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Developing Competitive and Sustainable Polish Generic Medicines Market

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Aim To descriptively analyze the policy environment surrounding the Polish generic medicines retail market.

Method The policy analysis was based on an international literature review. Also, a simulation exercise was carried out to compute potential savings from substituting generic for originator medicines in Poland using IMS Health pharmaceutical intelligence data.

Results Poland has a mature, high-volume, low-value generic medicines market, primarily driven by the establishment of the reference price at the price of the cheapest medicine in combination with pricing regulation and the low level of medicine prices. The practice of discounting in the distribution chain implies that the National Health Fund and patients do not capture the potential savings from a generic medicines market where companies compete on price. This high-volume market has benefited in the past from the limited availability of originator medicines and a short data exclusivity period, even though there are no incentives for physicians to prescribe generic medicines and a financial disincentive for pharmacists to dispense generic medicines. Increased generic substitution would be expected to reduce public expenditure on originator medicines by 21%.

Conclusion To develop a competitive and sustainable market, Poland needs to consider moving away from competition by discount to competition by price. This could be achieved by replacing maximum distribution margins by fixed margins. Also, Poland may wish to raise reference prices as a temporary measure to boost market entry for medicine classes with few generic medicines.

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Pressure to control pharmaceutical expenditure is fuelling the development of the Polish generic medicines market. Total pharmaceutical expenditure per capita amounted to US $253 (using purchasing power parity conversion rate) in 2007, and grew at an average annual rate of 4% between 2002 and 2007 (1). Furthermore, pharmaceutical expenditure made up 24.5% of total health expenditure in 2007, one of the highest proportions among countries of the Organisation for Economic Co-operation and Development (OECD). As in many other Central and Eastern European countries, Polish cost containment measures tend to focus on pharmaceutical expenditure because medicines are relatively easy to identify and introduce as compared with other health technologies (2).

A generic medicine is a product that is launched with no intellectual property or other protection after the protection expires on the originator medicine (3). It has the same qualitative and quantitative composition in active substances, same pharmaceutical form, and same bio-availability as the originator medicine (3). If two medicines have the same bio-availability, a similar therapeutic effect can be assumed (4). Generic medicines tend to be 20%-90% cheaper than originator medicines because generic medicines companies incur lower costs of research and development than originator medicines companies and because many countries regulate prices of generic medicines that wish to benefit from reimbursement. Competition from generic medicines may also bring down prices of off-patent originator medicines, thus generating additional savings to patients. Savings on the pharmaceutical budget, in turn, enable governments to reimburse newer, more expensive medicines (5).

The aim of this paper was to carry out a descriptive analysis of the policy environment surrounding the Polish generic medicines retail market. The analysis focuses on supply-side measures, such as market access, pricing, reference-pricing, and reimbursement of generic medicines, as well as demand-side measures, such as incentives for physicians to prescribe, for pharmacists to dispense, and for patients to use generic medicines. Finally, a number of avenues are proposed that policy makers can follow to create a competitive and sustainable Polish generic medicines market.

METHODS

A review of the international literature was carried out by searching the following electronic databases up to July 2009: PubMed, EMBASE, Bath Information and Data Services, Cochrane Library, EconLit, and Social Science and Citation Index. Search terms included "pharmaceutical policy," "generic medicines," "off-patent market," "pricing," "reimbursement," "reference pricing," "incentives," "prescribing," "physician budgets," "international non-proprietary name (INN)," "dispensing," "generic substitution," "patient co-payment," and "Poland," alone and in combination with each other. Additionally, the references of included studies were checked for other relevant studies. The review focused on studies published in English. The policy description and analysis was validated by experts working for the Polish Association of Employers of Pharmaceutical Industry, individual generic medicines companies in Poland, and Polfarmed, Polish organization of enterprises involved in the production of medicines and medical devices.

This study presents data on the market shares of generic medicines in European countries. With respect to both patented and off-patent medicines, the market shares of generic medicines in a country were expressed by volume (as measured by the number of packages) and/or by value (ie, the expenditure on generic medicines divided by total pharmaceutical expenditure). European data were compiled by the European Generic Medicines Association on the basis of country submissions (6), while country-specific data were derived from a Polish source (personal communication by Andrzej Cylwik, CASE – Advisors Ltd, unpublished data).

