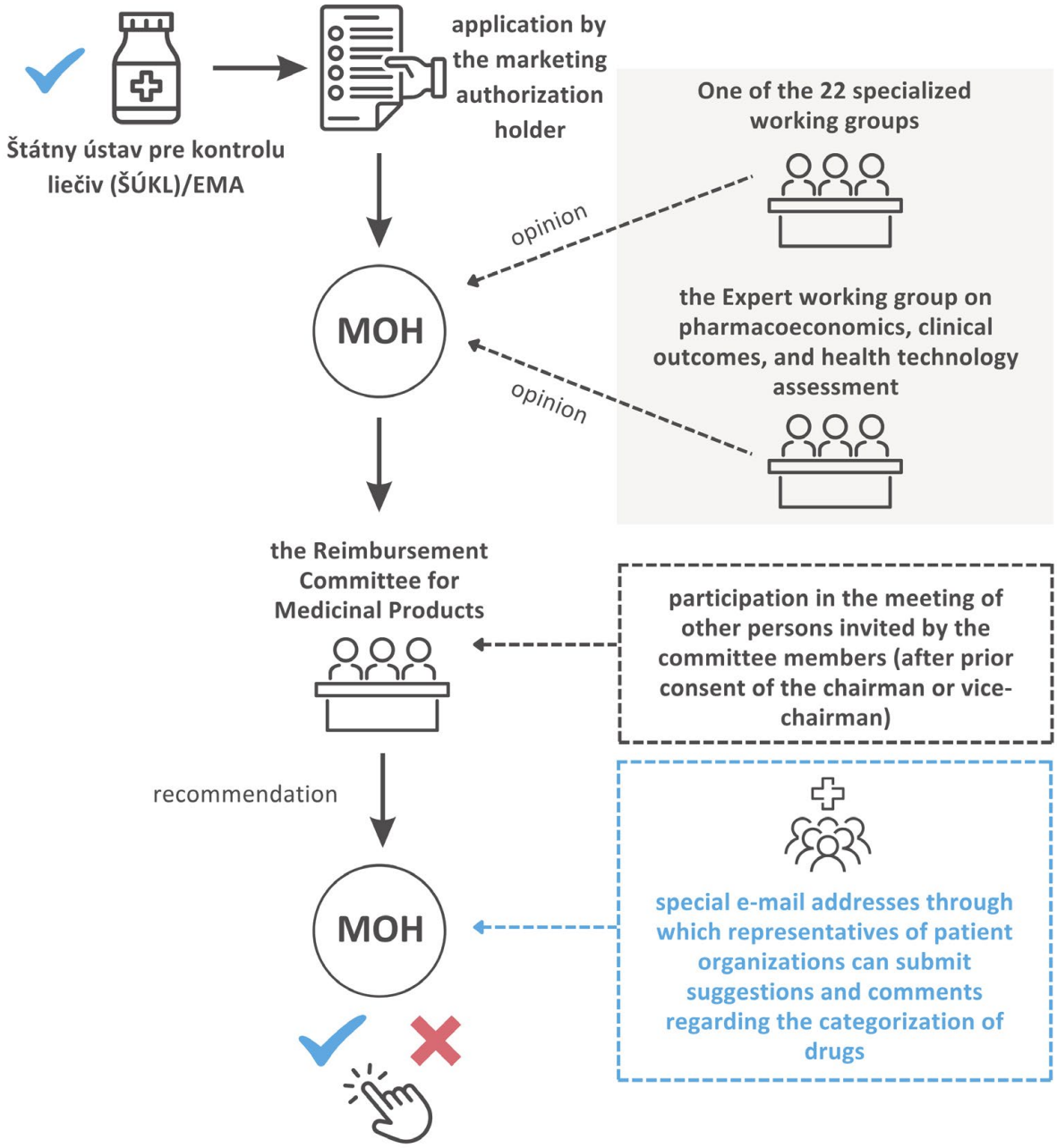
The presence of a representative of a patient organization in the advisory bodies of the Minister of Health on drug reimbursement may be a potentially beneficial solution both for Slovak patient organizations and the state, as shows the example of Czech Republic. It ensures that patients' voices are heard at the highest levels of decision-making, representing their interests and needs directly when making crucial decisions on drug reimbursement. Nevertheless, the practice shows that the position of the patient organization in the process should be clearly stated by the law, with specific criteria of selection of such an organization. The current situation with just one, disease-specific patient organization as a member of one of the advisory committee is far from optimal.

Additionally, according to § 79 (1) of the aforementioned Act, the basis for the Minister of Health to issue a decision regarding reimbursement includes "mainly applications and statements from participants in the proceedings, evidence, as well as facts generally known or known to the Ministry

202. Zákon z 13. septembra 2011 o liekoch a zdravotníckych pomôckach a o zmene a doplnení niektorých zákonov.
203. Smatana, M., Pažitný, P., Kandilaki, D., Laktišová, M., Sedláková, D., Palušková, M., van Ginneken, E., Spranger, A. (2016). Slovakia: Health system review. Health Systems in Transition, 2016; 18(6):1–210.
204. Tesar, T., Obsitnik, B., Kaló, Z., Kristensen, FB. How Changes in Reimbursement Practices Influence the Financial Sustainability of Medicine Policy: Lessons Learned from Slovakia. Front Pharmacol. 2019.
205. Štatút Kategorizačnej komisie pre lieky a odborných pracovných skupín pre anatomicko-terapeuticko-chemické skupiny liečiv [online] Available at: https://www.health.gov.sk/Zdroje?/kategorizacia/KK_lieky-OPS.pdf.
206. List of members of the 4 advisory bodies [online] Available at: https://www.health.gov.sk/?zoznam-clenov-kr-lieky, https://www.health.gov.sk/?zoznam-clenov-kk-zp, https://www.health.gov.sk/?zoznam-clenov-kk-dp, https://www.health.gov.sk/?clenoviaKK-SZM.

