Interface policies bridging outpatient and hospital sectors: Can cross-sectorial collaboration in reimbursement and procurement improve access to affordable medicines?

Sabine Vogler[1,2], Maximilian Salcher-Konrad[1,3], Katharina Habimana[1]

[1] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmacoeconomics Department, Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Vienna, Austria

[2] Department of Health Care Management, Technische Universität Berlin (Technical University of Berlin), Berlin, Germany

[3] Department of Health Policy, London School of Economics and Political Science, London, UK

Corresponding author: WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Pharmacoeconomics Department, Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute), Vienna, Austria. Email: sabine.vogler@goeg.at. Tel: + 43 1 51561 / 147. Orcid ID: 0000-0003-4853-4397

Keywords

Cross-sector collaboration, funding, interface, hospital, outpatient, pharmaceuticals, pharmaceutical policy, procurement, purchase, reimbursement

Interface policies bridging outpatient and hospital sectors in Europe: Can cross-sectorial collaboration in reimbursement and procurement improve access to affordable medicines?

Abstract

Introduction

Pharmaceutical systems are frequently characterised by fragmentation, and competences for outpatient and inpatient sectors sit with different authorities, payers and purchasers. This fragmentation of responsibilities can incentivize shifting expensive therapies and thus patients from one sector to the other.

Areas covered

Reimbursement and procurement policies in Europe addressing unwanted consequences of this fragmentation were identified through literature reviews and surveys with policy-makers. Good practice examples include cross-sectorial reimbursement lists managed by committees with representatives from the outpatient and hospital sectors, specific funding mechanisms, joint procurement involving purchasers from both sectors, actions against procurement contracts prohibiting generic competition, and an extension of Health Technology Assessment to the hospital sector.

Expert commentary

Recognising fragmentation as a major challenge for pharmaceutical systems, policy-makers in some countries reacted by implementing policies to support cross-sectorial collaboration. However, only a handful of good practice examples exist for reimbursement and procurement policies in Europe. Though robust evaluations are lacking, there are indications that pharmaceutical policies which ensure collaboration at the interface of the outpatient and inpatient sectors would likely result in efficiency gains and better use of public budgets and may serve as lever to improve access to medicines.

Plain language summary

In several European countries, the decision which medicines are funded by public money (reimbursement) and purchased by public institutions (public procurement) is taken independently for the outpatient sector and the hospital sector. There are different payers and procurers per sector, and even with a sector. Patients may be transferred between the sectors for financial reasons because one payer aims to shift the financial burden for the medication to the other sector.

Policy-makers have understood the importance of better collaboration between the sectors, and some European countries introduced policies addressing the issue.

The article presents examples of how reimbursement and procurement policies can be designed to improve the collaboration between the outpatient and hospital sectors. Committees that decide whether or not a medicine should be covered may contain representatives from both sectors; they may be mandated to take decisions that apply to medicines for outpatient use and administered in hospitals. Purchasers of both sectors may procure jointly a medicine. Supporting tools, such as the assessment of a medicine to support the decision on coverage and the price, may be used in both sectors. Financing solutions can reduce the incentive for one sector to shift a medicine to the other sector.

These measures can help that patients gain improved access to affordable medicines. However, despite the introduction of such interface policies in some countries, policy-makers still need to continue working on overcoming the fragmentation in the pharmaceutical system.

Highlights

Interface policies serve to bridge gaps due to fragmentation between outpatient and inpatient sectors.

Interface policies target both novel medicines with high budget impacts, which might be transferred from one sector to the other for economic reasons, as well as medicines with therapeutic alternatives, where initiation of a therapy in one sector can have implications for follow-up prescribing in the other sector.

Reimbursement and public procurement of medicines can play a role in bridging gaps between the two sectors, if these policies target both outpatient and inpatient sectors and do not apply to only one sector.

Communication and involvement of experts of both sectors are supportive to increasing awareness about the other sector.

There is need for evaluations of interface policies which investigate the impact of these policy measures whose progress have mainly been demonstrated on an anecdotal basis.

Key words

Cross-sector collaboration, funding, interface, hospital, outpatient, pharmaceuticals, pharmaceutical policy, procurement, purchase, reimbursement

1. Introduction

1.1. Background

Equitable and sustainable access to available and affordable medicines is a challenge globally and has increasingly also become a concern for high-income countries, including European countries with solidarity-based health care systems [1-5].

Several barriers limit affordability and availability of new and established medicines in most countries. Some medicines with very high price tags (e.g., gene and cell therapies, further cancer medicines, and medicines with an orphan designation), whose values have not always been demonstrated [6-8], pose considerable financial burden on health systems and patients [9,10]. Patients may face delays in accessing new treatments, in some cases due to strategic sequencing of the market launch by pharmaceutical companies [11-15]. In addition, there are availability issues due to increased numbers of shortages of critical medicines, including in high-income countries [16,17].

A specific challenge that hinders equitable access to medicines lies in the often fragmented nature of pharmaceutical systems in several European countries. The outpatient and hospital sectors are organised separately, and responsibilities for reimbursement (i.e., the decision which medicines are publicly covered and to which extent) and procurement of medicines often sit with different public bodies [18,19]. As a result, the medicines available in the inpatient and outpatient sectors might be different. The division between treatment initiation (often in hospital) and continuation (typically in the community setting) can have important economic implications for the outpatient sector, particularly if treatment is started (and expected by the patient to be continued) with a high-priced originator medicine supplied to the hospital at high discounts or for free in some countries [20]. Studies have shown use of this so-called “loss leader” approach in Austria and some other European countries, i.e. to offer for strategic reasons medicines at considerably lower prices (or for free) in one sector (hospitals) to ensure follow-up prescribing in the other sector [21,22]. If legislation does not encourage a switch to available lower-priced therapeutic alternatives, the health system might face high payments over extended periods of time for a high-priced therapy initiated during a patient’s hospital stay (price differences between originators and generic or biosimilar alternatives are frequently around 30% but may also range up to 50-90% [23-25]). Moreover, the organisational gap between the two sectors creates incentives for each to transfer financial responsibility for patients to the other sector [26,27]. Further fragmentation may exist within the hospital sector: In many countries, individual hospitals act as procurers for medicines, without centralized coordination of what products are purchased at what cost [28].

To achieve equitable and affordable access to essential, cost-effective medicines, policy-makers have a menu of policy options for different types of medicines [5,28,29]. Evidence exists on the impact of different pharmaceutical pricing, reimbursement and procurement policies to improve affordable access to medicines [30].

Pharmaceutical pricing, reimbursement and procurement lies in the national competence of countries – this is also the case for member states of the European Union (EU) where marketing authorization has been centralized. It is thus up to national policy-makers to design and implement policies to enhance availability and affordability of medicines. Regarding the above-described challenge of fragmentation in pharmaceutical systems, so-called interface policies are required to support collaboration across sectors.

1.2. Hypothesis and aim

Against the background of negative consequences for patients and health systems resulting from the fragmentation in pharmaceutical systems, we hypothesize that pharmaceutical policies which are designed to support cross-sectorial coordination and cooperation could contribute to improved access to medicines.

We aimed to identify and characterize interface policies in pharmaceutical reimbursement and procurement which have been implemented in European countries to bridge the gap between outpatient and inpatient sectors. We discuss identified examples with a view to their potential for improving access to medicines.

2. Methods

This perspective article builds on more than a decade's experience of the first author in the topic. Earlier insights were gained from a survey of interface policies in which public authorities and hospital representatives from 27 countries participated in 2009 [20], a literature review and a follow-up survey to capture updates in 2012 [31], a collation of good practice examples during a seminar organised by the World Health Organization (WHO) in 2012 [32] and a conference in 2015 [26]. We used the knowledge gained from previous research to build a theoretical framework for describing, surveying, and mapping relevant interface policies in this review.