A simulation exercise was conducted to compute potential savings in public expenditure from substituting generic for originator medicines in Poland using IMS Health pharmaceutical market intelligence data (7). This illustrative exercise was limited to the best-selling active substances that had the highest public expenditure of originator medicines in 2004. For each active substance, average price levels weighted by volume of sales of the various medicines belonging to the group of originator medicines and to the group of generic medicines were calculated. Annual savings were obtained by multiplying the price difference between generic and originator medicines by the volume of originator medicines to be substituted. In the Netherlands, actual generic substitution rates have attained 80%-90% in specific medicine classes (8), and some analysts have set generic substitution target rates at 95% (9). Our analysis considered that, following generic substitution, 5% of market volume for each active substance would be made up of originator medicines and 95% of generic medicines. Hence, this exercise calculated the potential savings from "increased" rather than "full" generic substi-

tution. The analysis was carried out in Microsoft Excel 2003 (Microsoft Corporation, Redmond, WA, USA).

RESULTS

The literature search generated 38 articles, 13 of which provided specific information about the Polish generic medicines market.

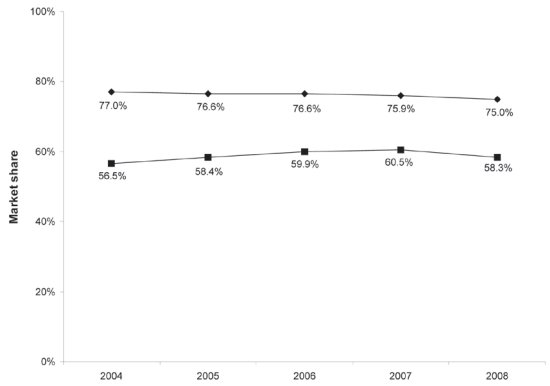
Polish generic medicines market

Poland has a mature generic medicines market with market shares that are among the highest among European countries. For instance, the market share of generic medicines by volume of 76.6% in Poland in 2006 exceeded the market share of 68.8% in Denmark, 57.5% in the United Kingdom, and 56.4% in Germany (Figure 1).

The evolution of generic medicines market shares in Poland over time (Figure 2) shows that the market share by volume slightly decreased over the 2004-2008 period, whereas the market share by value increased. There is continued interest in the generic medicines market shares in Poland in light of its aging population, the current financial and economic crisis, and the resulting need for cost-containment policies.

Figure 2 also indicates that the Polish generic medicines market is a high-volume, low-value market. This is exemplified by the gap in market share of generic medicines by volume and by value. The market share by value was 15%-20% lower than the market share by volume, indicating that generic medicines are considerably cheaper than originator medicines.

Figure 1.



Market share of generic medicines by volume in Europe, 2006. Focusing on the total pharmaceutical market, the market share of generic medicines by volume was expressed in terms of the number of packages. Data were compiled by the European Generic Medicines Association on the basis of country submissions (6).

Market access

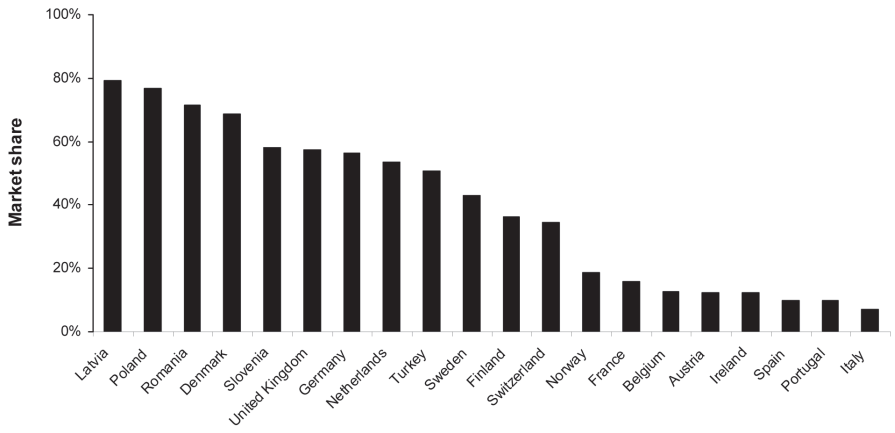
Intellectual property rights. As in many Central and Eastern European countries, prescription of generic medicines is common practice in Poland due to the limited availability of originator medicines in ambulatory care prior to the end of communism in 1989 and due to the absence of product patents until the early 1990s. The introduction of patents gave a 20-year protection to originator medicines. Furthermore, Supplementary Protection Certificates can extend this period for a maximum of 5 additional years for products that have a valid patent and that first gained market authorization after January 1, 2000 (10). These Certificates can be expected to restrain the development of the Polish generic medicines market in future years.

