

JPHS 2017, ••: ••–••
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Society
Received November 30, 2016
Accepted April 11, 2017
DOI 10.1111/jphs.12180
ISSN 1759-8885

Tendering for off-patent outpatient medicines: lessons learned from experiences in Belgium, Denmark and the Netherlands

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Abstract

Objectives To study the impact of tendering for off-patent outpatient medicines in terms of savings for payers and availability of medicines, to explore stakeholder perceptions and to elaborate prerequisites for a successful implementation of the policy.

Methods We selected three case studies (Belgium, Denmark and the Netherlands). Information was collected through literature review and stakeholder interviews.

Key findings The three case study countries used tendering in different designs. While Dutch health insurers have been tendering for off-patent medicines for more than a decade, Belgium applied this policy for only two substances in 2007/2008 and then stopped. Denmark has a kind of tendering practice: pharmaceutical companies have been submitting biweekly price bids for reimbursable outpatient medicines to the Medicines Agency since the mid-1990s. Stakeholder perception varies between the countries: generic industry, pharmacists and partially patients tend to oppose the tendering practice; in Denmark, however, the system is highly appreciated by all stakeholders. All three countries reported savings for public payers. Experiences related to availability limitations were mixed (Belgium – the winner of the second tender had no capacity to procure; Denmark – no indication of availability limitations; and the Netherlands – frequent medicine shortages, both for tendered and nontendered medicines).

Conclusions The findings suggest that tendering for off-patent medicines is able to contribute to cost-containment. However, as the policy possibly risks leading to availability limitations, it has to be strategically designed to avoid or at least deal with shortages through backup mechanisms. Further prerequisites for a successful introduction of tendering include a robust legal and organisational framework, an appropriate stakeholder management and demand-side policies to promote generic uptake.

Keywords generic drugs; health policy; health services research; procurement; tender

Introduction

In European countries, the expenses of a considerable number of medicines are, either fully or partially, covered by public payers such as social health insurances or national health services. Usually, the prices of reimbursable medicines are regulated by the state even for low-priced medicines. Given the past and expected market entry of new high-cost medicines, public payers have been exploring policies to contain cost. Promoting the uptake of off-patent medicines is considered as an appropriate policy option in this field.^[1–7] Several studies have confirmed the ability of generic competition to contribute to savings for public payers.^[1,8–12] These savings allow treating more patients compared to the use of higher priced medicines, and freeing resources to accept high prices for new medicines.

Generic promotion includes payers' approaches to achieve lower prices for off-patent medicines as well as strategies of public authorities to enhance the uptake of off-patent medicines through demand-side policies. The latter comprise, for instance, International Non-Proprietary Name (INN) prescribing (i.e. doctors' prescribing medicines by its active ingredient instead of the trade name^[13]) and generic substitution done by pharmacists (i.e. the practice of substituting a medicine, whether marketed under a trade name or generic name with a less expensive medicine, often containing the same active ingredient^[13]).

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Financial incentives can be targeted at doctors to prescribe lower priced medicines (e.g. prescribing budgets), at pharmacists to dispense generics (e.g. specific pharmacy remuneration in case of generic substitution) and at patients to ask for off-patent medicines (e.g. lower co-payments for generics, a reference price system in which reimbursement for identical or therapeutically similar medicines is capped).^[2,14,15] European countries have been applying a mix of these measures to enhance generic uptake.^[1,14–18] Some of these instruments apply not only to generics but also to biosimilar medicines, parallel imported medicines or simply ‘cheap’ medicines such as in Belgium.^[16]

With regard to pricing, several European countries regulate the prices of generic and further off-patent medicines through the so-called generic price link policy. Under this approach, authorities set the price of a generic at a certain percentage lower than the originator price.^[13] Another generic pricing policy is to tender for off-patent medicines, or to apply tendering elements in the price setting. Tendering is defined as ‘any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous’.^[13] In Europe, tendering for medicines is mainly known from the hospital sector.^[19,20] Tendering for medicines in the outpatient sector is mainly targeted at off-patent medicines to benefit from competition in this field. Typically, a tendering process allows the winning company to supply the whole reimbursement market for a specific period of time if the ‘winner-takes-it-all’ principle is applied. There are alternative tendering procedures that are less competitive and also provide for contracts between the public payer and the second- and third-ranked companies, however at less favourable conditions (e.g. lower reimbursement rates).

