Comparison between processes of HTA, pharmaceutical pricing and reimbursement, and their transparency in Germany and Poland

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Abstract

This paper focuses on HTA, pricing and reimbursement of pharmaceuticals in Germany and Poland. The authors analyzed processes of decision making related to pharmaceutical reimbursement, as well as their transparency. Both Germany and Poland have developed complex processes of pharmaceutical pricing and reimbursement, as well as incorporated HTA into decision making procedures. In Germany the stakeholders involvement and transparency of processes seem to be to higher than in Poland.

Key words: **Germany, health technology assessment, pharmaceutical policy, Poland, pricing and reimbursement of pharmaceuticals, transparency**

Słowa kluczowe: **ceny i refundacja leków, Niemcy, ocena technologii medycznych, polityka lekowa, Polska, przejrzystość**

Introduction

Pricing and reimbursement of pharmaceuticals in Germany and Poland are regulated at national levels, similarly to other countries of the European Union (EU). Therefore they are as different as health care systems of both countries are. In Germany the authorities of self-governing states called lands have a lot of power, so decision making within health care system is shared between federal and state levels [1]. The key policy maker and regulator in the Polish health care system is the Minister of Health (MoH), often supported by advisory bodies [2].

Nowadays, before a decision on medicine's reimbursement, pricing, or both of these issues is made within a given health care system, usually a particular medicinal product has to be thoroughly evaluated. The tools of Health Technology Assessment (HTA) are used for this purpose both in Germany and Poland. The HTA, which has an increasing role in today's health care systems, is often being applied in case of products which are new on the market and claimed to bring an additional therapeutic benefit to patients. In the growing number of countries there have been established agencies or programmes specialized to evaluate health technologies and this has been the case also in Germany and Poland. There are many challenges in implementation of HTA into decision making processes, including the assurance of appropriate level of transparency [3]. High transparency has been also considered as an important feature of robust pharmaceutical pricing [4]. Starting from 1989 it has become

a major requirement imposed on all EU Member States by the Transparency Directive [5].

The aim of this paper is to compare and critically assess the systems of pricing and reimbursement of pharmaceuticals in Germany and Poland, taking into consideration practical implementation of HTA and transparency of HTA and reimbursement processes within health care decision making.

There have been several reasons for choosing these two countries. Their national pharmaceutical markets are being influenced by each other through parallel trade, benchmarking in pharmaceutical policies and international price comparisons. Both pharmaceutical markets function in relatively stable economic environments, since both German and Polish economies have been doing quite well during the economic crisis and slowdown affecting countries of the EU since 2007.

Material and Methods

In order to achieve this study objectives, firstly the pharmaceutical reimbursement and HTA processes in Germany and Poland have been generally described and compared. Secondly, transparency of decision making related to pharmaceutical pricing and reimbursement and HTA processes in both countries has been analysed and assessed.

In order to compare transparency of processes of pharmaceutical pricing and reimbursement, and HTA, their measurable features have been identified and taken into consideration. Transparency has been expressed as the involvement of stakeholders (pharmaceutical companies, physicians, pharmacists and the general public) at various stages of HTA process, communication with health care system stakeholders and clarity of HTA guidelines.

The search for studies published after 2010 was conducted in databases Medline and Embase. In Medline the MeSH terms were used in searches when it was possible. The following search terms were used: "Germany, Poland, health technology assessment, pharmaceutical, reimbursement and pricing". The terms "Germany" and "Poland" were first connected with "health technology assessment" using operator AND. Subsequently they were connected with "economics, pharmaceutical [MeSH] OR pharmaceutical pricing OR drug pricing" with operator AND.

All records were screened for duplicates, which were subsequently excluded. After that, all titles and abstracts of identified studies were screened for relevance. The full texts of eligible studies were read and reviewed. Bibliography reference lists of the pertinent studies were also reviewed in order to identify other, possibly eligible studies. In addition to that, content of websites of German and Polish institutions involved in HTA and national pharmaceutical pricing and reimbursement policies was also reviewed. The language selection criteria in this systematic review included English or German. The studies were excluded if they did not match the inclusion criteria or if they appeared irrelevant to the study goals. The records describing processes of HTA and pharmaceutical pricing and reimbursement in Germany and Poland, taking into consideration also transparency of these processes, were included into analysis.