In the 1990s and early 2000s, the Polish generic medicines market benefited from regulation imposing a three-year data exclusivity period until accession of Poland to the European Union (EU) in May 2004. During the data exclusivity period, the application for marketing authorization for a generic medicine cannot refer to the pre-clinical and clinical documentation of the originator medicine. As the Polish data exclusivity period was shorter than the 6-10 years of data exclusivity granted in the EU at that time, this served to speed up entry of generic medicines into the Polish market.

Data exclusivity provisions have changed over time. During negotiations for EU accession, Poland agreed to implement a six-year data exclusivity period and ten years for high-technology products authorized by the European Medicines Agency. Current European legislation has created a harmonized EU data exclusivity period of 8 years plus 2 years of market exclusivity plus 1 additional year if the product obtains a new therapeutic indication (the so-called 8 + 2 + 1 rule) (3). Poland has asked for a 15-year transitional period to implement this legislation.

Registration. Conforming to European legislation, Poland has in place a simplified registration procedure that facilitates market entry for generic medicines (3). If the application relates to an active principle that has been registered for at least 8 years in one of the EU countries and if the generic medicine is essentially similar to the reference med-

Figure 2.



Market share of generic medicines in Poland, 2004-2008. Focusing on the total pharmaceutical market, market shares of generic medicines were expressed by volume (as measured by the number of packages) and by value (ie, the expenditure on generic medicines divided by total pharmaceutical expenditure) personal communication by Andrzej Cylwik (unpublished data). Rhombs indicate market shares by volume, while squares indicate market share by value.

icine, the generic medicines company does not need to provide pre-clinical and clinical documentation, but can refer to the documentation of the reference medicine. This implies that pharmaceutical companies can submit an abridged application for a generic medicine after the first 10 years of the patent on the original medicine have passed.

Pricing and reimbursement approval. Generic medicines enter the market after the determination of pricing and reimbursement status by Polish authorities. The Transparency Directive 89/105/EEC specifies a 90-day limit for adopting a pricing decision and a 90-day limit for reimbursement for all EU Member States (11). However, a market review undertaken by the European Generic Medicines Association in 2006 found that it takes an average of 180 days for a generic medicine in Poland to obtain pricing and reimbursement approval following marketing authorization (6).

Pricing

Poland operates a price-regulated system for generic medicines that wish to be entered on the reimbursement list. Regulations stipulate that the first generic medicine needs to be at least 25% cheaper than the originator medicine, the second generic medicine needs to reduce its price by a further 25%, and subsequent generic medicines must not have a higher price than the cheapest generic medicine in the therapeutic group. These rules were announced in a "Communication" by the Ministry of Health, but such a document does not have legal value (12). A company may set the price of a generic medicine freely if it decides not to be on the reimbursement list.

The Ministry of Health has imposed several price cuts, with the last price decrease of 13% being implemented in July 2006. In general, Polish medicine prices tend to be lower than those in other EU countries (13), thus lowering the potential profit margin for a generic medicine company and discouraging market entry. In the recent years, there has been a significant increase in the market share of imported originator medicines, thus resulting in an increase in health care costs (14).

The price for reimbursable prescription-only generic medicines is regulated at the level of the pharmacy purchasing price. The statutory wholesale margin system consists of a linear mark-up (9.91% of the wholesale price until 2003 and currently 8.91%) and the statutory pharmacy margin system is made up of a regressive mark-up. It should be noted that these margin systems for reimbursable prescription-only medicines constitute maximum mark-ups and that maximum mark-ups can be lowered by wholesalers and pharmacists. This implies that the

same product may have different retail prices between pharmacies. Different medicine prices have been observed for example between rural and city community pharmacies (personal communication by Cezary Sledziewski, Polish Association of Employers of Pharmaceutical Industry, unpublished data).

The implementation of maximum distribution margins allows wholesalers and pharmacists to offer discounts. For instance, a pharmacist may decide to lower his/her margin to enable a patient to buy the originator medicine rather than the equivalent generic medicine. In turn, pharmacists are usually rewarded for such behavior by manufacturers and by wholesalers in different ways (eg, by granting discounts on other medicines) (12). This practice of discounting is not clear to market actors and is not fair, as wholesalers and pharmacists are not rewarded for services rendered, but for their ability to negotiate discounts on artificial prices. Such a system may financially benefit wholesalers and pharmacists, but is not sustainable in the long run as the National Health Fund and patients do not capture the potential savings from a generic medicines market where companies compete on price.

Poland has a branded generic medicines market, meaning that generic medicines tend to be named by brand rather than by INN. Branded generic medicines are likely to attract higher profit margins as compared with INN generic medicines, which are less able to build on patient awareness and compete solely by way of differential pricing. Brand names of well-known locally-produced generic medicines benefit from higher patient loyalty and higher margins (15).