Tendering for off-patent medicines in the outpatient sector appears to be a policy that is used, however not very commonly, in European countries: as of 2008, 11 European countries reported to use tendering policies, or tendering elements, for outpatient medicines (the study was not focused on the off-patent sector).^[21] Another survey identified seven European countries that applied, at least at irregular intervals, tendering for off-patent outpatient medicines in 2010.^[22]

Due to its competitive character, tendering for off-patent medicines in the outpatient sector is expected to bring down prices of generic medicines and thus generate savings for public payers. At the same time, concerns have been raised that this policy may contribute to availability problems.^[23] In fact, these developments were observed in a non-European country with a similar reimbursement system: New Zealand introduced tendering for off-patent outpatient medicines in 1996 which led to high savings for the public payer, but medicine shortages were also reported.^[24–26]

While the effects of the New Zealand system were discussed in a few publications^[24,27–29], updated knowledge about the design and the effects of tendering for off-patent medicines in European countries is scant. Dylst *et al.*^[22] provided a descriptive overview of key features of tendering

systems in seven European countries but did not offer an in-depth review of country-specific policies. According to an analysis as of 2010, the Dutch tendering policy contributed to considerable savings but might also have been responsible for medicine availability problems.^[30] An evaluation of long-term implications of the tendering policy in European countries is lacking and has been called for.^[10,22,31]

Against this backdrop of limited evidence about Europe, our study aims to study tendering for off-patent medicines in the outpatient sector with regard to its effects related to savings for public payers and the availability of medicines as well as stakeholder perceptions. In addition, we aimed to explore supporting factors and barriers for the implementation of a tendering policy that is able to achieve expected outcomes.

Methods

Selection of the case studies

We conducted country case studies to address the defined research questions. We aimed to include European countries that were rather similar in size and economic terms and that had some, possibly different experience of tendering for off-patent medicines in the outpatient setting.

According to Dylst *et al.*,^[22] tendering for off-patent outpatient medicines was performed in Belgium, Denmark, Germany, Malta, the Netherlands, Romania and Slovenia. We excluded Germany, Malta and Romania that reported to do this policy at irregular intervals. As key information about the tendering policy was lacking for Slovenia in the above-mentioned study^[22] and we had some doubts about the relevance of the policy in that country, we decided to neither include Slovenia.

As a result, Belgium, Denmark and the Netherlands were chosen as case studies. The Dutch strategy is the best-known tendering system for off-patent outpatient medicines in Europe,^[20] and a tendering study without the consideration of the Dutch policy would likely be considered incomplete. The Danish outpatient reimbursement system is organised as a kind of a tendering scheme, with pharmaceutical companies submitting two-weekly price bids to the Medicines Agency. It is thus of interest due to its frequency and high level of competitiveness. According to the findings of a preliminary literature review, Belgium only launched tenders for two substances and then abolished the policy.^[30] This points to a possible failure of the policy and merits further investigation. The three selected countries are all middle-sized western European countries whose healthcare systems are based on universal coverage. General data of the health and pharmaceutical systems, including generic policies, of the three countries can be found in Appendix S1.

This focus on similar countries in terms of size, and the economic situation also supports our decision for the non-consideration of Germany (despite its application of preferred supplier contracts by health insurers^[32]), Malta, Romania, Slovenia as listed in Dylst *et al.*^[22] and a few further countries whose use of tendering has been reported in literature: Italy procured biosimilar medicines through

tendering, and Cyprus also applied tendering (both countries tendered medicines used in outpatient and hospital care).^[33,34]

Framework for the survey and analysis

We aimed to survey the following dimensions of the tendering policies in the defined case study countries: (1) description of the tendering policy for off-patent medicines as part of the overall outpatient pharmaceutical system, (2) impacts of the policy, (3) stakeholder perceptions and reactions and (4) possible supporting factors and barriers for a successful implementation of the policy. The latter was defined as the introduction of tendering as a policy that contributed to affordable access to medicines.

Survey

As a first step, we did a literature search in PubMed and Google Scholar on relevant terms ('tender\$', 'procure\$', 'generic\$', '\$patent') in combination with the country names (searches in English, Dutch and French). We considered both peer-reviewed and grey literature.

Additionally, information was collected through telephone interviews with representatives of different stakeholder groups, including competent authorities for pricing, public payers, patients/consumers, generic industry and pharmacists. The interviews were based on an interview guide (Appendix S2) that was adjusted to the individual interviews to account for country-specific and stakeholder-specific requirements. We partially prefilled the interview guides, summarising factual information retrieved from the literature review, with the aim to have it validated for accuracy and up-to-dateness in the interviews. The semi-structured interviews also aimed to assess stakeholders' perceptions and to identify further data (e.g. unpublished materials). The interviews were held in February and March 2016 and lasted between 20 and 100 min. We followed the Standards for Reporting Qualitative Research^[35] and the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist.^[36]

Results

Data sources and response rate

Appendix S3 provides an overview of studies, statistics and documents about Belgium^[16,21,22,30,31,37–39], Denmark^[21,22,40–45] and the Netherlands^[22,30,31,40,46–48] that were identified during the literature review or recommended by interviewees.