from its official activities (...)."[207] On this basis, the Ministry of Health has made available four special e-mail addresses on its website through which representatives of patient organizations can submit suggestions and comments regarding the categorization of drugs, medical devices, special medical equipment, and dietary food.[208] These submissions are considered individually, in connection with participants' submissions regarding categorization and prices.

Patient organizations should definitely take advantage of this opportunity and communicate their positions and opinions on drug reimbursement and other issues via dedicated e-mail addresses.



Making decisions regarding drug reimbursement in Slovakia.

207. Own translation.
208. Ministerstvo zdravotníctva SR. Podania pacientskych organizácií [online] Available at: https://www.health.gov.sk/?podania-pacientskych-organizacii

6.5. Patient advocacy opportunities in Slovakia

6.5.1. Specific framework

Commission of the Ministry of Health of the Slovak Republic for Rare Diseases (*Komisia Ministerstva zdravotníctva Slovenskej republiky pre zriedkavé choroby*)

According to § 5 (4) of the Act of 12 December 2001 on the organization of government activities and the organization of central state administration (*Zákon z 12. decembra 2001 o organizácii činnosti vlády a organizácii ústrednej štátnej správy*), the ministry operates advisory bodies established on the basis of separate provisions. One such advisory body is the Commission of the Ministry of Health of the Slovak Republic for Rare Diseases (*Komisia Ministerstva zdravotníctva Slovenskej republiky pre zriedkavé choroby*) established by the Minister of Health.

Pursuant to its statute, the Commission, among other duties, monitors the implementation of the National Program for the Development of Care for Patients with Rare Diseases (*Národný program rozvoja starostlivosti o pacientov so zriedkavými chorobami v Slovenskej republike)*, cooperates with other entities in developing draft legal regulations related to the issue of rare diseases, and submits comments on draft legal regulations prepared by the Ministry of Health regarding rare diseases.[209]

Importantly, from the perspective of patient organizations that associate patients with rare diseases, among the members of the Commission, there is one representative from the Slovak Alliance for Rare Diseases (*Slovenská aliancia zriedkavých chorôb*), who must be its chairman or vice-chairman[210] (currently, the Alliance is represented by its chairman).[211] In practice, this gives these organizations, through contact and agreement with a member of the Commission, the opportunity to submit their own comments on the implementation of the National Program.

Similarly to the Austrian organization Pro Rare Austria or the Romanian Alianţa Naţională pentru Boli Rare România, it should also be emphasized here that the role of the Slovak Alliance for Rare Diseases (*Slovenská aliancia zriedkavých chorôb*) has been clearly defined in the National Program for the Development of Care for Patients with Rare Diseases, and the organization was mentioned there by name.[212] The Action Plan for 2021-2022 of the National Program for the Development of Care for Patients with Rare Diseases until 2030 also indicates which activities the Alliance is responsible for.[213] Slovenská aliancia zriedkavých chorôb has been operating since 2011 and brings together 24 patient organizations. The Alliance has a significant impact on state policy regarding patients with rare diseases.

209. Art. 1 (3) Štatút Komisie Ministerstva zdravotníctva Slovenskej republiky pre zriedkavé choroby.
210. Art. 2 (2) e leg. cit.
211. Composition of the Commission of the Ministry of Health of the Slovak Republic for Rare Diseases available at: https://www.health.gov.sk/?zriedkave-choroby-komisoa-rd [26.02.2024].
212. Národný program zdravotnej starostlivosti o pacientov so zriedkavými chorobami do roku 2030 [online] Available at: https://www.health.gov.sk/Zdroje?/Sources/zdravotna-starostlivost/Zriedkave-choroby/Narodny-program-ZSZCH-2030.rtf [26.02.2024].
213. Akčný plán na roky 2021-2022 Národného programu zdravotnej starostlivosti o pacientov so zriedkavými chorobami do roku 2030 [online] Available at: https://www.health.gov.sk/Zdroje?/Sources/zdravotna-starostlivost/Zriedkave-choroby/Akcny-plan-ZSZCH-21-22.rtf [26.02.2024].

Cooperation of patient organizations with ŠÚKL and NIHO

As we mentioned earlier, Štátny ústav pre kontrolu liečiv (ŠÚKL) is the Slovak state administration body responsible for the regulation and supervision of pharmaceutical products, including prescription drugs, over-the-counter drugs, and dietary supplements. It assesses the safety and effectiveness of drugs before they are allowed on the Slovak market, monitors the side effects of drugs, and controls the quality of pharmaceutical products. The Institute also plays a role in drug price regulation and maintains registers of medicinal products. Its activities are crucial for the protection of public health and patient safety in Slovakia.[214]

In turn, Národný inštitút pre hodnotenie a technológie v zdravotníctve (NIHO) is a national health technology assessment (HTA) institution established in 2022. It operates independently of political institutions and the health technology industry. Its task is to ensure transparency in the decision-making process in healthcare, especially in the categorization of new technologies such as medicines and medical devices.[215]

"ŠÚKL and NIHO have concluded an agreement under which patient organizations interested in cooperating with them – submitting data for NIHO assessments or participating in consultations with ŠÚKL – must meet certain requirements."