In 2022, we conducted a survey in 32 European countries (all 27 EU member states, plus the European Economic Area (EEA) / European Free Trade Association (EFTA) members Liechtenstein, Norway, Switzerland, as well as the United Kingdom) with a view to identifying interface policies for reimbursement and procurement and to learning about their impact. We first conducted pragmatic country-specific literature reviews and reviewed previous research of the first author and information collected over the last decade from public authorities included in the Pharmaceutical Pricing and Reimbursement Information (PPRI) network [33]. National procurement experts and public authority representatives were then addressed to review information collated from the literature and other sources. Information was validated by country experts for 26 countries (validation of all collated information for 19 countries and validation of individual components for seven countries), while no validation was performed for six countries. The pragmatic literature review as of 2022 included search terms such as the country name, key words around "medicines" (medicine*, drug*, pharma*), policies (polic*, measure*) and cooperation (cooperat*, coordinat*, interface) and specific names of known relevant measures in English and national languages, run in PubMed and Google Scholar. The 2022

survey was part of a large study on public procurement of medicines and was designed to collate information on various aspects of public procurement in both the inpatient and outpatient sectors in 32 European countries [34].

3. Framework

Figure 1 visualises the conceptual framework applied for this body of research. The framework is based on the pharmaceutical value chain framework, as proposed in the literature, such as by the WHO [27,28]. It describes the path a medicine takes from research and development to its consumption, and depicts regulatory and policy interventions along the value chain, alongside measures taken by individual actors, such as hospitals. The policies which are in the scope of this article concern the so-called peri-launch phase, which spans the time between marketing authorization (i.e., the regulatory approval for a pharmaceutical company to bring a medicine to the market) and the actual launch of the product in the market. In the peri-launch phase, the price of the medicine will be determined, and in several countries public authorities apply price regulation through different pricing policies to ensure affordable prices. Another major decision in the peri-launch phase is the question of whether the expenses for purchasing the medicine will be covered by public funds, and to which extent (e.g., partial reimbursement of a product, patient co-payments). During this phase, public institutions may also engage in procurement procedures such as open tenders in order to secure supply for treating their patients (e.g., in hospitals). Pricing, reimbursement and procurement decisions of public authorities and payers can be supported by evidence collated and appraised, as done in formalised Health Technology Assessment (HTA) processes.

Insert Figure 1 around here

In many European countries, the peri-launch phase is also characterized by the separation of policies by sector. This article investigates the cross-sectorial coordination and collaboration in pharmaceutical reimbursement and procurement policies at the interface of the outpatient (i.e., community) and inpatient (hospital) sectors (thereafter also referred to as “interface policies”). Policies are defined as “instruments, tools and approaches that allow policy-makers to achieve defined objectives” [35]. Policy measures take place at the “macro” level and are distinct from activities and strategies by the private sector at the “micro” level (e.g., setting medicine prices statutorily based on an HTA and/or an algorithm which considers the prices in other countries is a policy, while consideration of a pharmaceutical company to lower a price close to patent expiry is a business strategy). Policies are typically taken at national levels, or sometimes also intra-country regional levels. Single collaboration projects between the outpatient and hospital levels based on the initiatives of individuals in health care (e.g., measures to better collaborate at the discharge of patients) are not covered by this review, unless they result from a policy at national or regional levels.

4. Results

4.1. Identified interface policies in reimbursement and procurement

Some European countries have implemented reimbursement, procurement and related peri-launch policies which aim to ensure better cooperation across the inpatient and outpatient sectors (Table 1).

Insert Table 1 around here (References: Scotland [32,36,37], Stockholm [32,38,39], "H prescriptions" NO [40,41], Nza NL [42], BPOC AT [43], PHT formulary IT [34], CPM PT [44,45], Antitrust NL [46], Antitrust RO [47], Antitrust BE [48], "Lock" NL [5,49], Nye Metoder NO [5,50], H HTA DE [51], HTA AT [34], committees – England [34,52], Latvia [34], PTC AT [34,53], Andalusia [34])

In several European countries (e.g., Belgium, Bulgaria, Cyprus, Czech Republic, Greece, Hungary, Malta, Italy, Portugal, Romania, Slovenia, and Sweden), the reimbursement list (i.e., a formulary which lists medicines that are eligible for public funding) applies to both outpatient and inpatient sectors. However, it is usually supplemented by hospital pharmaceutical formularies (HPFs), comprising medicines which have been given approval for procurement in a specific hospital or a group of hospitals (e.g., hospital-specific HPFs, regional HPFs). These sector specific HPFs tend to be smaller than the general reimbursement lists. As a policy measure to support cross-sectorial cooperation, some countries (and regions in a country, e.g., Scottish and Swedish regions), have established specific reimbursement lists for those medicines, which are considered eligible (and are recommended) for use in outpatient and inpatient settings. These cross-sectorial lists are decided by committees involving representatives of both sectors. Some countries (e.g., Italy, Portugal) have specific cross-sectoral lists of medicines to be procured.

To address the potential risk of transferring the responsibility for treatments from one sector to the other for financial reasons, cross-sectorial funding arrangements might be an option. However, at the time of the 2022 survey, Norway was the only European country identified which had a cross-sectorial funding mechanism at national level in place: hospitals (and not the social health insurance, the standard payer for outpatient medicines) pay for so-called "H prescriptions" in the outpatient sector, which have frequently been initiated in the hospital setting. This policy of hospitals carrying the financial responsibility for the other sector aims to incentivise responsible prescribing at the start of the therapy in hospitals.

Given the relevance of the therapy initiated in hospitals for follow-up medication in the community, measures to tackle illegal procurement practices which tie hospital procurers to higher-priced originator medicines also fall within the scope of interface policies. Examples of these measures are legal actions taken by authorities in Belgium, the Netherlands, and Romania.

Another important group of relevant policies concerns streamlining processes and raising evidence requirements for both sectors. As some European countries had fewer and less stringent policies for the inpatient sector, the decision of some countries (e.g., Germany) to conduct HTA for medicines in

the hospital sector (adding to HTA for medicines for outpatient use) is also a measure of relevance in this area.

Further peri-launch policies to support cross-sectorial coordination include institutional and organisational measures, such as the establishment of centralised procurement covering both sectors (e.g., in Portugal) or representation from both sectors in committees mainly responsible for one sector, such as hospital pharmaceutical and therapeutics committees (e.g., in Austria).

4.2. Impact analysis

To our knowledge, no study has been published that investigated the impact of cross-sectorial policies in reimbursement and procurement on access to affordable medicines or on any other outcome parameters at macro level (national / regional policy levels).

Assessments, including economic evaluations (for a systematic literature review see Simoens, Spinewine [54]), have focused on the micro level of interventions that aimed to improve continuity of care (or seamless care) for medication. Only local-level initiatives and projects (micro level) done between hospitals and primary care (e.g., at discharge) have been subject to evaluations. Evaluations of interface policies at national or regional levels thus seem to be missing.

Only anecdotal evidence on the relevance of national interface policies in reimbursement and procurement for ensuring access to affordable medicines is available. One example of a successful interface policy is the “H prescriptions” in Norway. Given its success, an increasing number of medicines has been included in this programme over the last two decades [41].

5. Discussion

Several European countries have identified the gap between inpatient and outpatient care as a barrier to providing equitable and affordable access to medicines. Some countries have been working on optimising reimbursement and procurement policies to ensure a more integrated and coordinated approach, and good practice examples have been identified. However, evidence on the impact of policies at the interface of the inpatient and outpatient sectors on access to medicines is largely missing.