Results

The flow diagram describing selection process of the published studies has been presented in **Figure 1**. Altogether 302 records were identified. After removing duplicates and screening records for relevance, nine papers [3, 4, 6–12] in full-text versions and eight conference abstracts [13–20] were selected for further analysis. The summary set of analyzed features of pharmaceutical pricing, reimbursement and HTA utilization in both countries has been presented in **Figure 2**.

Processes of pharmaceutical reimbursement and HTA in Germany and Poland

Prices of pharmaceuticals are being set and defined in different ways in various countries. According to the Glossary of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, list prices are "the prices that purchasers display as the prices at

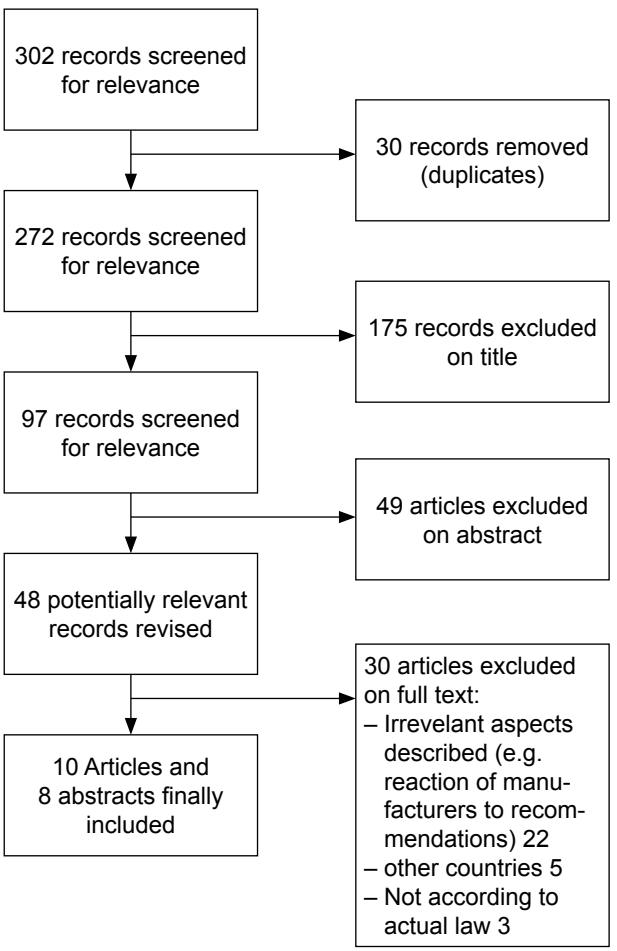

Figure 1. *Flow diagram of study selection process.*

Source: Own elaboration.

Processes of pharmaceutical reimbursement and HTA	Transparency of decison making within drug pricing and reimbursement	Stakeholder involvement in pharmaceutical pricing and reimbursement sales
• rules of patient co-payment • methodology of HTA applied in pharmaceutical reimbursement • complexity of pricing and reimbursement rules • involvement of state institutions	• compliance with the EU's Transparency Directive • approach to publication of documents related to pricing and reimbursement processes	• payers • health care professionals • patients and the general public • politicians and the MoH • manufacturers

Figure 2. *The summary set of analyzed features of pharmaceutical pricing, reimbursement and HTA utilization in Germany and Poland.*

Source: Own elaboration.

which they are prepared to sell their products and/or regulated by legislation. The prices of products as quoted in the purchaser's price list, catalogue, internet site, advertisements, in a national price list/formulary, etc. They are not necessarily actual transaction prices." [21]. According to the same bibliographic source the reimbursement price "is the basis for reimbursement of medicines in a health care system, i.e. the maximum amount paid for by a third party payer" [21]. However, pricing processes can be different across countries, therefore notion of a medicine's price of should be seen in context of a particular health care system's legislation.

The reimbursement of pharmaceuticals is closely related to patient co-payment rules, which exist in a particular country. In Germany patient pays usually 10% of medicine's price, but minimum EUR 5.00 and maximum EUR 10.00. If price is lower than EUR 5.00, patient pays it in full [1]. There are four levels of pharmaceutical co-payment in Poland, i.e. flat rate (PLN 3.20) per package containing up to 30 Defined Daily Doses (DDD) of a medicine, 0%, 30%, 50% and 100% of reimbursement limit, which is set closely to price of the cheapest medicine either from among equivalents having the same international name and form or from among similar drugs within the same therapeutic group [2]. If a particular medicine's price exceeds its reimbursement limit a difference has to be paid by patient.