ŠÚKL and NIHO have concluded an agreement under which patient organizations interested in cooperating with them – submitting data for NIHO assessments or participating in consultations with ŠÚKL – must meet certain requirements.

A patient organization must be a non-profit entity focused on patients and their loved ones, protecting their rights, promoting their needs and interests, and ensuring representation on its bodies by patients or their legal representatives when patients cannot represent themselves. Members of the organization must include individuals suffering from a specific disease or health problems, as well as their relatives or their legal representatives as defined by the Civil Code, or an association/society (*združenia/spolky*), whose members are associations/societies meeting the previous requirements. The patient organization must publish its financial reports and funding sources on its website. It must have been operational and carrying out its core activities for at least 12 months.[216]

According to the agreement, the list of collaborating organizations should be publicly available on the NIHO website. However, as of the date of this report's publication, this list remains unpublished.[217]

The cooperation of patient organizations with ŠÚKL and NIHO can be considered important. Including patient organizations in decision-making and health technology assessment ensures that patients' perspectives are considered. This could contribute to the development of more targeted, effective, and safer therapies that meet the real needs of patients. Moreover, cooperation with ŠÚKL and NIHO will enable organizations to access up-to-date and reliable information, contributing to a better understanding of the available treatment and care options.

214. Zákon z 13. septembra 2011 o liekoch a zdravotníckych pomôckach a o zmene a doplnení niektorých zákonov.
215. Zákon z 22. septembra 2021 o Národnom inštitúte pre hodnotu a technológie v zdravotníctve a o zmene a doplnení niektorých zákonov.
216. Cooperation agreement between ŠÚKL and NIHO available at: https://www.crz.gov.sk/data/att/4357276.pdf [27.02.2024].
217. List of NIHO and ŠÚKL partners (Zoznam partnerov NIHO a ŠÚKL) available at: https://niho.sk/zverejnovanie [27.02.2024].

6.2.3. General administrative framework

Slovakian patients have access to several legal tools allowing them to influence legislation and gather information. What is worth mentioning is the right to submit a petition, which is a proven way of obtaining comprehensive answers to questions from the authorities. Additionally, patient organizations can submit comments on drafts of legal documents and request public information from all entities performing public administration tasks.

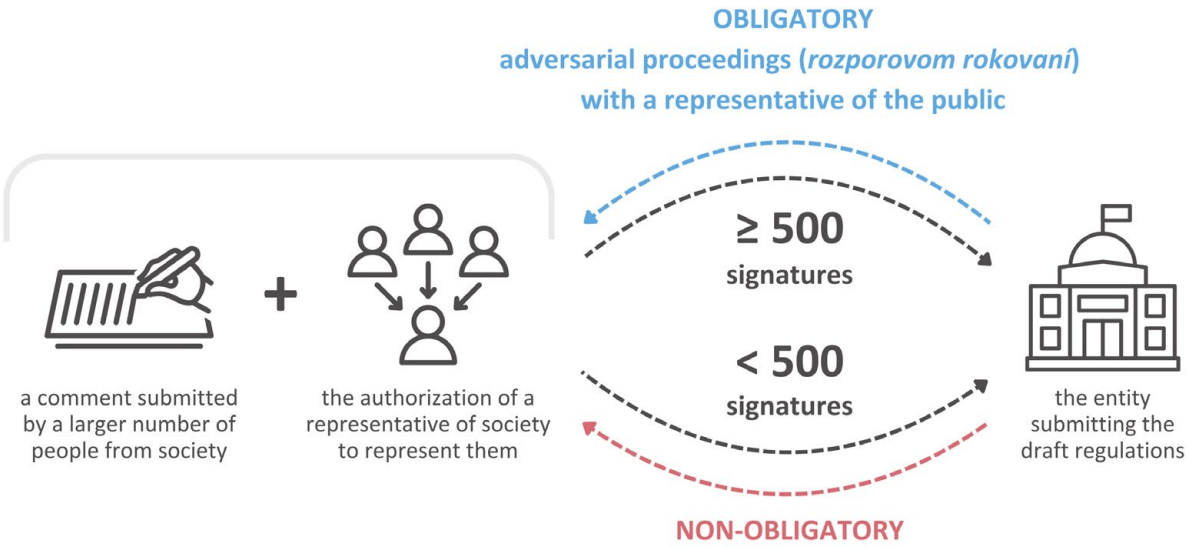
Commenting on draft legal acts

As we already noted at the beginning of the chapter, Slovak citizens do not have the right to legislative initiative, which is available only to the National Council committees, MPs and the government. However, there is a statutory obligation to consult draft laws and other legal provisions with interested parties - including ministries and other public bodies.[218]

Once the draft law is approved, it must be published on the Slov-Lex website.[219] Any interested party – a natural person, a legal person, a group of people, social organizations or other public authorities – has the right to submit comments on the proposed legislation within the deadline set by the person submitting the project, with the Act specifying that it should not be shorter than 15 days working days (in exceptional situations, the deadline may be shortened to a maximum of 7 working days). Opinions on the project are provided via the online portal after mandatory registration. All comments must be responded to, whether they are accepted in full, partially or rejected, with reasons.