The investigation of policy measures over time shows that policy-makers have increasingly turned their attention towards medicines used in hospitals and have introduced some policies in the inpatient sector that were previously only used in the outpatient sector to, including tools to support evidence-based decision-making (e.g., HTA). This can be understood as a response to developments in the pharmaceutical sector, since an important share of new medicines with high prices, which entered European markets over the last ten to fifteen years, are mainly used in hospitals and have considerable financial impact on public budgets [55]. Twenty years ago, medicine spending in hospitals was not considered a major political concern [56], and the hospital-related shares of public pharmaceutical budgets were frequently not reported [20,55]. This may explain why the hospital sector tended to be less subject to (national) policies, which have been standard for outpatient medicines

(e.g., no price regulation for medicines used in hospitals in Austria; instead, prices are set during negotiations between individual hospitals or hospital owner groups and industry [57]). With the extension of policies that were previously only applied for medicines in the outpatient sector, policy-makers acknowledged the challenges in the hospital sector posed by the emergence of promising but sometimes high-priced and even unaffordable therapies. Experience that had been gained with the tools in outpatient care was transferred to inpatient care. In some cases, the institutions responsible for these policies in the outpatient sector were mandated to implement, or at least to support policy implementation, in the hospital sector. Outpatient sector experts helped to build capacity in the hospital setting. Given recent and expected developments in the pharmaceutical markets with the advent of highly specialised medicines with high price tags for small patient populations that are mainly used in the hospital setting (e.g., gene therapies) [58,59], it is important to further scale up capacity and policy action in the hospital sector.

While the above-described group of interface policies is aimed at ensuring affordability and financial sustainability of high-priced medicines in hospitals, another motivation for cross-sectorial collaboration mechanisms in reimbursement and procurement is to address the impact of hospital prescribing of medication initiated during a patient's hospital stay on outpatient use (see Gallini, Legal [60] on empirical evidence on the relationship between use of originator brand medicines in hospitals and their surrounding catchment areas). Treatment of chronic diseases may require continuous medication for years. Increased use of therapeutically equivalent but less expensive alternatives, such as generic and biosimilar medicines, would ease the burden on public budgets for treating chronic conditions without compromising quality of care [61], thus enhancing patient access [24]. Potential efficiency gains for health care payers may be missed due to continued use of higher-priced medicines, if these were started in the hospital setting and patients have not been switched to less expensive alternatives subsequently in the community. In some countries hospitals receive originator medicines for free (where national legislation allows to do so) or at high discounts, with the supplier's expectation that the same product would continue to be prescribed and used after discharge of the patient [21]. These challenges can be addressed through appropriate demand-side measures, such as generic substitution or prescribing by the International Non-Proprietary Name (INN) in the outpatient sector. Since these policies would require patients in the outpatient setting to be switched to lower-priced medicines or their prescribed products to be substituted with lower-priced alternatives, there would be no need for additional cross-sectorial interface policies in reimbursement and procurement. Potential savings from these demand-side measures are most likely to be realised if they were implemented on a mandatory basis, or coupled with financial initiatives for patients, such as an internal reference price system, in which patients would pay the difference between the reimbursement amount and the higher pharmacy retail price if they insist on a higher-priced medicine [35]. INN prescribing and substitution policies for outpatient medicines take place in the post-launch setting (see Figure 1) and were therefore not described in the results section, which focused only on reimbursement and procurement policies. Public authorities (such as competition authorities and courts) have sometimes taken action to prevent and counteract suppliers' practices in procurement that impede generic and biosimilar competition (e.g., contracts that hospitals tie to an originator medicine).

In addition, some interface policies aim to overcome the fragmentation in the pharmaceutical sector and its negative effects, such as weak negotiation power of individual procurers and payers. There appears to be increased awareness of the drawbacks of fragmentation, and group procurements and centralised public procurement of medicines (however, frequently only in the hospital sector) [44], have been implemented in response. Policies of this building block frequently imply institutional and organisational changes and have resulted in the establishment of new institutions and committees, with representation from both sectors (e.g., mandate of centralised procurement covering both sectors, cross-sectorial reimbursement committees and treatment guideline development groups).

The collection and analysis of the findings has some limitations. Despite the importance of the topic, it is still a rather novel research area which lacks an accepted terminology and taxonomy. In research and practice, different terms are used to describe the link (or lack thereof) between inpatient and outpatient sectors, such as “interface management”, “seamless care”, “continuity of care”, “cross-sector” and “cross-sectorial”, and this has caused challenges for the literature review. In some countries, none of these terms may be in use, yet policies with a cross-sectorial character and which support collaboration at the interface might exist in these countries. Most policies were identified through intensive search of grey literature (in local languages), discussion with policy-makers and monitoring of identified policies over the years. While this approach appeared to be the most rewarding to identify relevant policies, it is not a systematic literature review, and information could not be fully validated by national experts for all countries. Additionally, possibly relevant initiatives and policies might have been missed.

6. Conclusions

The review highlighted the importance of cross-sectorial collaboration in pharmaceutical reimbursement and procurement since fragmentation in the pharmaceutical system incentivizes public payers and procurers to shift medicines, particularly those of high budget impact, to the other sector. This mostly economically motivated shift is irritating for patients, and it constitutes a missed opportunity since collaboration between outpatient and hospital sectors could strengthen the purchasing power and improve the evidence base for decision-taking.

Policy-makers in European countries appear to be aware of this problem, and some countries have reacted by implementing policies. The number of good practice examples that could be identified was, however, rather limited, and focused on some countries. A few countries decided to discontinue a policy and substituted it by another that was considered more appropriate. This confirms the general need for monitoring the effectiveness of policies and eventually adapting them.

While there is a strong rationale for the importance of improved cross-sectorial collaboration in national (or regional) reimbursement and procurement policies, and its contribution to access to affordable medicines can be well-argued, the review highlighted lack of impact evaluations. There is room for further research to assess interface policies in terms of their ability to achieve intended policy objectives. In addition, there is need for broadly disseminating findings of such future studies, in order

to showcase the potential of intra-country collaboration and thus encourage policy-makers moving into this direction.

7. Expert opinion

7.1. How could cross-sectorial collaboration in reimbursement and procurement impact access to medicines?

This review has highlighted the importance of cross-sectorial collaboration in pharmaceutical reimbursement and procurement. However, the extent to which interface policies helped improve access to affordable medicines has not been assessed. Despite the strong WHO recommendation to always accompany policy implementation by monitoring and evaluation [62], evaluations of pharmaceutical policies, including cross-sectorial collaborative policies, are frequently lacking [27,30].

While we await more robust evidence, it appears fair to argue that interface policies can have positive effects on different outcomes. First, through cross-sectorial collaboration, stakeholders may gain a better understanding of the challenges in the other sector and may take a broader health system perspective. Organisational measures such as the participation in committees can be helpful to raise cross-sectorial awareness. Second, interface policies are expected to contribute to improved rational use of medicines, in contrast to a fragmented system, which incentivizes transfer of patients across sectors for financial reasons. Better coordination across sectors may reduce the risk that patients, who do not understand and accept frequent medication changes, become less therapy compliant and may also lose trust in the system. Third, fragmented systems are likely to be disadvantageous for public budgets. Individual payers and procurers do not have all the information about existing alternatives, their prices, and required doses in a country available which weakens their negotiation power. In addition, due to smaller volumes per individual procurers, their markets may be less attractive, and medicines might be made available at a later stage. Suppliers may use the limited knowledge and purchasing power of single procurers to play the purchasers off against each other, by, for instance, promising each of them the “best deal” (through confidential discounts, where the correctness of the statement is not possible to check).

7.2. Areas for improvements and potential barriers

Our research has shown that policy-makers in some European countries have become aware of the challenges posed by gaps between the inpatient and outpatient sectors and have reacted by introducing policy measures. However. we did not identify examples of interface policies from several other countries. Nonetheless, given existing fragmentation and reported problems [20,26], there is a clear need for such policies.