In Germany the processes of pharmaceutical reimbursement and HTA associated with it are the same for nearly all medicines, with exceptions only for drugs with low budgetary impact and drugs used in treatment of rare diseases [4]. The overview of these processes are presented in **Figure 3**. They start with a review of dossier provided by pharmaceutical manufacturer. If manufacturer applies to negotiate a reimbursement price for a new drug with the Statutory Health Insurance (SHI), it is obliged to present a dossier containing evidence on the additional therapeutic benefit of a given drug. There are six levels of this benefit: (1) major additional benefit, (2) considerable additional benefit, (3) minor additional benefit, (4) unquantifiable additional benefit, (5) no additional benefit and (6) benefit smaller than that of medicines which are already present on the market [6].

If manufacturers do not provide any evidence on additional benefit, their drugs are included directly into the

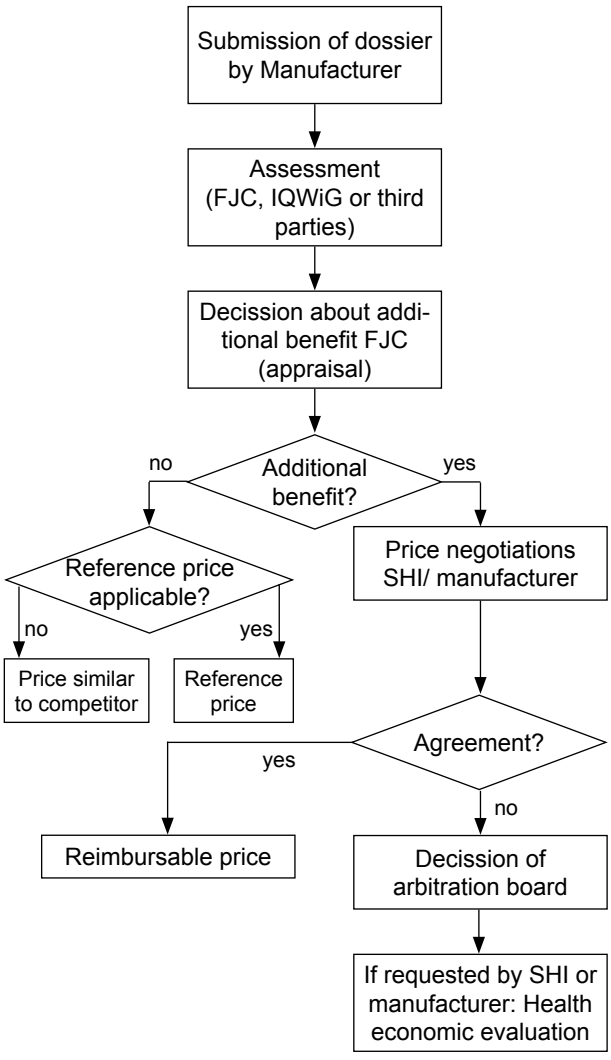

Figure 3. *Reimbursement and HTA process in Germany.*

Source: Own elaboration on Gerber A., Stock S., Dintsios C.-M., Reflections on the changing face of German pharmaceutical policy: how far is Germany from value-based pricing?, "PharmacoEconomics" 2011; 29(7): 549–553 [11]; IQWiG, Contracting agencies and funding of iqwig, https://www.iqwig.de/en/about-us/responsibilities-and-objectives-of-iqwig/contracting--agencies-and-funding.2951.html; accessed: 10.04.2015 [23].

reference price system. Knowing that additional benefits of particular drugs are low, manufacturers sometimes decide not to submit their dossiers at all. Then such products are being directly introduced into the reimbursement system, which may turn out to be cheaper for manufacturers saving substantial resources necessary for preparation of full dossiers [6].

Nevertheless, the regular process is associated with submission of a dossier to the Federal Joint Committee (FJC), being the highest decision making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany[1]. The additional benefits of a medicine need to be verified either by the FJC itself or this task can be transferred to the Institute of Quality and Efficiency (IQWiG) [22]. The IQWiG is an independent scientific HTA agency, financed through levies for inpatient and outpatient medical treatment paid by the sickness funds. In other words, the IQWiG is financed through contributions from members of all statutory health insurance funds, which are being fixed every year by the FJC. The IQWiG assists the FJC in decision making and it is divided into eight departments. One of them is responsible for producing reports from assessments of pharmaceuticals [9, 10].