> **"Any interested party – a natural person, a legal person, a group of people, social organizations or other public authorities – has the right to submit comments on the proposed legislation."**

Therefore, if patient organizations know that a regulation is being prepared on topics of interest to them or that the regulation directly affects the patients they represent, they should monitor the portal so as not to



The mass comment (hromadná pripomienka) in Slovakia.

218. Zákon z 18. novembra 2015 o tvorbe právnych predpisov a o Zbierke zákonov Slovenskej republiky a o zmene a doplnení niektorých zákonov.
219. The Slov-Lex website: slov-lex.sk.

miss the deadline for submitting comments on the draft laws.

It is also possible to submit the so-called mass comment (*hromadná pripomienka*), i.e. a comment submitted by a larger number of people from society, and at the same time part of the comment is the authorization of a representative of society to represent them. Then, if the person submitting the project has not complied with such comments submitted by a larger number of people from the public, he may carry out the so-called adversarial proceedings (*rozporovom rokovaní*) with a representative of the public. However, such adversarial proceedings with a representative of the public will always take place if the project submitter has not complied with the mass comment, which was supported by at least 500 natural or legal persons.

Therefore, if patient organizations want to negotiate the draft legal act with the legislator, it is necessary for them to obtain at least 500 signatures for a mass comment.

Similarly to the Austrian regulation regarding citizens' initiative (*Bürgerinitiative*), which gives a group of citizens the opportunity to submit an interpellation question to the National Council provided they collect 500 signatures, also in the case of the Slovak mass comment, collecting 500 signatures from, for example, about 100 people who have the status of a member of the organization does not seem to be a problem, and in return, patient representatives receive a guarantee that the legislator will carry out the so-called adversarial proceedings regarding new statutory regulation.

According to research, patient organizations in Slovakia are relatively passive in the described area. The Health Policy Institute observations show that in the period 2010-2012 only 14 out of 300 Slovak patient organizations submitted comments and only 7 out of 110 legal acts. And, what is worth emphasizing, their comments were considered substantive in 63% of cases, and 77% of them were accepted.[220]

Slovak patient organizations may find it beneficial to use the opportunity to comment on draft legal acts. Advocating for patient-centered legislation may be a part of the advocacy efforts to protect for patients' rights and improve the access to treatment.

Access to public information

The right to access public information in Slovakia is regulated by Act No. 211/2000 Coll., on Free Access to Information and on Amendments of Certain Acts (*Zákon zo 17. mája 2000 o slobodnom prístupe k informáciám a o zmene a doplnení niektorých zákonov*). Any natural or legal person may request information (with certain statutory exceptions[221]) held by obligated entities, including state and local government bodies as well as health insurance companies.[222] The person submitting the request is not obliged to justify his/her inquiry in any way.[223]

The request for information must be considered without undue delay, no later than within 8 business days from the date of submission of the request, and within 15 business days if the information is made available to a blind person in an accessible form. The deadline for providing a response may be extended for significant reasons by a maximum of 8 business days, and by 15 business days if the information is provided to a blind person.[224]

As with other countries, access to public information in Slovakia is an extremely useful tool for patient organizations. The

220. Balík, P., Starečková, L., Analýza postavenia pacientov v súčasnom zdravotníctve, Health Policy Institute, 2012 [online] Available at: http://www.hpi.sk/cdata/Documents/Analyza_postavenia_pacientov.pdf [26.02.2024].
221. § 8 - § 12 Zákon z 17. mája 2000 o slobodnom prístupe k informáciám a o zmene a doplnení niektorých zákonov.
222. § 4 (1) and § 2 (1) and (3) leg. cit.
223. § 3 (3) leg. cit.
224. § 17 (1) and (2) leg. cit.

information obtained in this manner can effectively support their positions on matters important to patients.

Right to submit a petition

The Constitution of the Republic of Slovakia guarantees everyone the right to petition. This means that anyone, alone or jointly with others, may submit requests, motions, and complaints to state bodies and local self-government on matters of public or other common interest. Therefore, patient organizations can also submit a petition. Such documents may be submitted either in writing or electronically.

These entities are obliged to respond to the person submitting the petition within 30 days from the date of receipt of the petition. This deadline may be extended to 60 days in particularly complicated cases.

Similar to the considerations in the chapter on Romania, in Slovakia, the right to submit petitions can also be a tool that patient organizations use not only to influence government decisions but also to report problems or propose legislative changes. Again, at least in theory, public authorities have a 30-day deadline to respond to the petitions.

Public Defender of Rights (*Veřejný ochránce práv*). The Ombudsman

As mentioned at the beginning of the chapter, the Constitution of the Slovak Republic guarantees everyone the right to health care, with citizens entitled to free health care and medical assistance under health insurance.

The Public Defender of Rights (*Veřejný ochránce práv*), the equivalent of an ombudsman, is an independent institution tasked with protecting the fundamental rights and freedoms of both natural and legal persons in proceedings before public administration bodies and other public authorities. Therefore, health care issues also fall within its purview. It is important to emphasize that the Slovak regulation regarding the ombudsman differs from those described in previous chapters, which focused solely on the rights of natural persons. In Slovakia, patient organizations, as legal entities, can benefit from the protection of their rights and interests similarly to individual patients. This means they have a formal avenue for filing complaints when they believe the actions of public administration or other public authorities have unlawfully infringed upon the interests of the patients they represent.