Existing institutional settings and split of responsibilities may not only cause fragmentation but also prevent implementation of policies to support cross-sectorial collaboration. Each sector is responsible for funding and procuring medicines for its own setting and is typically not encouraged (and not rewarded) for taking a holistic system approach. At first glance, more collaboration could even bring

financial disadvantages (e.g., need to share discounts that used to be granted by industry to the procurer of one sector, or the obligation to pay for medicines used in the other sector, as in the Norwegian case of “H prescriptions”). From a single-sector perspective, shifting expensive therapies to the other sector might seem to be an easier solution. Furthermore, successful collaboration requires trust and openness towards the partners of the other sector. For instance, in cross-sectorial procurement, purchasers need to agree on a common procurement strategy which might be informed by experience in previous procurements conducted as single-sector procurers. While any pooled procurement tends to increase transparency and good governance, this may result in a loss of power of the individual procurers. Responsibility may even be shifted to a procurement body at a more central level which takes an overarching coordinating role and assumes tasks previously assigned to outpatient and hospital procurers. Cross-sectorial collaboration is therefore unlikely to be initiated by stakeholders in one of the sectors. Instead, introducing a cross-sectorial approach requires a third party, that ideally has the legal mandate to launch change processes and is accepted by all parties. In European fragmented pharmaceutical systems, where competences for reimbursement and procurement for outpatient medicines frequently lie with the social health insurance, whereas medicines for the inpatient sector are funded and purchased by the hospitals, or the hospital owners (e.g., regions in several countries), an authority such as a Ministry of Health could serve as “third party” to initiate change.

However, it is to be acknowledged that pharmaceutical systems, with defined competences for each sector, have evolved over decades and that changes might be difficult and require strong political will. For example, transparency about net prices paid might be difficult to achieve due to actors on both sides (suppliers and procurers / payers) being mindful of protecting potentially valuable information – although some countries have introduced legislation that requires prices of publicly procured medicines to be published [63]. Still, a large reform to build a better coordinated pharmaceutical reimbursement and procurement system may not always be feasible. Thus, small steps, which do not require legislative and organisational change, and piloting measures may be a useful approach in such situations (e.g., communication and exchange with representatives of the other sector). Institutions with responsibilities for funding or reimbursing medicines in both sectors can play an important role in facilitating exchanges and nurturing a culture of collaboration across inpatient and outpatient care.

7.3. Potential for further research

There is need for future research to identify further good practice examples, including in other regions of the world, where appliable, and to assess if existing policies were able to improve access to affordable medicines and meet further defined policy objectives. Study findings could inform the countries that already implemented interface policies when they aim to optimise them, and additionally they would offer important cross-learnings for other countries.

As described in the discussion section, a challenge for this review was the lack of an accepted terminology and taxonomy for this area of research. To support future research, we propose a

framework for interface policies (Figure 1), which was built on a definition we had developed previously. This framework, as well as the examples presented in the review, aim to encourage future research on the range of various interface policies, and their contribution to patient access to medicines, in European countries and globally.

7.4. Areas of future attention

This review investigated the policy areas of reimbursement and procurement as well as related supportive policies and tools, such as HTA. This focus was selected since these dimensions are key to ensure access to affordable medicines. In addition, they have not yet been much studied, in contrast to the initiatives and programs at the micro level (e.g., medicine reconciliation after hospital admission, discharge programs [54,64]).

However, there are other policy areas in the pharmaceutical value chain which might also require some attention for optimisation through cross-sectorial collaboration. For instance, policies targeting prescribing, dispensing or monitoring and evaluation have frequently been designed for only one sector. While specifications for one sector might be legitimate, a more holistic approach would still be beneficial. For instance, the different organisation of each sector may fully justify a specific design of a measure such as generic substitution or prescribing by international non-proprietary name per sector, but implementation of such a measure in only one sector might be difficult for health professionals to deal with as well as for patients.

Adding to cross-sectorial collaboration, improved coordination across the pharmaceutical value chain would be another area of importance. For instance, the requirements for evidence to be presented in applications for marketing authorization differ from those applied in HTA, reimbursement and pricing decisions [65,66]. Raising the bar for evidence requirements in marketing authorization would be beneficial for the downstream actors in the pharmaceutical value chain, such as payers, procurers and pricing authorities [65]. Another example is the package of integrated policy measures in the pre- and peri-launch phases to manage the market entry of high-priced medicines, such as the “Nye Metoder” method in Norway [50], the integrated approach applied in the cross-country collaboration Beneluxa Initiative [67] and similar examples from other countries [68]. These approaches typically include a horizon scanning exercise, which informs the next steps [69], such as the extent of the HTA and the reimbursement and procurement processes. As shown, these cross-phase activities benefit if designed in a cross-sectorial manner.

7.5. Five-year perspective

Looking back, we see that some countries have recognised the need for action on the interface of sectors more than a decade ago and have implemented appropriate measures. Interestingly, the number of newly introduced measures in the last years was rather limited. New initiatives were also concentrated in countries that had started cross-sectorial collaboration earlier. These developments could indicate that the number of newly introduced measures in the next five years would continue to be rather small. Furthermore, given the launch of therapies with premium prices, policy-makers may

well continue their past focus on the inpatient sector and tend to disregard cross-sectorial collaboration.

Having said this, it should be noted that collaboration has been promoted as one of the most promising future avenues for improving access to medicines [70-72]. The EU HTA Regulation [73] was passed in the spirit of fostering collaboration, and it is hoped to build on successful joint procurement exercises, such as the one for COVID-19 vaccines in the EU, to make medicines available and affordable. But collaboration is usually considered to be cross-country, which can be challenging given different national jurisdictions for reimbursement and pricing. Frequently, it is not considered that fragmentation in pharmaceutical systems can be a hindering factor for countries to participate in cross-country collaboration. Thus, ensuring coordination in national pharmaceutical reimbursement and procurement settings (e.g., defining a procurer that can represent the country) is a prerequisite for effective cross-country collaboration.

Given the complexity and the extent of changes needed, the problem of fragmentation in pharmaceutical systems is likely to continue to exist in five years. Still, we assume that a larger number of countries compared to today will be aiming to address the challenge. In particular, we expect an increase in cross-country collaborations aiming to improve patient access to medicines, and we assume that this development could also result in some countries working on improving intra-country cross-sectorial collaboration in reimbursement and procurement.

To support these developments, it is important to bring the attention of policy-makers to the gaps in medicine access, which may result from lacking coordination across outpatient and hospital sectors, and to share good practice examples of interface policies from other countries. We are confident that cross-learning can support countries to further develop their national pharmaceutical reimbursement and procurement systems to improve access to affordable medicines.

8. Declaration of Interest

8.1 Funding

This perspective article draws from several pieces of research conducted over the last 15 years. In particular, it was informed by a review and survey done in the 2022 “Study on Best Practices in the Public Procurement of Medicines” commissioned by the European Health and Digital Executive Agency (HaDEA) as contracting authority under the mandate of the European Commission through the Framework contract SANTE/2016/a1/039 concerning the provision of services in the area of evaluation, impact assessment, monitoring and implementation and of other relevant services, in relation to the health and food policies (LOT 1) with reopening of competition.

No funding was received for conducting the analysis for this review and writing the article.

8.2. Acknowledgements

The authors are grateful to experts of several European countries who provided input on interface policy matters in their countries and to their colleagues Margit Gombocz, Valentin Kandler, Peter Schneider and Nina Zimmermann of the Austrian National Public Health Institute, who surveyed country information for the “Study on Best Practices in the Public Procurement of Medicines”.

8.3 Conflict of Interest

The authors declare no conflicts of interest.