We held a total of 15 interviews and received one written response to the interview guide. The interviewees were affiliated to competent authorities for pricing, public payers, patients/consumers, generic industry, pharmacists and research (Table 1).

Characteristics of tendering systems

The design of the tendering systems differs, partially considerably, between the three case study countries (Table 2).

Belgium had an experience with tendering in the outpatient sector during 2007 and 2008 that became known as the 'Kiwi light model' in reference to the New Zealand system. From 2005 on, the legal basis for this policy was established. In 2007 and 2008, the National Institute for Health and Disability Insurance RIZIV/INAMI invited for bids of two substances (simvastatin and amlodipine). The winner of the tender was compensated for having the lowest price by becoming eligible for higher reimbursement rates (of 75% and 85% for defined population groups respectively), whereas the other bidders were granted the normal reimbursement rate (50%). For simvastatin, the tender was once awarded, while the amlodipine tender was withdrawn because the winning company had no capacity to procure. Belgium has discontinued tendering since then.

In the Danish tender-like system, pharmaceutical companies are obliged to report to the Danish Medicines Agency their planned pharmacy purchasing prices of all medicines on the market for the next 2 weeks. Since 2009, this has been done through an IT-based system. Based on the incoming data, the Medicines Agency defines the lowest priced medicine within a reference group of substitutable, reimbursable products as the preferred product that will be reimbursed during a 2-week period (i.e. the notified price is set as the reimbursement price).

The Netherlands started operating a tendering system, called 'preference price policy', in 2005. Initially, all health insurers jointly tendered. However, as Dutch health insurers should compete, they were forbidden to collectively run tenders. Since 2008, health insurers have been launching individual tenders. The range of products under the preference price policy varies between health insurers, and so does the frequency of tenders. Instead of using the preference price policy, some health insurers have been experimenting with similar procurement and reimbursement models to generate savings from generics.

Impacts

All three case study countries reported savings for public payers that could be attributed to tendering. In Belgium, however, increased utilisation of further publicly funded, not tendered statins in the year of the first tender neutralised the savings of 14.6 million euro made on the simvastatin tender. While health insurance expenditure for medicines containing simvastatin decreased by 30% in 2009, it increased by 6.5% for all statins, following an increase observed earlier (+10.5% in 2007), mainly due to increased expenditure for atorvastatin and rosuvastatin.^[39] Similarly, although initial savings following the introduction of the tendering policy in the Netherlands were reported to have exceeded expectations, the dispensing fee (i.e. the remuneration for pharmacies) was temporarily increased to compensate pharmacists for their decrease in profits. This impacted the pharmaceutical bill in the early years of tendering.^[30] Nonetheless, longer term statistics published by the Dutch National Health Care Institute showed rising savings for public payers over the years. The savings due to tendering were assessed to amount to 352 million euro in

Table 1 Organisations in Belgium, Denmark and the Netherlands, represented by interview partners

Stakeholder group	Belgium	Denmark	The Netherlands
Public authority/payer	National Institute for Health and Disability Insurance [†]	<ul style="list-style-type: none"> ● Danish Medicines Agency ● The Regions' pharmaceutical procurement service (AMGROS) 	<ul style="list-style-type: none"> ● Health insurance company VGZ ● National Health Care Institute (ZINL)
Generic industry	– [‡]	<ul style="list-style-type: none"> ● The Danish Generic Medicines Industry Association (IGL) ● Danish Association of the Pharmaceutical Industry (LIF)[§] 	Dutch generic and biosimilar medicines association (BOGIN)
Community pharmacy	Belgian Pharmaceutical Association	The Association of Danish Pharmacies	Royal Dutch Pharmaceutical Association [¶]
Patients/consumers	– ^{**}	– ^{††}	Consumer association (Consumentenbond)
Research	Catholic University of Leuven	– ^{‡‡}	Netherlands institute for health services research (NIVEL)

[†]Written response instead of an interview.

[‡]Generic industry nominated a representative for an interview, but eventually, the interview did not place.

[§]LIF represents originator medicine industry.

[¶]Two interviews (one interview with a staff member of the Royal Dutch Pharmaceutical Association and another interview with a community pharmacist).

^{**}Request for an interview submitted to two patient organisations (Luss – Ligue des Usagers des Services de Santé and VPP – Vlaams Patiëntenplatform), but no representative was available for an interview. We asked other Belgian stakeholders whether, or not, they would inform us about patients' attitudes towards the tendering policy for off-patent outpatient medicines.

^{††}Request for an interview submitted to the Danish Cooperation of Patient Organisations but no representative was available for an interview. We included a question in the interviews with other Danish stakeholders whether, or not, they would inform us about patients' attitudes towards the tendering-like system for off-patent outpatient medicines.