Anyone has the right to contact the Public Defender of Rights if they believe that the proceedings, decisions, or inactions of a state authority have unlawfully violated their rights and freedoms.[225] The Public Defender of Rights acts upon the initiative of a natural or legal person or on their own initiative.[226] Therefore, patient organizations also have the right to request intervention, especially concerning the right to health care – be it barriers to access, discrimination, or violations of patient rights, including issues related to access to therapy and medicines, particularly regarding their reimbursement. Patient organizations, often possessing better resources and expertise, can effectively advocate for the rights of their members than individuals can, thus reporting violations on a wider scale.

If the Public Defender of Rights deems a complaint warrants further investigation, they will conduct an investigation. Upon completion, they formulate conclusions and, if it is determined that rights have been violated or misconduct has occurred, may issue recommendations on how to rectify the situation. The Public Defender of Rights also submits annual activity reports to the National Council, presenting findings regarding the observance of fundamental rights and freedoms of natural and legal persons by public authorities, along with

225. Art. 151a Ústava Slovenskej republiky.
226. § 13 (1) Zákon č. 580/2004 Z. z. zo 4. decembra 2001 o verejnom ochrancovi práv.

proposals and recommendations for addressing identified deficiencies. It is crucial to note that the Public Defender of Rights operates based on recommendations and lacks the legal authority to enforce decisions. However, the moral authority and public reporting often lead institutions to follow the recommendations made.

In specified cases, the Public Defender of Rights may request that individuals acting within public authorities be held accountable if they have violated a fundamental right or freedom of a natural or legal person.[227] He may submit a request to the Constitutional Court to initiate proceedings to determine the compliance of law provisions, which, in their opinion, infringe upon the fundamental right or freedom of a natural or legal person, with the Constitution and other legal acts.[228]

"(...) the Slovak regulation regarding the ombudsman differs from those described in previous chapters (...). In Slovakia, patient organizations, as legal entities, can benefit from the protection of their rights and interests similarly to individual patients. (...) they have a formal avenue for filing complaints when they believe the actions of public administration or other public authorities have unlawfully infringed upon the interests of the patients they represent."

6.5.3. Alternative routes

Members of the National Council

As already mentioned, draft laws may also be submitted by committees and deputies of the National Council, both individually and as a group of deputies. If patient organizations are interested in a bill proposed by an MP, they should contact the politician either through a committee, a parliamentary club, or directly through the MP's office. The website of the National Council provides the contact details of each MP, as well as lists of parliamentary clubs and committees along with their members. On the other hand, patient organizations can submit their own bills through politicians, presenting their proposals and ideas for legal regulations. Then, an MP supportive of a given concept will be able to submit a bill as his or her own.

Moreover, an opportunity for patient organizations can be identified at the stage of the second reading of the bill, when the bill is considered in the committees to which it has been assigned.[229] Both the subjects of their deliberations and the dates are published on the website of the National Council. Committee meetings are public (with some exceptions), and public participation is allowed until the seats in the room where the committee meets are filled.[230] This regulation warrants emphasis because, for example, in Poland, as mentioned in the chapter devoted to it, the presence of the public during committee meetings is only possible at the invitation of the committee's presidium or its chairperson. Slovak committees may also invite experts and other individuals to their meetings and seek their opinions.[231] Participating in committee meetings presents another opportunity

227. Art. 151a (1) Ústava Slovenskej republiky.
228. Art. 151a (2) leg. cit.
229. § 75 (1) Zákon Národnej Rady Slovenskej Republiky z 24. októbra 1996 o rokovacom poriadku Národnej rady Slovenskej republiky.
230. § 50 (1) leg. cit.
231. § 54 (1) leg. cit.

for patient organizations to express their opinions or positions on specific legislative proposals.

Maintaining fully transparent contact with politicians, especially those sitting on these committees, may be an action to consider by the patient organizations. This increases the chance of at least receiving an invitation to such meetings, during which representatives of patient organizations will have the opportunity to present their position.

Furthermore, deputies of the National Council have the opportunity to submit so-called parliamentary interpellations, i.e., questions addressed to the Government, its individual members, or heads of other central state administration bodies, concerning the application and execution of laws, the implementation by the Government and its members of the government program assumptions, and resolutions of the National Council.[232,233] The MP should receive a response to the interpellation within 30 days.[234,235]

Members of parliament often include individuals with medical education who are, or at least should be, particularly attuned to health issues, and acting in this area should be a priority. MPs can present interpellations on behalf of the organization, raising issues important to patients in the parliamentary forum. Owing to the obligation to respond to interpellations, patient organizations can monitor these responses, analyzing how the government intends to address the reported problems. This may provide patient organizations with valuable information for further activities or information campaigns.

Cooperation with other entities

In situations where patient organizations do not have direct opportunities to influence decisions made by some bodies, cooperation with members of these bodies becomes an action to consider by the organization.