9. References

1. Campbell JD, Kaló Z. Fair global drug pricing. Expert Review of Pharmacoeconomics & Outcomes Research. 2018 2018/11/02;18:581-3
2. Inotai A, Kaló Z. How to solve financing gap to ensure patient access to patented pharmaceuticals in CEE countries? – the good, the bad, and the ugly ways. Expert Review of Pharmacoeconomics & Outcomes Research. 2019 2019/11/02;19:627-32
3. Scalo JF, Rascati KL. Trends and issues in oncology costs. Expert Review of Pharmacoeconomics & Outcomes Research. 2014 2014/02/01;14:35-44
4. Vogler S. Can we achieve affordable cancer medicine prices? Developing a pathway for change. Expert Review of Pharmacoeconomics & Outcomes Research. 2021:1-5
5. Vogler S. Payer policies to support innovation and access to medicines in the WHO European Region. Copenhagen: World Health Organization. Regional Office for Europe; 2022. Available from: https://apps.who.int/iris/handle/10665/361753 (accessed 28 January 2023)
*** This WHO review describes policies for managing the market entry of novel, potentially high-priced medicines, including some policies of interface character**
6. Janzic U, Knez L, Janzic A, et al. Time to access to novel anticancer drugs and the correlation with ESMO-Magnitude of Clinical Benefit Scale in Slovenia. Expert Review of Pharmacoeconomics & Outcomes Research. 2019 2019/11/02;19:717-23
7. Davis C, Naci H, Gurpinar E, et al. Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. BMJ (Clinical research ed). 2017;359:j4530
8. Hwang TJ, Ross JS, Vokinger KN, et al. Association between FDA and EMA expedited approval programs and therapeutic value of new medicines: retrospective cohort study. BMJ (Clinical research ed). 2020;371:m3434
9. Michel M, Toumi M. Access to orphan drugs in Europe: current and future issues. Expert Review of Pharmacoeconomics & Outcomes Research. 2012;12:23-9
10. Peppercorn J. The financial burden of cancer care: do patients in the US know what to expect? Expert Review of Pharmacoeconomics & Outcomes Research. 2014;14:835-42
11. Kaló Z, Alabbadi I, Al Ahdab OG, et al. Implications of external price referencing of pharmaceuticals in Middle East countries. Expert review of pharmacoeconomics & outcomes research. 2015;15:993-8
12. Kalo Z, Annemans L, Garrison LP. Differential pricing of new pharmaceuticals in lower income European countries [Review]. Expert Review of Pharmacoeconomics & Outcomes Research. 2013 Dec;13:735-41
13. Danzon PM, Wang YR, Wang L. The impact of price regulation on the launch delay of new drugs—evidence from twenty-five major markets in the 1990s. Health economics. 2005;14:269-92
14. Kyle MK. Pharmaceutical price controls and entry strategies. The Review of Economics and Statistics. 2007;89:88-99

15. Vogler S, Schneider P, Zimmermann N. Evolution of Average European Medicine Prices: Implications for the Methodology of External Price Referencing. PharmacoEconomics - Open. 2019;3:303-9

16. Chapman S, Dedet G, Lopert R. Shortages of medicines in OECD countries. OECD Health Working Papers. Paris: Organisation for Economic Co-operation and Development; 2022. Available from: https://www.oecd-ilibrary.org/content/paper/b5d9e15d-en (accessed 26 March 2023)

17. Vis C, Pelsy F, Dijkstal F, et al. Future-proofing pharmaceutical legislation: study on medicine shortages: final report. Brussels: European Commission Directorate-General for Health Food Safety, Publications Office; 2021. Available from: https://www.oecd-ilibrary.org/content/paper/b5d9e15d-en (accessed 15 March 2023)

18. Vogler S, Zimmermann N, Haasis MA. PPRI Report 2018: Pharmaceutical pricing and reimbursement policies in 47 PPRI network member countries Vienna: WHO Collaborating Centre for Pricing and Reimbursement Policies, Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute); 2019

19. Vogler S, Haasis MA, Dedet G, et al. Medicines Reimbursement Policies in Europe. In: World Health Organization Office for Europe, editor. Copenhagen2018. Available from: https://www.who.int/europe/publications/i/item/9789289053365 (accessed 15 March 2023).

20. Vogler S, Habl C, Leopold C, et al. PHIS Hospital Pharma Report. Vienna: Pharmaceutical Health Information System (PHIS); 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Hospital%20Pharma_Report_2.pdf (accessed 4 January 2022)
**** One of the earliest pieces of research which investigated interface policies in pricing, reimbursement and procurement**

21. Vogler S, Zimmermann N, Habl C, et al. The role of discounts and loss leaders in medicine procurement in Austrian hospitals - a primary survey of official and actual medicine prices. Cost Effectiveness and Resource Allocation. 2013;11:15

22. Vogler S, Zimmermann N, Leopold C, et al. Discounts and Rebates Granted for Medicines for Hospital Use in Five European Countries. The Open Pharmacoeconomics & Health Economics Journal 2013;5:1-10

23. Perelman J, Duarte-Ramos F, Melo Gouveia A, et al. How do hospital characteristics and ties relate to the uptake of second-generation biosimilars? A longitudinal analysis of Portuguese NHS hospitals, 2015–2021. Expert Review of Pharmacoeconomics & Outcomes Research. 2023;23:99-109

24. Simoens S. How do biosimilars sustain value, affordability, and access to oncology care? Expert Review of Pharmacoeconomics & Outcomes Research. 2020:1-3

25. Manova M, Savova A, Vasileva M, et al. Comparative Price Analysis of Biological Products for Treatment of Rheumatoid Arthritis. Frontiers in Pharmacology. 2018: -20;9

26. Vogler S, Zimmermann N, Wirtz VJ. Policy cooperation and interface issues. Journal of Pharmaceutical Policy and Practice. 2015;8:E3
*** Editorial for the PPRI Conference 2015 with a specific strand on the need for and examples of interface policies**

27. WHO. Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research. Copenhagen: World Health Organization Regional Office for Europe; 2015. Available from: https://apps.who.int/iris/handle/10665/159405 (accessed 20 April 2023)

28. Vogler S, Paris V, Panteli D. Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? In: European Observatory on Health Care Systems, editor. Policy Brief and Summaries. Copenhagen: WHO Regional Office for Europe; 2018. Available from: http://www.euro.who.int/__data/assets/pdf_file/0009/379710/PolicyBrief_AUSTRIA_PB30_web_13082018.pdf (accessed 25 October 2022)

29. Vogler S, Paris V, Ferrario A, et al. How Can Pricing and Reimbursement Policies Improve Affordable Access to Medicines? Lessons Learned from European Countries. Appl Health Econ Health Policy. 2017:14

30. WHO. WHO Guideline on Country Pharmaceutical Pricing Policies. Second edition. Geneva: World Health Organization; 2020. Available from: https://apps.who.int/iris/rest/bitstreams/1309649/retrieve (accessed 4 January 2023)

31. Vogler S, Zimmermann N, Habl C, et al. OHP-073 Survey of Interface Management Measures Regarding Medicines. European Journal of Hospital Pharmacy: Science and Practice. 2013;20:A161-A

32. Björkhem-Bergman L, Andersén-Karlsson E, Laing R, et al. Interface management of pharmacotherapy. Joint hospital and primary care drug recommendations. Eur J Clin Pharmacol. 2013;69:73-8
**** Collation of some interface policies reported in a seminar on this topic**

33. Vogler S, Leopold C, Zimmermann N, et al. The Pharmaceutical Pricing and Reimbursement Information (PPRI) initiative–experiences from engaging with pharmaceutical policy makers. Health Policy and Technology 2014;3:139–48

34. Vogler S, Salcher-Konrad M, Habimana K. Study on best practices in the public procurement of medicines: final report. Brussels: European Commission, European Health and Digital Executive Agency, Publications Office of the European Union; 2022. Available from: https://data.europa.eu/doi/10.2925/044781 (accessed 20 April 2023)
**** A recent study on public procurement which also surveyed good example examples on interface policies in procurement and further peri-launch policies**

35. WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies. Glossary of pharmaceutical terms. Available from: https://ppri.goeg.at/ppri-glossary (accessed 13 March 2023). Vienna: Gesundheit Österreich (GÖG / Austrian National Public Health Institute); 2023

36. Matusewicz W, Godman B, Pedersen HB, et al. Improving the managed introduction of new medicines: sharing experiences to aid authorities across Europe. Expert Rev Pharmacoecon Outcomes Res. 2015;15:755-8

37. Herms S, Rutledge P. The Lothian Joint Formulary: overcoming the barriers to formulary success. Pharmacy in Practice. 2002;12:279-85

38. Gustafsson LL, Wettermark B, Godman B, et al. The 'wise list'- a comprehensive concept to select, communicate and achieve adherence to recommendations of essential drugs in ambulatory care in Stockholm. Basic & clinical pharmacology & toxicology. 2011 Apr;108:224-33

39. Eriksen J, Gustafsson LL, Ateva K, et al. High adherence to the 'Wise List'treatment recommendations in Stockholm: a 15-year retrospective review of a multifaceted approach promoting rational use of medicines. BMJ open. 2017;7:e014345

40. Weise N, Festoy H, Hagen C, et al. PPRI Pharma Profile: Norway 2018. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2018. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PPRI%20Norway%202018.pdf (accessed 20 June 2022)

41. Aure OH, Festoy H. PPRI Pharma Profile: Norway 2022. Vienna: Pharmaceutical Pricing and Reimbursement Information (PPRI); 2022. Available from: https://ppri.goeg.at/system/files/inline-files/PPRINorway2022_final.pdf (accessed 20 January 2023)

42. Storms H, Schreurs M. PHIS Pharma Profile The Netherlands. Vienna: Pharmaceutical Health Information System (PHIS); 2010. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20NL%20Hospital%20Pharma%20Report%202009_5.pdf (accessed 2 February 2023)

43. Federal Ministry of Health, Main Association of the Austrian Social Health Insurance institutions, Austrian provinces. Zielsteuerungsvertrag auf Bundesebene. Zielsteuerung-Gesundheit 2013-2016 (Target control agreement at federal level. Target control - Health 2013-2016). Vienna 2013. Available from:

https://www.parlament.gv.at/PAKT/VHG/XXV/III/III_00038/imfname_336346.pdf (accessed 13 January 2022)

44. Vogler S, Bauer E, Habimana K. Centralised Pharmaceutical Procurement: Learnings from Six European Countries. Applied Health Economics and Health Policy. 2022;20:637–50

45. Vogler S, Habimana K, Bauer E, et al. Centralised Procurement of Medicines in Portugal – Final Report. Vienna: Gesundheit Österreich; 2021. Avallable from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/GOe_FP_PT_CPM_Full%20Report_total_bf.pdf (accessed 15 April 2023)

46. ACM. Drug manufacturer Pfizer to discontinue its steering pricing structure for Enbrel following discussions with ACM. Authority for Consumers & Markets; 2022. Available from: https://www.acm.nl/en/publications/drug-manufacturer-pfizer-discontinue-its-steering-pricing-structure-enbrel-following-discussions-acm#:~:text=discussions%20with%20ACM-,Drug%20manufacturer%20Pfizer%20to%20discontinue%20its%20steering%20pricing%20structure%20for,Enbrel%20through%20its%20discount%20schemes. (accessed 12 March 2023)

47. Biosimilar Development. The Competition Council Sanctioned Roche Romania With Fines Of 128 Million Euro. 2020. Available from: https://www.biosimilardevelopment.com/doc/the-competition-council-sanctioned-roche-romania-with-fines-of-million-euro-0001 (accessed 8 April 2023)

48. AFMPS. Circulaire No. 646: À l'attention des hopitaux, des officines hospitalières, des fabricants et distributeurs en gros de médicaments et des fabricants importateurs et distributeurs de dispositifs médicaux [Circular No. 646: To the attention of hospitals, hospital pharmacies, manufacturers and wholesale distributors of drugs and manufacturers importing and distributing medical devices]. Brussels: Agence fédérale des médicaments et des produits de santé,; 2019. Available from: https://www.afmps.be/sites/default/files/content/DC-CT/20190625151638.pdf (accessed 26 March 2023)

49. Angelis A, Lange A, Kanavos P. Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. The European Journal of Health Economics. 2017:1-30

50. Sekretariatet for nye metoder. Nye Metoder. 2021. Available from: https://nyemetoder.no/english (accessed on 29 March 2023]

51. Vogler S. Gratulation mit Wunschliste - Europäischer Blick aus dem Nachbarland [Congratulation and a wish list. European viewpoint from the neighbouring country]. In: Greiner W, Witte J, Gensorowsky D, et al., editors. AMNOG-Report 2020. 10 Jahre AMNOG - Rückblick und Ausblick [AMNOG report 2020. 10 years AMNOG – Looking back and looking forward]. Hamburg: DAK-Gesundheit; 2020. Available from: https://www.dak.de/dak/download/report-2335144.pdf (accessed 15 March 2023)

52. James D, Kullman D. PHIS Hospital Pharma Report United Kingdom. Vienna: Pharmaceutical Health Information System (PHIS); 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS%20Pharma%20Profile%20UK%20Feb2011_5.pdf (accessed 13 March 2023)

53. Zimmermann N, Vogler S. PHIS Hospital Pharma Report Austria. Vienna: Pharmaceutical Health Information System (PHIS); 2009. Available from: https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/PHIS_Hospital_Pharma_AT_Report_Final_version_090630_6.pdf (accessed 13 March 2023)

54. Simoens S, Spinewine A, Foulon V, et al. Review of the cost-effectiveness of interventions to improve seamless care focusing on medication. International journal of clinical pharmacy. 2011;33:909-17
*** Evaluation of cost-effectiveness of some micro-level interventions of continuity of care with regard to medication**

55. Belloni A, Morgan D, Paris V. Pharmaceutical Expenditure And Policies. Paris: Organisation for Economic Cooperiaton and Development; 2016.

56. Vogler S, Zimmermann N, Mazag J. Procuring medicines in hospitals: results of the European PHIS survey. EJHP Practice. 2011:20-1

57. Vogler S. Pharmaceutical regulation and policies in Austria. Revista Brasileira de Farmácia Hospitalar e Serviços de Saúde. 2022;13:639

58. Dranitsaris G, Zhu X, Adunlin G, et al. Cost effectiveness vs. affordability in the age of immuno-oncology cancer drugs. Expert Review of Pharmacoeconomics & Outcomes Research. 2018 2018/07/04;18:351-7

59. Quinn C, Ciarametaro M, Sils B, et al. Medicaid best price reforms to enable innovative payment models for cell and gene therapies. Expert Review of Pharmacoeconomics & Outcomes Research. 2023 2023/02/07;23:191-203

60. Gallini A, Legal R, Taboulet F. The influence of drug use in university hospitals on the pharmaceutical consumption in their surrounding communities. Br J Clin Pharmacol. 2012;7:1365-2125

61. European Medicines Agency, Heads of Medicines Agencies. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. Amsterdam: EMA; 2022. Available from: https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf (accessed 26 April 2023)

62. WHO. Indicators for monitoring national drug policies. A practical manual. 2nd Edition. Geneva: World Health Organization; 1999. Available from: https://apps.who.int/iris/handle/10665/60706 (accessed 29 April 2023)

63. Vogler S. Access to information in markets for medicines in the WHO European Region. Oslo Medicines Initiative technical report. Copenhagen: World Health Organization. Regional Office for Europe; 2022. Available from: https://apps.who.int/iris/rest/bitstreams/1462628/retrieve (accessed 16 November 2022)

64. Spinewine A, Foulon V, Claeys C, et al. Seamless care focusing on medication between hospital and home. Brussels: Belgian Health Care Knowledge Centre (KCE); 2010. Available from: https://kce.fgov.be/sites/default/files/atoms/files/kce_131c_seamless_care.pdf (accessed 21 April 2023).