Based on the assessment, after an additional hearing of manufacturer, the FJC finally decides on the additional benefit which a particular medicine could bring. If the decision is negative and no additional benefit is identified, a drug is being added to one of already existing reference groups. It is assumed in such case that a drug has the same effect as other drugs belonging to this group have. If a drug cannot be added to the existing reference price group, a price of that drug will be similar to its comparator's price [22, 23].

If additional benefit of a new drug exists, price negotiations between the SHI and manufacturer take place. The process ends with agreement of both parties. If there is no agreement, then the arbitration board makes a final decision on reimbursement price. Objection of this reimbursement price leads to a new evaluation performed by the IQWiG [22].

The positive decision on reimbursement of a medicine in Poland is always accompanied with setting its price. The HTA and reimbursement processes in Poland have been presented in **Figure 4**. The procedure starts with submission of a dossier to the MoH. In case of a new molecule or a new indication for use, a copy of a dossier is transferred further to the President of the Agency for Health Technology Assessment and Tariff System (AOTMiT). It is accompanied with a request to prepare a set of documentation enabling the MoH to make reimbursement decision. The AOTMiT is publicly financed and it is under supervision of the MoH [8].

The set of documentation consists of a verifying analysis of the AOTMiT, a position paper of the AOTMiT's Transparency Council and a recommendation of the AOTMiT's President. These documents are prepared on a basis of HTA report prepared by a pharmaceutical company. Neither recommendation of the AOTMiT's President nor appraisal contained in a position paper of the AOTMiT's

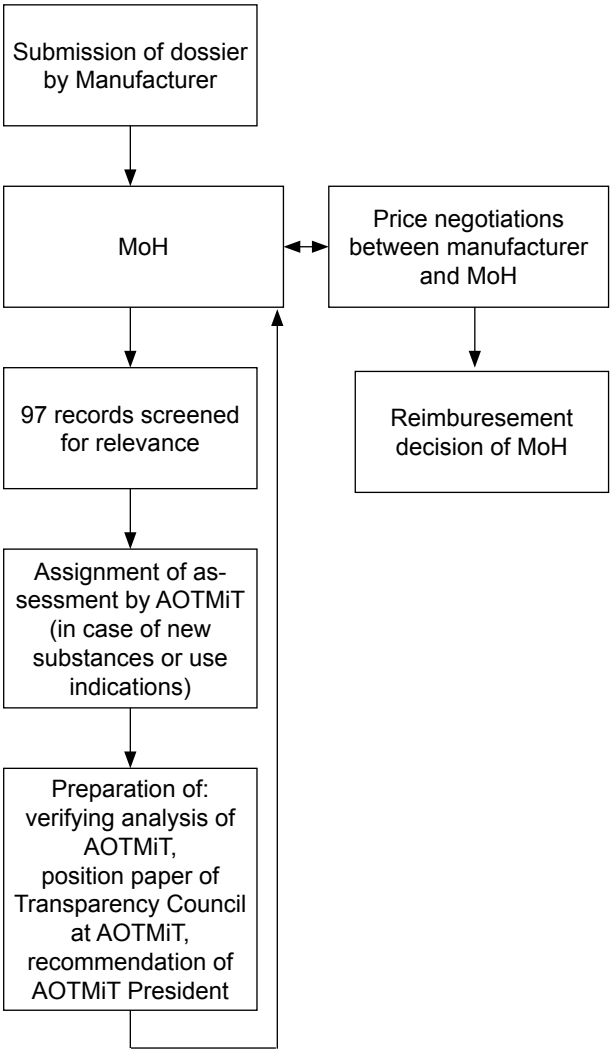

Figure 4. *HTA process in Poland [24].*
Source: Own elaboration.

Transparency Council are binding for the MoH in making a final decision on reimbursement [24]. Another document which is necessary for the MoH to make that decision is a resolution of the Economic Commission of the MoH. This resolution is being issued after price negotiations performed between the Economic Commission and a given pharmaceutical company. The differences within reimbursement processes between Germany and Poland can be highlighted at this point. Whereas in Poland a list price of reimbursed medicine is set as a result of negotiations and a reference price is set by the MoH based on rules specified in the reimbursement law, in Germany a list price is regulated by the market and a reimbursement price is negotiated. If a given pharmaceutical's market price is more than 30% cheaper than a negotiated reference price, a German patient does not have to make a 10% co-payment (between EUR 5.00 and EUR 10.00), which has been described above [25].