Take, for example, representatives of health insurance companies who sit on the ministerial commission that determines the basic package of benefits, i.e., health services covered by compulsory health insurance. Five representatives of health insurance companies also serve on the Committee for the Reimbursement of Medicinal Products, which acts as its advisory body in the reimbursement processes, as mentioned earlier.

Additionally, the Committee includes three representatives from the Ministry of Health and three representatives from the Slovak Medical Society (*Slovenská lekárska spoločnosť*). The Slovak Medical Society is an association comprising professional medical and pharmaceutical associations and regional associations of doctors and pharmacists, boasting almost 20,000 members.

The Committee is supported by 22 specialized working groups and an expert working group on pharmacoeconomics, clinical outcomes, and health technology assessment (*Odborná pracovná skupina pre farmakoekonomiku, klinické výsledky a hodnotenie zdravotníckych technologií*)[236].

Cooperation with representatives of these entities presents an excellent, indirect method for patient organizations to influence decisions regarding the package of basic services covered by social insurance or drug

232. § 129 (1) and (2) Zákon Národnej rady Slovenskej republiky č. 350/1996 Z. z. o rokovacom poriadku Národnej rady Slovenskej republiky v znení neskorších predpiso.
233. Art. 80 (1) Ústava Slovenskej republiky.
234. §130 (1) Zákon Národnej rady Slovenskej republiky č. 350/1996 Z. z. o rokovacom poriadku Národnej rady Slovenskej republiky v znení neskorších predpiso.
235. Art. 80 (1) Ústava Slovenskej republiky.
236. Composition of the Working group on pharmacoeconomics, clinical outcomes and health technology assessment avaliable at: https://www.health.gov.sk/?clenovia-os-farmakoekonomika-klinickevystupy-hodnotenie-technologii [28.02.2024].

reimbursement. Through this collaborative approach, patient organizations can present their positions and opinions on these matters.

Media campaigns

When patient organizations have limited institutionalized methods for influencing the decisions of state authorities or for enacting changes in law, they can employ effective strategies such as media campaigns. These campaigns are a powerful tool, enabling patient organizations to reach a broad audience and effectively influence changes in health policy or legislation. According to the Health Policy Institute in Slovakia, this method is very rarely utilized.[237]

An illustrative example of an effective media campaign occurred in 2008 with the Children's Cardiology Center (*Detské kardiocentrum*). There was a protest in front of the Slovak government's seat against the proposed merger of the Children's Cardiology Center with the Departmental Children's Hospital (*Detská fakultná nemocnica*). Protesters were concerned that the merger would lead to inefficiencies and long waiting times. A petition campaign was also initiated. Thanks to the active media campaign, the government heeded the protesters' demands and decided instead to merge the Children's Cardiology Center with the National Institute of Heart and Vascular Diseases (*Národný ústav srdcových a cievnych chorôb, NÚSCH*).[238]

Umbrella organizations

In Slovakia, a civil association known as the Association for the Protection of Patients' Rights of Slovakia (*Asociácia na ochranu práv pacientov SR*) exists, uniting 50 Slovak patient organizations. Its primary mission is to protect the rights, defend, and promote the interests of patients, disabled people, and individuals in socially disadvantaged situations across social, health, educational, cultural, and community sectors.[239] It also engages in providing opinions and shaping laws. The list of legislative activities published on the Association's website demonstrates its active involvement in this area.[240]

A member from one of the patient organizations within the Association for the Protection of Patients' Rights participates in the advisory bodies of the Ministry of Health, including the Categorization Commission for Dietary Foods, the Categorization Council for Medicines, the Categorization Commission for Medical Devices, and the Categorization Commission for Special Medical Materials.

The Slovak Alliance for Rare Diseases (*Slovenská aliancia zriedkavých chorôb*), which encompasses 24 patient organizations, similarly to the Austrian organization Pro Rare Austria and the Romanian Alianța Națională pentru Bolile Rare România, holds a formalized role within the Slovak National Program for the Care of Patients with Rare Diseases. Moreover, one representative is a member of the Ministry of Health's Commission for Rare Diseases, an advisory body to the Minister of Health responsible for implementing the Plan.

As with the Austrian and Romanian umbrella organizations, it is important to highlight that the Slovak Alliance for Rare Diseases is an important ally in advocating for the rights of patients with rare diseases.

237. Balík, P., Starečková, L., Analýza postavenia pacientov v súčasnom zdravotníctve, Health Policy Institute, 2012 [online] Available at: http://www.hpi.sk/cdata/Documents/Analyza_postavenia_pacientov.pdf [29.02.2024].
238. Ibidem.
239. Statute of the Association for the Defense of Patients' Rights available at: https://www.aopp.sk/o-nas/stanovy-a-sociacie-na-ochranu-prav-pacientov-sr [01.03.2024].
240. Asociácia na ochranu práv pacientov SR. Legislativne aktivity [online] Available at: https://www.aopp.sk/co-robime/legislativne-aktivity.

6.6. Summary

In Slovakia, there is a lack of specific and comprehensive legal solutions dedicated to patient organizations. Their strength solely comes from the position they have developed over the years. Nevertheless, there are some signs of hope in government initiatives, including the establishment of a formal communication channel in the form of a dedicated email address.

It is also worth mentioning the participation of patient organizations in advisory committees of the Ministry of Health, although the procedure for selecting such organizations remains unclear. Only the organization representing patients with rare diseases enjoys a strong position in the process of implementation of the rare disease plan, but this is already a standard in countries that have introduced such plans – ultimately arising from the recommendations of the European Union in this regard.