^{‡‡}Researchers were not primary target interviewees. But they were consulted in Belgium to compensate for a lower number of interviews and in the Netherlands to provide background information about a report in Dutch language. In Denmark no research institution was contacted.

2009, 654 million euro in 2012 and 679 million euro in 2014.^[49] In Denmark, public pharmaceutical expenditure decreased by more than 20% from 2007 to 2015, whereas medicine consumption increased by more than 25% in the same period of time. In the period of 2008–2012, prices of outpatient medicines were reported to have decreased by approximately 8% while volume increased by 10%.^[50]

Availability limitations were, together with fierce stakeholder opposition and pending court cases, the major reasons why Belgium stopped tendering. In the Netherlands, medicine shortages occurred at large scale during the last decade. According to interviewees of different stakeholder groups and as documented in a database run by the pharmacy association for managing shortages, availability problems in the Netherlands targeted both tendered and nontendered medicines. Interviewees from industry and pharmacy suggested that low prices of medicines incentivised industry and wholesalers to keep small stocks. In Denmark, shortages did not appear to be an issue. The country has a backup strategy: if a pharmaceutical company or a wholesaler reports supply problems for the preferred product, reimbursement prices will be recalculated through the IT system of the Medicines Agency, and the next lowest priced medicine will become the preferred dispensed product.

In none of the surveyed countries, withdrawals of medicines from the market by companies that were attributable to the tendering practice could be confirmed.

Stakeholders

Stakeholders were neither consulted nor otherwise involved in the preparation and implementation of tendering in Belgium. However, the implementation of tendering followed widespread political discussions since 2004. The Dutch system was introduced in the course of stakeholder negotiations about generic medicine prices. We were not able to collect information whether, or not, stakeholders were involved when the tendering elements in the Danish outpatient system were introduced around 20 years ago.

Across all stakeholder groups, the Belgian experience was felt to have failed. Stakeholder perceptions in Denmark were completely different: all stakeholders, including industry and pharmacists, expressed a positive attitude towards the tendering-like system. Dutch stakeholders that had initially been opposing the tendering policy (particularly generic industry and pharmacists) continued disapproving but now aimed for changes within the system. For details see Table 3.

Supporting and hindering factors

Differences between the countries also existed with regard to interviewees' perception of prerequisites, success factors and barriers for a functioning tendering policy for off-patent outpatient medicines (Appendix S4).

Belgian stakeholders attributed the failure of their tendering system to an unclear legal framework and

Table 2 Specifications of tendering policies for outpatient medicines in Belgium, Denmark and the Netherlands

Specifications	Belgium	Denmark	The Netherlands
Name of the tendering policy	Sometimes referred to as 'Kiwi model' or 'Kiwi light model' (in reference to the tendering policy for outpatient medicines in New Zealand that has, however, a winner-takes-it-all principle)	No tendering policy but a pro-generic reimbursement system with tendering elements	'Preference price policy' (or 'preferential price policy')
Legal basis	Two decrees	Introduction of a reference price system (internal reference pricing) and mandatory generic substitution based on a law	The reform of the social health insurance law provided the legal basis for tendering in the outpatient sector
Date of implementation	During 2005 and 2006, the legal basis was introduced. In 2007/2008, two tenders were launched, one of which was withdrawn. Afterwards, the tendering policy for off-patent outpatient medicines was no longer applied	The reference price system was introduced in 1993, and the tendering elements were added in April 2005: since then, the lowest price within a group of substitutable medicines (reference group) has been considered as reimbursement price	The preference price policy was introduced in 2005. In 2008, individual tenders of health insurance companies replaced joint tendering of health insurers that had been done initially. Court sentences had prohibited joint tendering because health insurers should compete
Reported objectives	Savings for public payers resulting from increased competition in the off-patent segment	Savings resulting from lower prices in the off-patent segment that are to be achieved through enhanced competition	Main objectives: Generate savings for public payers with a view to freeing resources for further investment Further objectives: enhanced competition, improved quality in health care
Institution(s) in charge of tendering	While the Ministry of Social Affairs was the competent authority, the actual launch and follow-up of tenders was done by the National Institute for Health and Disability Insurance (RIZIV/INAMI)	Danish Medicines Agency (it does not launch tenders, but it calculates the reimbursement prices based on the price bids submitted by pharmaceutical companies)	Health insurance companies
Duration of the tender contracts	A few months	Two weeks	Initially 6 months. In later stages, the duration of the contracts was extended to usually 1 year. In some cases, contracts were also concluded for 2 years
Medicines covered by the reference price system (internal price referencing)	Reimbursable medicines that have generic alternatives or parallel products on the market, generics and parallel imported products	In principle, all outpatient medicines considered eligible for reimbursement	Reimbursable medicines used in the outpatient sector whose patent expired, their generic and biosimilar alternatives (a few biosimilar medicines were added by some health insurers during 2016)
Scope of active ingredients tendered in the outpatient sector	Two active ingredients: amlodipine and simvastatin (the legal basis would have allowed for further tenders)	Active ingredients of the whole outpatient reimbursement market	More than hundred active ingredients in general. Differences in scope between health insurance companies
Criteria for awarding the tender	Lowest price; in addition, some further conditions such as guarantee of supply and quality	Lowest price within a group of substitutable medicines (reference group)	Lowest price is the main but not sole criterion, the winner has to be able to supply
Application of the winner-takes-it-all strategy	No. The winner was granted the so-called preferential reimbursement rates of 75% and 85%, respectively, whereas the competitors were reimbursed at the normal reimbursement rate of 50%. The higher reimbursement rates are normally used for therapeutically important	In principle yes but modified. The winner (provided that the company is able to supply the market) is awarded almost the whole reimbursement market of the respective active ingredient for a period of 2 weeks, as the price of the cheapest product is calculated as the reimbursement	Yes, under the preference price policy. In addition, some health insurers started implementing further models: Under the IDEA model, the health insurer ACHMEA has offered to the pharmacies a fixed price for all off-patent medicines plus an increased pharmacy