65. Naci H, Salcher-Konrad M, Kesselheim AS, et al. Generating comparative evidence on new drugs and devices before approval. The Lancet. 2020;395:986-97
*** A study highlighting evidence gaps of comparative evidence generation required for decision-making and different responsibilities of authorities across the pharmaceutical value chain**

66. Panteli D, Eckhardt H, Nolting A, et al. From market access to patient access: overview of evidence-based approaches for the reimbursement and pricing of pharmaceuticals in 36 European countries. Health Res Policy Syst. 2015;13:39

67. Vogler S, Haasis MA, van den Ham R, et al. Cross-Country Collaborations to improve access to medicines and vaccines in the WHO European Region. World Health Organization Regional Office for Europe; 2020. Available from: https://apps.who.int/iris/bitstream/handle/10665/332933/9789289055031-eng.pdf (accessed 8 May 2022)

68. Malmstrom R, Godman B, Diogene E, et al. Dabigatran - a case history demonstrating the need for comprehensive approaches to optimise the use of new drugs. Frontiers in pharmacology. 2013;4

69. Vogler S. “Ready for the future?”–Status of national and cross-country horizon scanning systems for medicines in European countries. GMS German Medical Science — an Interdisciplinary Journal. 2022;22:Doc05

70. WHO/Europe. Better access to effective, novel and affordable medicines: a new vision for collaboration between the public and private sector. Regional Committee for Europe EUR/RC70/Inf.Doc./6, 70th session. Virtual session, 14–15 September 2020. Copenhagen: World Health Organization Regional Office for Europe; 2020. Available from: https://apps.who.int/iris/bitstream/handle/10665/334171/70id06e-AccessMed-200722.pdf?sequence=1&isAllowed=y (accessed 5 February 2023)

71. European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Pharmaceutical Strategy for Europe. COM/2020/761 final. 25 November 2020. Brussels2020. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761 (accessed 17 January 2023)

72. Vogler S, Zimmermann N, Babar Z-U-D, et al. Addressing the medicines access challenge through balance, evidence, collaboration and transparency: key take-away lessons of the 4th PPRI Conference. Journal of Pharmaceutical Policy and Practice. 2021 2021/01/25;14:18

73. Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU. Brussels2021. Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32021R2282 (accessed 8 April 2023)

List of figures and tables

Legend: AMR – antimicrobial resistance; HTA – health technology assessment; MA – marketing authorization; R & D – research and development

Table 1: Good practice examples of interface policies to support cross-sectorial collaboration in European countries

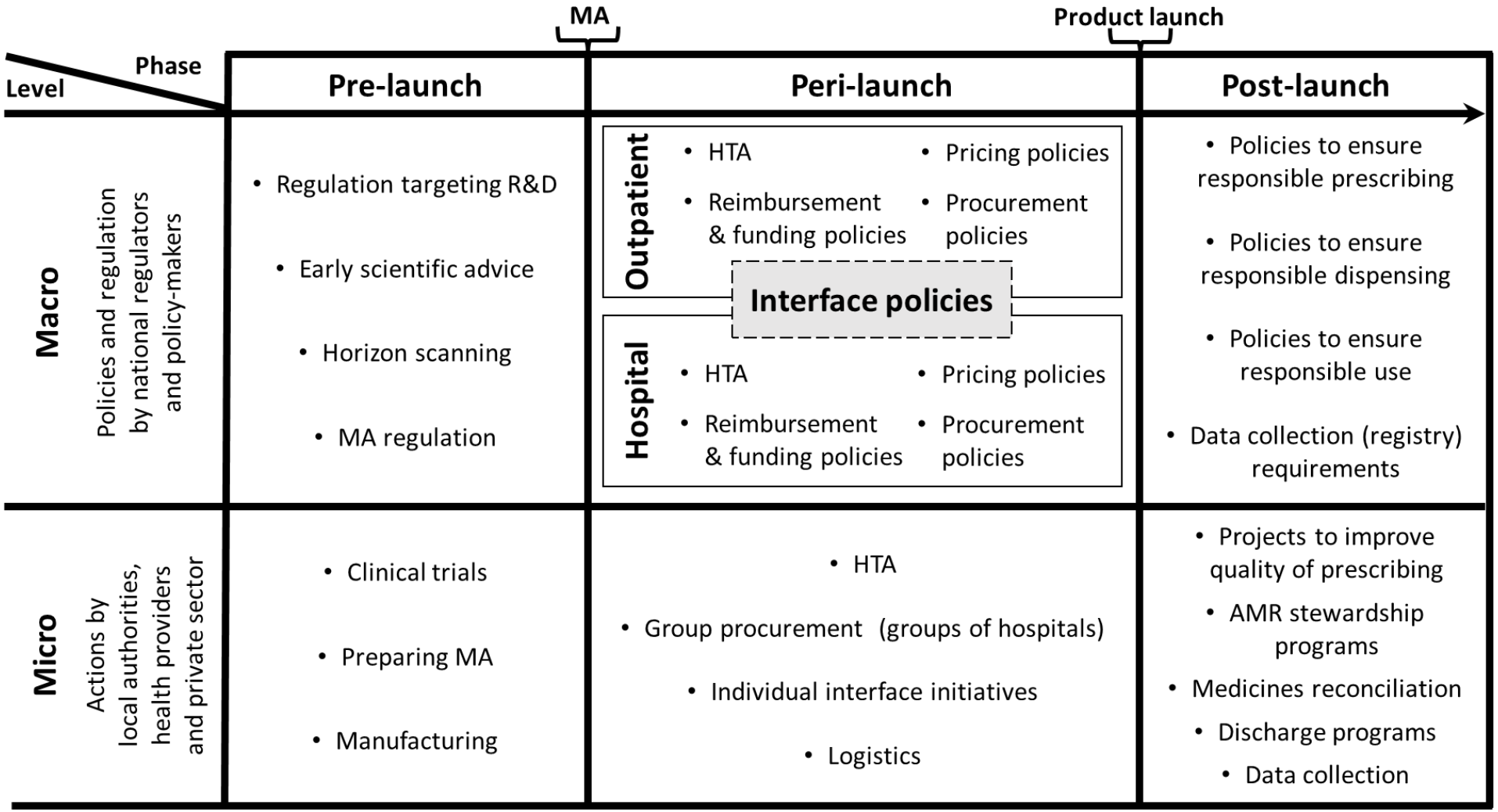
Policy	Brief description	Country	Ref.
	Reimbursement and funding policies		
Cross-sectorial formularies	Formularies which include medicines recommended for outpatient and inpatient use have been in place for some decades in Scotland. The Health Board of the Grampian region was the first to introduce such a formulary in Scotland in 1993. In the same year, all Scottish health boards were encouraged to produce a similar joint formulary covering both primary and hospital care, with the aim of improving the quality and cost-effectiveness of prescribing. Several regions followed this idea, e.g., in Lothian, the Area Drug and Therapeutic Committee formed a Formulary Subcommittee to produce a Lothian Joint Formulary, which was first launched in 2001.	Scotland (regional level)	[32,36, 37]
"Wise List"	The "Wise List" is an example of a cross-sectorial formulary of recommended medication managed by a committee with representation of outpatient and hospital sectors in the Swedish county council (region) of Stockholm, which was based on a previous list only applicable for one sector (outpatient care) and which was later extended. The rationale of this list (called "Kloka Lista", in English: "Wise List") is to encourage rational prescribing. Medicines on the "Wise List" are recommended for prescribing. The list does not include all medicines that would be, in principle, eligible for reimbursement as decided at national level. Promotion of focusing prescribing on the medicines on the "Wise List" has been supported by active information activities targeted at prescribers (outpatient and, since the extension of the list, also inpatient), and the public. The "Wise List" contains around 200 medicines for treating common diseases in outpatient and hospital care and additional 100 medicines for specialised care. It is updated annually, based on guidance provided by expert panels representing different fields. Following the concept of the "Wise List" in Stockholm, other Swedish regions have introduced similar lists.	Sweden (regional level)	[32,38, 39]
"H pre-scriptions"	Since 2006, hospitals have been paying for selected medicines used in the outpatient sector (including medicines for treatment of tumour necrosis factor, multiple sclerosis, HIV, Hepatitis B and Hepatitis C. This usually applies to medicines whose initial therapy is started in a hospital and then continued in outpatient care. With this policy measure, a shift of the funding responsibility from the social health insurance (in principle, the payer for outpatient medicines) to the hospitals took place for defined medicines. The rationale was and is to incentivise hospital doctors to prescribe more rationally.	Norway	[40,41]
NZa list (abolished)	The so-called NZa list for high-priced medicines used in hospitals, which was issued by the Dutch Health Care Authority (Nederlandse Zorgautoriteit / NZa) was a special national hospital formulary, which aimed to support hospitals funding expensive medicines. The expenses for medicines on that list were largely (80%) funded by the social health insurance (i.e., the payer for outpatient medicines), contrary to other medicines in the hospital sector, which were usually funded from the hospital budget. The remaining 20% of the expenses for medicines on that list were to be funded from the hospital budgets, to enhance hospitals' responsibility for these medicines. This specific funding scheme was abolished in 2014, when a new policy approach to assess and fund hospital medicines (see below "the lock") was introduced.	Netherlands	[42]