It seems that a necessary step is to establish a definition of patient organizations, create a registry of such organizations, and legally empower their advisory role – this being the primary focus. Furthermore, Slovak legislators could examine solutions from the Czech Republic, which place patient organizations in the role of an important, legally empowered entity in the drug reimbursement process, while simultaneously safeguarding the interests of the state.

IV Conclusions

The analysis of healthcare systems and patient advocacy frameworks in Austria, Czech Republic, Hungary, Poland, Romania, and Slovakia reveals a diverse landscape with varying degrees of patient involvement and legal support for patient organizations. Key conclusions and recommendations are as follows:

Austria: The role of patient organizations in Austria is limited due to lack of specific legal regulations. There is also room for improvement in HTA processes, as cooperation with POs is only declaratory. Formalizing the advisory role of patient representatives in HTA and expanding their influence beyond limited advisory capacities seems to be the right direction of changes.

Czech Republic: The Czech Republic has a well-structured patient advocacy framework, with patient organizations actively participating in healthcare policy development through the Patient Council. Ensuring that patient feedback is consistently integrated into decision-making processes remains a challenge. Strengthening the legal provisions for patient involvement in policy decisions could address this issue.

Hungary: Hungary's healthcare system includes patient advocacy efforts, primarily through the National Patient Forum and regional health councils. However, the absence of a formal legal definition for patient organizations limits their potential. Establishing specific legal frameworks and formalizing patient advocacy practices could enhance their impact on healthcare policies and HTA process.

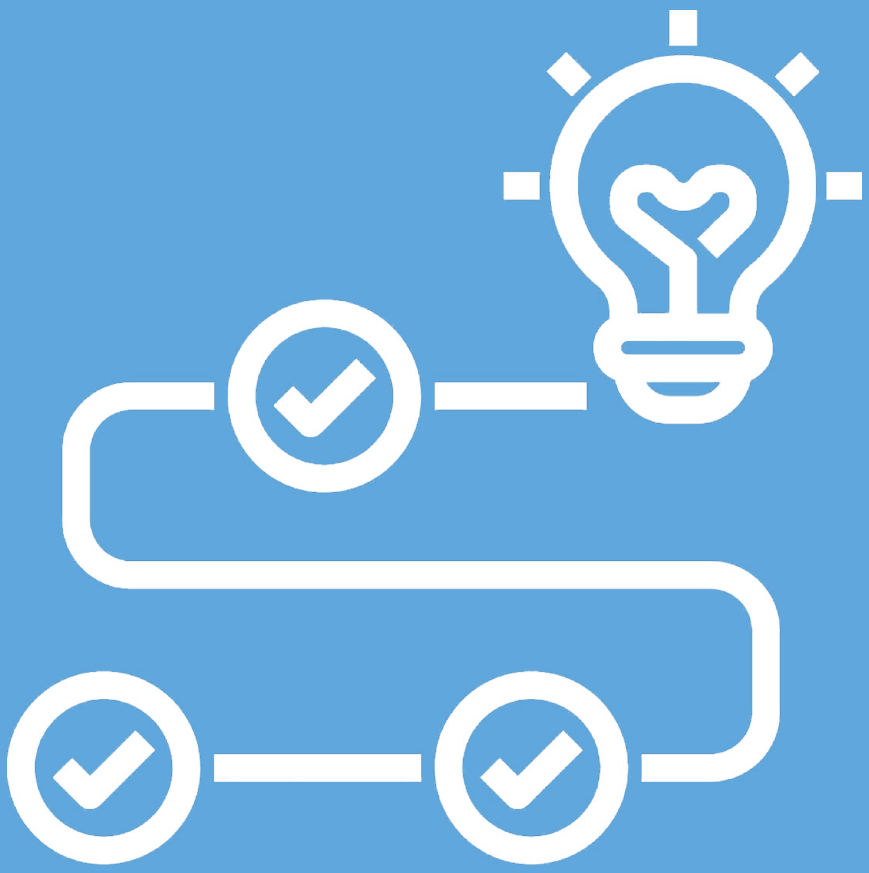
Poland: Poland provides multiple options for patient organizations to influence healthcare policies, including public consultations and administrative proceedings. The involvement of patient organizations in the HTA process is possible only on invitation, also the integration of patient feedback into policy decisions is inconsistent. The next step may be formalizing the involvement of POs in the HTA process, ideally by an act of law, not an ordinance.

Romania: In Romania, the Social Dialogue Act establishes structures for consultations with civil society, but the practical impact of these consultations is limited. The success of advocacy activities is possible only due to the strength and position of the patient organization, which limits the possibilities for smaller patient communities. A systemic reform may be needed to implement a clear definition of patient organizations and place their strong consultative role in law- and decision-making processes.

Slovakia: Slovakia's patient advocacy landscape is developing, with patient organizations participating in advisory committees, particularly for rare diseases. However, the lack of a clear legal framework for patient organizations limits their influence. Establishing a formal definition and registry for patient organizations and empowering their advisory role in healthcare policies are essential steps for enhancing patient advocacy.