Table 2 (continued)

Specifications	Belgium	Denmark	The Netherlands
	medicines (85% is the increased rate for 'preferentially insured', i.e. retired people, widowers, orphans and those individuals that receive disability benefits as well as people being supported by these)	price. However, pharmacists may dispense prescribed medicines with prices within a defined triviality limit at the expense of the public payers (optional generic substitution instead of the mandatory one)	remuneration. The fixed remuneration price is set by the health insurer, and pharmacies are incentivised to procure at a lower price and retain the difference. Participation to this model is voluntary; however, in case of nonparticipation, the preference price policy is applied
Strategies to prevent shortages	The tendering authority reported to check the tenderers' ability to supply. No sanctions were foreseen, and so in case of the second tender (amlodipine) no sanction or penalties were applied when the winner did not procure	Pharmaceutical companies and wholesalers report about their ability to supply to the Danish Medicines at a biweekly or daily basis respectively	Different strategies applied by health insurers; some of them ask for delivery guarantees. Some health insurers (e.g. VGZ, Achmea) obliged the winner to inform about the availability status of the medicines on a weekly basis, and published the information about delivery problems on their website. Health insurers have been experimenting with other models (e.g. IDEA model, see above) with the aim to reduce dependency on a single supplier
Approaches to deal with supply limitations	At the time of the tenders, no backup strategy was applied. Meanwhile, an online database has been established on the website of the Federal Public Pharmaceuticals and Health Products Agency that informs about supply problems of medicines. The database is publicly accessible	Based on price bids, substitutable medicines are ranked and classified into A, B and C products (A products are the lowest priced ones, B products have prices within a defined tolerance range, and the remainder are C products, often originator products). If the winner cannot supply, the product will be removed from the price list for the tendering period (2 weeks), and the company that offered the second-lowest price will be asked to supply at the price it bid	No backup strategy under the preference price policy. The Pharmacy Association has been running a register about delivery shortages, including information about the expected date of supply

uncertainties in the tendering procedures, in particular a lack of provisions to back up if the winning company cannot supply. In contrast, all Danish stakeholders considered their reimbursement model with tendering elements as a success story. They attributed their positive perception to the stepwise establishment of the system over the years, that allowed adaptations, and a culture of cooperation of the involved market players. Elements such as the short tendering periods of 2 weeks, mandatory generic substitution, mechanisms to successfully address medicine shortages as well as IT support tools that kept the workload at a low level were considered as further supporting factors. Reasons for the negative stakeholder perception of the Dutch preference price system included financial losses for pharmacists due to accompanying changes in the reimbursement system and insufficient information policies: patients did not understand the rationale of the tendering policy and were irritated by changes and the nonavailability of

their prescribed medication (frequently not even related to the tendering practice). Dutch representatives of public authorities and payers recommended a robust legal framework (that helped win many court cases) and longer tender periods as a way to reduce confusion for patients.

Discussion

Our study surveyed and analysed tendering, and tendering-like systems, for off-patent outpatient medicines in selected European case study countries. It responded to the call for studies on long-term effects of tendering for outpatient medicines. Our research adds to existing literature on this issue that was, to a major extent, published between 2008 and 2012.