There are also differences between HTA processes in Germany and Poland. One of them relates to perspective

which should be adopted in economic analyses within HTA reports. In Germany the law says that this should be a perspective of the insured persons, which means that not only the payments of the sickness funds have to be taken into account but also the patients' co-payments. It is not clear if also other private expenditures should be considered in the decision-making. In reality, the perspective the IQWiG changes from case to case and sometimes also the indirect costs are being considered [10]. In Poland the perspective of the entity financing health care services (public payer) has to be adopted obligatorily but also the social perspective can be included in justified cases [26].

Another difference between both countries can be observed within approach to cost-effectiveness thresholds. The IQWiG in Germany uses the efficiency frontier approach to make recommendation. In this approach the existing therapies provide a threshold for comparison of therapeutic benefits and costs between already existing therapies and a new medicine. A new drug which provides benefit equal to that of existing therapies should not be more expensive than these therapies [27]. Therefore while adopting this approach a flexible threshold is being used [10]. Similarly in Poland a medicine, which is not more effective than an already reimbursed therapy, cannot cost more than that therapy. However for new medicines with an added therapeutic value a cost-effectiveness threshold is being applied. It is calculated as 3 times GDP per capita per one QALY (Quality Adjusted Life Year) or LYG (Life Year Gained) obtained due to application of a new therapy instead of its old alternative [8].

There are also other differences between the two national HTA agencies within recommended methodologies of performing economic analyses. In Germany the cost-effectiveness analysis is used [9]. In Poland all kinds of economic analyses can be applied in appropriate instances, including cost-effectiveness or cost-utility approaches. If there is no difference between health effects also the cost minimization analysis can be applied [26]. The Polish HTA guidelines seem to offer more options, whereas the German way of evaluation seems to be more fixed.

Transparency of decision making within drug pricing and reimbursement in Germany and Poland

Transparency of decision making within pharmaceutical pricing and reimbursement is crucial for preventing corruption and implementing efficient national health policy. The transparency entails several issues. For example, according to the International Monetary Fund it relates to creating "an environment in which the objectives of policy, its legal, institutional, and economic framework, policy decisions and their rationale, data and information related to monetary and financial policies, and the terms of agencies' accountability, are provided to the public in a comprehensible, accessible, and timely manner" [28]. On the EU level the Transparency Directive 89/105/EEC has been issued in order to ensure transparency within control of prices and reimbursement of medicinal products [29]. Several requirements for pharmaceutical reimbursement in the Member States of the EU have been set there, including that respective decisions must be made within a specific timeframe; must be communicated to the applicant and contain a statement of reasons based on objective and verifiable criteria; must be open to judicial appeal at national level [29]. These requirements are fulfilled both in Germany and Poland.

In Germany the assessments and dossiers, as well as results of clinical trials included into HTA must be published on the FJC's webpage (https://www.g-ba.de/informationen/nutzenbewertung) [6, 11]. In Poland the scope of published documentation on processes of medicines pricing and reimbursement is smaller. The HTA documentation is being published on the AOTMiT website (www.aotm.gov.pl), including recommendation, HTA dossier submitted by applicant and assessment reports with comments which can be submitted within seven days after publication of these assessments. However the published documents have been censored in Poland on demand of the pharmaceutical industry, especially extensively until the middle of 2014.

In assessment performed by Jebrail et al. who applied 33 parameters, the transparency of the IQWiG performance was positioned on level of 97% [17]. Analyzing application of HTA and pharmacoeconomics into health policies of 14 European countries and evaluating nine characteristics relevant for decision making processes, Marusakova et al. ranked Germany on the second place, whereas Poland on the third [18].

Stakeholder involvement in pharmaceutical pricing and reimbursement processes in Germany and Poland

There are payers, health care professionals, patients, the general public, politicians and producers among stakeholders within the pharmaceutical reimbursement process. In Germany payers are represented by the SHI, which directly performs price negotiations with pharmaceutical manufacturers and is involved in valuation of the additional benefit of medicines. In addition, five payer representatives are part of the FJC [7]. In Poland the public payer has its representatives within the Economic Commission of the MoH, which is involved in price negotiations. The Polish public payer has representatives also within the Transparency Council of the AOTMiT.

The involvement of health care professionals and providers seems to be similar in both countries. In Germany, similarly to payers also providers are represented in the FJC by five members with a voting right [7]. Besides, they have also the same rights to make comments as everyone else. Providers have no special role in the Polish process, thus their involvement in both countries is rather small. Members of advisory bodies active at various stages of decision making processes in Poland should have appropriate professional background, experience and expertise.