Overall Recommendations

- **Define Patient Organizations:** Include a definition of patient organizations in the legal system, preferably in an act regarding healthcare.
- **Create Registries of Verified Patient Organizations**: Such registries serve as credible tools for the ministry or the payer when they need to consult the patient community (voluntarily or obligatorily).
- **Formalize Legal Frameworks**: Establish clear legal frameworks specifically for patient organizations to enhance their role in creating healthcare policies.
- **Patient Organizations' Rights in Acts of Law**: The fundamental regulations affecting patient organizations should be stipulated in acts of law enacted by parliament, not in ordinances or other types of regulations that can be changed by one person.
- **Expand Meaningful Roles in HTA**: Formalize and expand the advisory roles of patient representatives in Health Technology Assessment (HTA). This can include a voting right and/or the right to submit evidence. By implementing these recommendations, Central and Eastern European countries can create more patient-centered healthcare systems and improve health outcomes for their populations.



V Comments

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Optimal healthcare systems, regardless of geographic location or level of maturity, all strive towards a balance between three principles: Equity, Efficiency and Sustainability. Each one of these principles requires a deep understanding of patient needs, outcomes that matter to patients, and trade-offs that patients are willing to make to reach these outcomes. As such, patient inclusion or patient engagement in healthcare decision-making processes is fundamental; a fact that policy-makers, regulators and providers have started to recognise in their attempts to adjust or re-design some of the key processes and procedures, such as marketing authorisation (Risk-Benefit analysis), health technology assessment (HTA) or joint clinical decision-making.

However, creation of legal frameworks for systemic patient inclusion in decision-making is a relatively new phenomenon. European Medicines Agency (EMA) issued its first "Engagement Framework" for patients and consumers as late as 2022. Similarly, many of the HTA bodies in Europe had been consulting patients informally for many years, but have only recently started developing legal or practical guidance documents on the matter. Many, like the Netherlands and Sweden, have linked patient engagement to development of Value Based Healthcare ecosystem (VBHC), others, like France, have grounded the practice in a broader concept of civic society. The former, VBHC, is a particularly relevant framework, as it posits a dramatic paradigm shift - from treating patient as an „object of care" to considering patient a „subject in healthcare".

This report, by meticulously exploring all facets of patient engagement in the CEE, is of utmost value to all healthcare stakeholders and of high utility for all patient organisations in the region and beyond. It clearly spells out the best practices, such as the novel patient voting system in the Czech HTA, which ought to be studied and used as a benchmark for any government agency wishing to increase patient engagement. It also provides a useful comparison of key barriers to overcome and key enablers to embrace, resulting in a first of its kind guidance for a step-by-step development of a truly anthropocentric and collaborative healthcare system.

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How did we convince policymakers that involving patients' voices is a step in the right direction? They say that it always takes the right moment and the right people to implement something new. And we were lucky to have that at the time. It also takes good preparation and learning from others who started this path before us.

It was around 2012 when patient organizations began to really grow in the Czech Republic thanks to initiatives such as the Academy of Patient Organizations (APO) and engaged deputies and patient advocates cooperating with the Czech Ministry of Health. It was clear that patient voice and advocacy needed a stable place within the ministry. This is how the Patient Council of the Minister of Health was born. At the same time, as its support and part of the ministry's organizational structure, a department for patients' rights support was established.

The Patient Council started to function in 2017, and its representatives had, among other things, also a possibility to participate in working groups of the ministry. And it was exactly at a time when a working group was formed to prepare special legislation for a new way for orphan drugs to enter reimbursement. At that time, the only possible way orphan drugs could make it to the patient was through a special paragraph, a so-called "exception" which was overused and its approval by the payers was not systemic. We knew that a different criterion had to be put in place to decide on reimbursement of such predominantly expensive drugs. If we were to decide on the basis of prices, almost no treatment would make it to the patient. In the end, the legislation took in new stakeholders into the decision-making process besides the state and the payers: the experts and the patients. We actively took part in preparing a special form which helps us contribute to the process as patients.

The first applications for reimbursement based on this legislation started to come in very slowly, however, later on it started to pick up and presently, we register over 40 such applications. Patients take part in all of them and most of them receive reimbursement. We are very proud of that.

But no good deed never stays unpunished. Recently, we encountered political forces which pushed for changes in the definition of the patient organization. To conclude my comment, it must be said that everything that we achieved is indeed very fragile. It can be gone quickly. What we need to do is keep working together, keep pushing forward to make sure more patients' voices are heard in decision making processes.

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Notes

Authors

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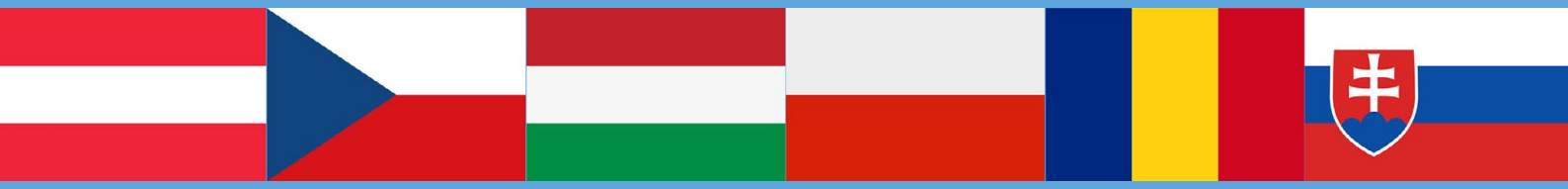

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