Policy	Brief description	Country	Ref.
Point-of-care assessment (discontinued)	To mitigate the risk of shifting pharmaceutical therapies between sectors for financial reasons, a “Medicines Commission” with representatives of both sectors was established, which was tasked to jointly determine the “best point of care” (either outpatient or inpatient) of a medicine based on medical-therapeutic, health care and security of supply criteria. Public procurers and payers could submit an application for an eligible medicine (i.e., one with a high budget impact or a speciality medicine) to the Medicines Commission to request a decision on the best point of care and thus the funding responsibility. The work of “Medicines Commission” was discontinued and replaced by other initiatives which were also aiming at supporting cross-sectorial collaboration (see below).	Austria	[43]
	Procurement policies		
Hospital-outpatient formulary for procurement by health authorities	In addition to reimbursement lists for outpatient and inpatient sectors and hospital pharmaceutical formularies, a specific formulary for procurement purposes is in place: Medicines listed in the “hospital – outpatient” PHT formulary (Prontuario Ospedale – Territorio) can be supplied in so-called “direct distribution”. As such, local public health authorities procure these medicines for the community pharmacies which dispense them to patients discharged from hospitals. Health authorities act as procurers because they are expected to obtain lower prices.	Italy	[34]
Cross-sectorial centralised procurement	Establishment of a centralised public procurement system at national level (mandatory for defined medicines, and voluntary for any other medicines) for institutions of the National Health Service which operate in the outpatient and inpatient sectors (i.e., regional health administrations for primary care and hospitals).	Portugal	[44,45]
Investigation of procurement contracts	In the Netherlands, the Competition Authority investigated procurement contracts with hospitals for possibly illegal clauses. In the case of one active ingredient (etanercept), the manufacturer of the originator biological included a clause in the procurement contracts offered to hospitals, which tied the hospitals to purchasing that product instead of being able to switch to lower-priced biosimilar medicines, since the offered discounts would decrease in line with future purchase volumes. The competition authority considered this clause as a breach to competition rules, and the company agreed in stopping using this scheme. In Romania, the courts enforced competition rules. Court cases concerning the active ingredients rituximab, trastuzumab, and erlotinib revealed manufacturer practices that impeded market entry for competitor products. These practices included charging wholesalers a different price for the same product in order to minimize the chances of a wholesaler getting a contract who could supply the manufacturer’s as well as competitor products, and locking patients into using the originator product through use of patient support schemes and financial subsidies covering the price difference between the originator and biosimilar products.	Netherlands Romania	[46] 47[]
Prohibition of unrelated services in medicine procurement	Legislation prohibits that additional services (e.g., support or training programs for use of the medicines, educational materials, software for monitoring) are provided free-of-charge as part of medicine procurement. Any services (even if paid) that are not related to the supply of a medicine must not be integrated in the procurement contract. Penalties are foreseen in legislation in case of violation of these rules. The medicines agency had an information campaign in 2019 to remind procuring hospitals and suppliers of this legislation.	Belgium	[48]
	Extension of HTA processes		
“The Lock”	Previously, only medicines that were considered for inclusion in the outpatient reimbursement list were subject to Health Technology Assessment (HTA). No systematic evaluation of medicines for hospital use had been conducted. Hospital medicines were automatically funded. With the introduction of the “lock” system in 2014, medicines intended for the hospital sector and with a defined high budget impact were blocked from public funding until a full HTA process has taken place.	Netherlands	[]

Policy	Brief description	Country	Ref.
"New Methods"	In 2013, the "New Methods" ("Nye Metoder") system was introduced for the managed introduction of new health technologies, including medicines. It consists of a horizon scanning exercise followed by an HTA (mini HTA, single technology assessment or full HTA, depending on the outcome of the horizon scanning) to support reimbursement and procurement decisions. In the beginning, this system only applied to the outpatient sector, but it was extended to medicines used in hospitals in 2016.	Norway	[5.50]
HTA for hospital medicines	In the beginning after the introduction of the AMNOG procedure in 2011, only medicines for outpatient use were subject to an HTA; medicines for exclusive hospital use were exempt. Since 2018, HTA has become mandatory for hospital medicines.	Germany	[51]
HTA pilot	Decisions on the inclusion of a medicine for outpatient use into reimbursement are based on an assessment of therapeutic benefits and an economic evaluation by the social health insurance, which is the outpatient payer. No systematic HTA has been installed for medicines used in hospitals. In a pilot project, three medicines (with high price tags), which are mainly used in hospitals, were selected for a national HTA. Technical support in the assessment was provided by the social health insurance. The establishment of this HTA procedure as a routine process is under discussion.	Austria	[34]
	Further related policies		
Cross-sectorial prescribing and medicines management committees	So-called "Area Prescribing and Medicines Management Committees" (in some cases now called "Integrated Medicines Optimisation Committees") have been established and comprise outpatient and hospital care commissioners and providers. Their purpose is to discuss medicines management approaches, including prescribing issues.	England	[34, 52]
Cross-sectorial treatment guidelines	Hospitals are responsible for developing and issuing treatment recommendations for outpatient care.	Latvia	[34]
Representa-tion in PTCs	While no cross-sectorial reimbursement committees have been established, legislation introduced the participation of social health insurance representatives (responsible for reimbursement decisions on medicines in the outpatient sector) in the hospital Pharmaceutical and Therapeutics Committees (PTCs). Though representatives of the outpatient sector have no voting right, their participation allows learning about challenges and approaches across the sectors.	Austria	[34.53]
"Integrated Areas"	In "integrated areas" ("Areas Integradas"), the manager serves as director of the hospital and the community centres in the area.	Spain (Andalusia)	[34]

HTA: Health Technology Assessment, NZa: Nederlandse Zorgautoriteit (Dutch Health Care Authority, note: institution was meanwhile renamed), PHT: Prontuario Ospedale – Territorio (hospital – outpatient formulary), PTC(s): Pharmaceutical and Therapeutics Committee(s), Ref.: reference(s)

1 Figure 1: Conceptual framework of interface policies in the pharmaceutical value chain



2