The involvement of representatives of patient organizations seems to be smaller than that of providers or health care professionals. In Germany up to five patient representatives can take part in meetings held by the FJC,

however without a voting right. Their input is limited to contribution to discussions and proposition of agenda items. These patient representatives are nominated by the national umbrella organizations of self-help groups and organizations of consumers or patients [7].

In Germany and Poland the public opinion's involvement is associated with possibility to provide comments on published documents. In addition, the German IQWiG has to provide a proposal for the assessment after specifying the research question. Furthermore, the IQWIG has to publish an interim report describing the process of assessment [10]. The general public has an opportunity to make comments on all of these published documents. The FJC has no process to elicit the public's value judgement [7]. Therefore initiative and motivation to make comments has to originate from inside the general public. These comments do not necessarily have to change anything about the official decision. Nevertheless opportunities for the general public to express their comments on documents before final decision is made are bigger in Germany than in Poland.

In Poland politicians are directly involved in the described processes, since it is the MoH who makes decision on drug reimbursement. In Germany politicians are not involved in the process.

Obviously, pharmaceutical industry is involved in pricing, reimbursement and HTA processes in Poland as well as in Germany. In both countries the pharmaceutical companies prepare and submit their dossiers starting the whole process and then they take part in list price negotiations. However, in Poland the pharmaceutical industry can censor documents before making them open to the general public, while in Germany it is not possible.

It seems that various stakeholders' involvement in pharmaceutical reimbursement and HTA processes is generally higher in Germany than in Poland. Apparently the only stakeholder in Poland which is more involved in these processes is the MoH. In fact, the German MoH is not involved at all, whereas the Polish MoH actually makes the decision on medicine's reimbursement and its reference group allocation (reference price is based on formal calculations described in the statutory law) and the Economic Commission of the MoH negotiates medicines prices.

Discussion

Marusakova et al. evaluated transparency of decision making processes in 14 European countries using nine criteria, including: "legislative background, implementation, binding force, institutionalization, qualified personal resources availability, existing methodology/guidelines, clarity of the process, patient involvement in the process, and respecting the deadline of 180 days for issuing a decision" [18]. A ranking of process transparency was then prepared, in which the UK system was assessed as the most transparent. Germany and Austria were on the second place, while Poland and Hungary ranked third [18]. This correlates with our findings, suggesting that the German processes may be more transparent than Polish.

Overall involvement of stakeholders is stronger in Germany than in Poland, which goes in parallel with transparency of the German processes. However, another published study based on analysis of benefit assessments in Germany showed that although patient preferences were included in 26% of analyzed reports, they were practically not considered within benefit assessments [19]. This shows that utilization of stakeholders involvement in Germany still needs to be enhanced. On the other hand, involvement and inclusion of more stakeholders could lead to higher complexity of processes, making them more difficult to understand and lowering their transparency.

In addition, analysis techniques used in the German process are very complicated. For lay people it is difficult to understand the efficiency frontier approach and to retrace a decision. It could seem that the fixed threshold approach applied in Poland is quite straightforward, so in these aspects the Polish system could be more transparent than German. However, Jebrail et al. developed an instrument to measure transparency of HTA organisations, assessing 33 transparency parameters in eight countries. According to them the IQWiG achieved the best result (97% of the maximum score), whereas the Agenzia Italiana del Farmaco in Italy scored only 25% [17].

Not only assurance of appropriate level of understanding of pricing and reimbursement, and HTA processes to the wider audience is important. If not all information on main aspects of these processes is being published, the level of their transparency becomes diminished. Apparently the processes in Germany are more transparent than in Poland, where even the final HTA recommendation can be censored and not published in full.

It has to be acknowledged that only scientific reports published in German and English languages were taken into consideration in this study, which could influence findings presented therein.

Conclusions

It can be concluded that both Germany and Poland have developed complex processes of pharmaceutical pricing and reimbursement, as well as incorporated HTA into decision making procedures. The German reimbursement and HTA processes seem to be more transparent than Polish. One of the main reasons for that is censoring HTA documents before their publication in Poland, still occurring although less intensive now than in the previous years. In addition, involvement of stakeholders in Germany seems to be higher than in Poland.

The biggest disadvantage of the German system is its high complexity. Using the efficiency frontier approach makes the HTA reports difficult for patients to understand. Therefore these reports, although published and uncensored, are rarely read by a wide public in Germany.

Note

[1] In the German health care system the government delegates competencies to membership-based, self-regulated organizations of payers and providers [1].

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