We selected countries that were similar in size, economic wealth and their organisation of the health and

Table 3 Stakeholders' attitudes towards the tendering policy for outpatient medicines in Belgium, Denmark and the Netherlands

Stakeholders	Belgium [†]	Denmark	The Netherlands
Public authorities/ payers	<p>The social health insurance considers the Belgian tendering policy as a 'light version' as the winner-takes-it-all-principle was not applied. The key objective for its implementation was the expectation to generate savings. However, even if the failure of the tendering policy was 8 years before the time of the survey, there appears to be no interest on behalf of the authorities and payers to reintroduce a tendering policy in the outpatient sector.</p> <p>Moreover, the savings did not meet the expectations of policymakers. This was partially attributable to the fact that on-patent medicines were not included in the tendering process as initially recommended (on-patent medicines accounted for 90% of pharmaceutical expenditure in 2008). Furthermore, the design of the tendering policy was not considered inappropriate to encourage competition as the winner-takes-it-all-principle was not put in place^[37]</p>	<p>The Danish Medicines Agency highly appreciates the current system that is considered as very efficient and dynamic. The two-weekly changes of prices and reimbursement lists are not seen as an administrative burden as these tasks are supported by sophisticated IT tools, and the price recalculations (also in case of supply problems) are done automatically.</p> <p>There is no interest to change the policy, only to improve</p>	<p>The Ministry of Health, Welfare and Sport established the legal framework, but it was not involved in the implementation of the 'preference price policy'.</p> <p>Health insurers who do tendering acknowledged the sound legal framework. While tendering practices were frequently contested in court, the health insurers won most of the cases. This was attributed to the robustness of the legal framework.</p> <p>Health insurers highly appreciated large savings that they were able to generate thanks to the 'preference price policy'. Given forthcoming patent expiries further savings were expected. Thus, tendering, or a tendering-like system, was seen as a model for the future. Medicine shortages were acknowledged as a major problem but they targeted both tendered and nontendered medicines. Still, some health insurers have been experimenting with new models, mainly because they aim to address availability issues. It was believed that problems (i.e. patient irritation and opposition) at the beginning of the tendering policy were solved</p>
Patients/ consumers	<p>The tendering policy contributed to rising awareness about generics. As the tendering experience in 2007/2008, several off-patent medicines have come on the market, and patients got used to them[‡]</p>	<p>Patients have had more than two decades of experience with generic substitution, and they were reported to be used to it.</p> <p>While the frequent changes of the preferred (reimbursed) medicines could be expected to negatively impact medicines adherence, these issues have neither been confirmed nor falsified[§]</p>	<p>Although the introduction of the 'preference price policy' was done at a time when patients already had long-term experience with generic substitution, it led to some irritation with patients. This was mainly the case with perceived frequent nonavailability of prescribed (tendered) medicines.</p> <p>According to patients, information activities of health insurers and pharmacists were initially poor but improved over the years. This contributed to a better understanding and acceptance of the tendering policy. Patients welcome that tender contracts were extended to longer durations. Patient acceptance of the tender policy also appears to be linked to the expectation that savings for the health insurers will be passed on to the insured (lower insurance premiums). A study^[47] with patients of lung medication found no or only minor differences between patients that experienced generic substitution and those who had not (based on self-assessment). According to a recent study^[48] on cardiovascular medicines patients whose medicines were substituted at the initiative of the</p>

Table 3 (continued)

Stakeholders	Belgium [†]	Denmark	The Netherlands
Pharmacists	<p>Pharmacists did not feel to have been impacted by the tendering policy. Despite the failure of the previous tendering policy for outpatient medicines, pharmacists appear to be open to a possible relaunch of such policy to address high public pharmaceutical expenditure</p>	<p>According to pharmacists, the system is well established, and it functions well. While the two-weekly changes require logistical challenges as most stock items have to be replaced, this is not considered as a burden: pharmacies can return the stock to pharmaceutical companies and wholesalers that provide a credit note. As they do not keep large stocks, pharmacists do not run any financial risk.</p> <p>Regarding patient interaction in pharmacy, there appears to be no need for additional time-intensive explanations as patients have been used to the established system. Should pharmacists identify problems with medication adherence of patients, they said they would actively seek the dialogue with patients</p>	<p>pharmacy reported more frequently practical problems, adverse reactions and poor treatment adherence than patients without substitution. No difference between the two groups was found in relation to the perceived health status[¶]</p> <p>According to their own views as well as in the perception of other stakeholders, pharmacists appear to be the major losers of the preference price policy (in addition to generic industry) as they encountered financial disadvantages: before the introduction of the preference price policy, they directly negotiated with industry and received discounts. Due to the direct negotiations between health insurers and industry pharmacists were no longer involved and lost these bonuses. Furthermore, the tendering policy is seen as associated with higher workload, including searching alternative medicines in case of shortages and increased information activities towards patients. The longer duration of tender contracts is welcome by pharmacists.</p> <p>The preference price policy was introduced when a stakeholder dialogue about generic medicine prices had come to a halt. Retrospectively, the measures discussed in that process would have hit pharmacists less hard than tendering.</p> <p>Single pharmacists (not the pharmacy association) filed court cases against the tendering policy but usually lost them. At the time of survey, pharmacists still opposed tendering but rather saw it as an unchangeable fact. A new policy dialogue with pharmacists that started some months before the interviews were held was appreciated</p>
Generic industry	<p>Generic industry fiercely contested the tendering policy. Several court cases were filed, aimed at challenging the legal framework that was considered to be very unclear. No trials took place as the policy was abolished before court cases started.**</p> <p>Already before the implementation generic industry strongly opposed the system. As a result, no winner-takes-it-all-principle as originally discussed (i.e. the winner should be awarded 100% and the competitors would be excluded from reimbursement) was introduced^[37]</p>	<p>Generic industry appreciated the current reimbursement system that they considered as highly efficient. The two-weekly price bids were seen as an incentive to be able to submit another, possibly winning bid the next time in case they were not successful previously.</p> <p>An interviewee representing the research-based industry judged the Danish model as the 'best system of the world'</p>	<p>Generic industry (still) opposed the preference price policy. However, as it had become quite clear that this policy was here to stay, they sought new approaches: generic industry now aimed to persuade health insurers to apply alternative models of generic pricing and/or to use less strict designs of the policy (i.e. moving away from the winner-takes-all principle but reimbursing all suppliers that have prices within a price corridor – the latter approach was already applied by one health insurer). In earlier times, generic manufacturers filed several court cases but usually lost.</p>

Table 3 (continued)

Stakeholders	Belgium [†]	Denmark	The Netherlands
			<p>The longer duration of the contracts was not appreciated by the generic industry as it might incentivise withdrawals from the market.</p> <p>Generic industry could not provide any data about business developments (e.g. number of companies, sales), as these data were classified as confidential. Such data would have allowed evaluating information about the alleged negative financial implications for industry. One generic company was known to have withdrawn from the Dutch market</p>

[†]In addition to stakeholder interviews, information was drawn from a master thesis in sociology.^[37]

[‡]Information gained from an interview with the pharmacy association.

[§]Information gained from an interview with a representative of the pharmacists' association. Reference was also made to research^[41–44] about generic substitution in Denmark that aimed to assess patients' views on and experience with generic substitution. It showed that patients with experience in generic substitution were more likely to have less concerns about generic substitution.

[¶]Patients without generic substitution showed slightly better results related practical problems (e.g. of the inhaler), side effects and self-assessed health status. However, according to an author of the study^[47], the tendering system appears to play a minor role for lung medicines. A similar study^[48] about cardiovascular medicines that was published a year later was said to be more relevant.

**Information gained from an interview with a researcher.

pharmaceutical systems (Appendix S1). Nonetheless, tendering was implemented in different designs in the three countries.

Our findings confirmed earlier research that had shown the ability of the tendering policy to contribute to savings. We found indications that this was also the case in the long run. Interviewees attributed growing savings due to tendering to an increased number of patent expiries during recent years. At the same time, it was shown that further policies are also able to contain costs and may even be more effective. For instance, while the Dutch preference price policy was a growing and the second largest factor for savings in public spending, the price regulation through external price referencing (i.e. setting medicine prices based on prices in other countries^[13]) was identified to have the highest impact on savings in the last decade.^[49]

Previous analyses of the tendering policy raised concerns about availability issues.^[22,30,31] We did not find any strong evidence to confirm or refute the assumption of tendering being a cause for availability limitations. Several European countries, including those without a tendering policy, have been confronted with considerable shortages in recent years.^[51,52] Shortages in the Netherlands concerned both medicines procured under tendering and medicines that were not tendered.

Based on the experiences in the three case study countries, we would consider the following elements relevant for a successful implementation of tendering or a tendering-like system for off-patent medicines in the outpatient sector. These elements can be divided into internal and external factors.

Internal factors comprise the legal and organisational framework and the design of the policy. The relevance of a clear and sound legal framework that cannot be contested in

court proceedings appears to be a key prerequisite, particularly in settings where opposing stakeholders would go to court. While our research pointed to the robustness and clarity of the legal and organisational framework as a major enabling factor, there is no 'one-size-fits-all' solution of how the tendering policy should be designed.^[53] Different approaches were taken in the three case study countries and even within a country (differences between Dutch health insurers). This concerned, for instance, the frequency of tenders. All Danish interviewees appeared content with the two-weekly changes of prices: from the payer's perspective, this enhances competition and is considered as a driver for lower prices and savings, and manufacturers appreciated to have more frequently the opportunity to participate and to possibly win. It was argued that shorter contract periods would reduce the risk that suppliers would withdraw from the market. But shorter term contracts require more logistical and administrative efforts of the stakeholders involved. Furthermore, frequent changes may contribute to increased patient irritation, as observed in the Netherlands,^[54] possibly resulting in lower medication adherence,^[43,55] even if a link between changes due to generic substitution and compliance has not largely been confirmed.^[56,57] A major decision concerns the question to apply, or not, the 'winner-takes-it-all' principle. Although the rationale of tenders is to be competitive and to generate savings,^[58,59] there is concern that the 'winner-takes-it-all' principle might bring prices down at a low level which could drive companies out of the market, create monopolies and disturb a 'healthy market'. Therefore, a 'divide-the-pie' strategy has been advised.^[22,53] In fact, none of the case study countries applied a pure 'winner-takes-it-all' principle: in the Netherlands, not all health insurers have always been applying the preference price

policy but have also been experimenting with ‘divide-the-pie’ models (see Table 2). Denmark has been allowing a small price corridor and is able to respond quickly to non-delivery of the winning bidder by securing delivery from other second- or third-ranked suppliers. It was reported that this caused no extra workload thanks to IT support.

External factors concern the pharmaceutical policy framework, including policies that possibly support or hinder the tendering practice, and targeted stakeholders, including patients, pharmacists and generic industry that can support or oppose the policy. Strong opposition of some stakeholder groups towards tendering was observed in Belgium and the Netherlands, and these stakeholders felt that they had not sufficiently been involved. The acceptance was considerably higher in Denmark, and this was also attributed to dialogue and cooperation with stakeholders. Elements of an effective stakeholder management can include consultancy, debate and information activities that should start before the launch of a policy. Several interviewees stressed the need for educational activities to explain the tendering system, including its rationale and its practical consequences, to patients. However, stakeholder management may still fail in those cases when stakeholders are strongly targeted by the policy, also in financial terms. A major reason of Dutch pharmacists’ opposition was that the preference price policy introduced a new supply chain management model that excluded pharmacists from financial bonuses. If tendering were introduced in a policy framework that had already enhanced generic uptake, we could expect reduced communication work of pharmacists because patients had high ‘generic literacy’. Overall, our analysis suggests that demand-side measures promoting generic uptake are supportive to tendering. A prerequisite for encouraging health professionals and patients to enhance generic uptake is to build trust into generics; this needs to be established based on the evidence that there are no quality issues.^[60] While generics appear to be generally accepted by patients in the three case study countries, there are indications of room for improvement on this matter in other European countries.^[1,14,40,61–63] This might be a barrier for the successful implementation of tendering in those countries.

The study has some limitations. We are aware that interview partners represented different stakeholders and had different interests. We did not perform primary research to assess effects such as possible savings. Using secondary data, we had no influence on the methodology of analyses carried out by other researchers, and in some publications, the methodology was not explained in detail. It is always difficult to disentangle the impact of a policy as it is always part of a mix of measures. Furthermore, it was a challenge to identify interviewees that had sufficient knowledge of the tendering experience in Belgium around 8 years ago. In two of the three countries, we were not able to arrange an interview with patients’/consumers’ representatives.

Conclusion

Tendering for off-patent medicines is one policy option that some European countries have been applying in the outpatient pharmaceutical sector. Our findings of three European

case study countries with different experiences of this policy suggest that tendering for outpatient off-patent medicines can contribute to affordable access to medicines through reduced generic prices and increased uptake of generics. Tendering does not necessarily result in negative effects such as quality problems or shortages if it were designed appropriately. For a successful implementation, policymakers should consider the establishment of a robust legal and organisational framework, a strategic design of the tendering policy, the development of strategies to avoid or at least address shortages, an appropriate stakeholder management and demand-side policies to promote generic uptake. After introduction, it is suggested monitoring the performance of the tendering policy and adapting its design if needed.

Declarations

Conflict of interest

The authors declare that they have no conflicts of interest to disclose.

Funding

This work was supported by the Main Association of Austrian Social Insurance Institutions. No funding was provided for the writing of the manuscript.

Acknowledgements

We would like to express our sincere gratitude to the interviewees in the three case study countries (list of institutions provided in the article) for being available for an interview.

Authors’ contributions

SV and MG developed the methodology of the survey in the case study countries, and SV, NZ and MG jointly developed the methodology of the analysis. MG did the research on Belgium, NZ on Denmark and SV on the Netherlands. SV wrote the first draft of this article and did revisions after reviews of NZ and MG.

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Appendix S2. Sample interview guide.

Appendix S3. Literature findings on case study countries.

Appendix S4. Prerequisites, supporting and hindering factors of tendering policy for off-patent outpatient medicines in Belgium, Denmark and the Netherlands – analysis done based on information from literature review and stakeholder interviews.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Key data of the health and pharmaceutical system, including generic policies, in Belgium, Denmark and the Netherlands.