Reference-pricing

Since 1998, Poland has a reference-pricing system which establishes a reimbursement level or reference price for a group of interchangeable medicines. The Polish reference-pricing system groups medicines based on a mix of level 5 of the Anatomic Therapeutic Chemical classification (16) (ie, medicines having the same active substance), level 4 (ie, medicines belonging to the same pharmacological class), and level 3 (ie, medicines belonging to the same therapeutic class). The reference price is set at the level of the cheapest medicine marketed in a specific reference group. The reference price is based on the price per dose unit and updated when the price of the cheapest medicine changes. If a medicine is priced above the reference price, the patient pays the difference between the price of the medicine and the reference price.

Setting the reference price at the level of the cheapest medicine in combination with the low level of medicine prices in Poland would be expected to keep down profitability of generic medicines. Also, the company that has the cheapest medicine may not be able to cover the whole Polish retail market. In this case, patients are forced to buy more expensive medicines and need to pay the difference between the price of the medicine and the reference price.

Reimbursement

Poland applies different reimbursement rates for different types of medicines: 1) 100% reimbursement (eg, medicines for oncology, epilepsy, and chronic diseases); 2) 100% reimbursement, but for a lump sum prescription fee of 3.2 Zloty (or approximately € 0.73) (eg, antibiotics); 70% reimbursement (eg, Parkinson disease and Alzheimer disease); and 50% reimbursement (eg, antihypertensive medicines). Prescribing of generic medicines is common in Poland because physicians are conscious of the limited ability of patients to meet medicine co-payments (5).

Incentives for physicians

Overall, physicians face no incentives to prescribe generic medicines. Physicians can prescribe using the name of the originator medicine, the name of a branded generic medicine, or the INN of a generic medicine. They are not assisted in generic prescribing. Nevertheless, physicians tend to prescribe generic medicines because they have long-term, positive experience with generic medicines.

Incentives for pharmacists

Generic substitution of generic for originator medicines by community pharmacists is allowed, but not obligatory. In the case of the prescription of a branded generic medicine, the pharmacist can dispense any generic medicine. If the physician prescribes by INN, the pharmacist may deliver any originator or generic medicine. Pharmacists are required to inform patients of the availability of cheaper generic medicines and of generic substitution. Generic substitution by pharmacists is conditional on the physician not forbidding substitution (ie, "NZ" or "Nie zamieniac," meaning "Do not substitute") (12).

Until the mid-1990s, pharmacists earned a margin of 33% on local medicines and 25% on imported medicines irrespective of whether this concerned originator or generic

medicines. Since 1995, Poland has adopted a sliding scale where the percentage remuneration decreases as the price of the medicine rises. However, the regressive effect of this scale is not sufficient to remove the financial incentive to dispense originator medicines. The financial incentive to dispense originator medicines may be lessened if pharmaceutical companies of generic medicines offer discounts.

Incentives for patients

Poland has not fully recognized the role that patients play in generic medicines consumption. Generally, few policy measures are in place that either incite patients to demand generic medicines or penalize patients for not demanding generic medicines. The extent to which patients contribute to the cost of medicines is likely to play a role in the use of generic medicines. A reference-pricing system may promote generic medicines use by imposing a co-payment on originator medicines priced above the level of the reference price. The Polish experience indicates that the impact of patient co-payments depends on the extent to which physicians are conscious of the level of patient co-payments and take it into account in their prescribing decisions (5).

Potential savings from generic substitution

Table 1 presents public expenditure on the best-selling originator medicines in Poland in 2004 and savings from increased generic substitution pertaining to the National Health Fund. Increased substitution of generic for originator medicines could yield considerable savings, amounting to an estimated total of around € 11 million (or 21% of public expenditure on originator medicines). The size of potential savings varies widely between active substances, ranging from 1% for azithromycin to 61% for budesonide. This indicates that prices of originator and generic medicines are similar for substances such as azithromycin, gliclazide, and simvastatin; whereas generic medicines are considerably cheaper than originator medicines for substances such as budesonide, donepezil, and atorvastatin.

TABLE 1. Potential savings (in Euro) from increased generic substitution in Poland, 2004

Active substance	Public expenditure on originator medicines	Savings from generic substitution*
Simvastatin	10 088 853	623 500 (6%)
Gliclazide	8 145 560	304 841 (4%)
Azithromycin	7 756 479	84 458 (1%)
Amoxicillin	6 232 929	811 800 (13%)
Donepezil	6 028 764	3 012 783 (50%)
Budesonide	6 317 025	3 855 495 (61%)
Atorvastatin	4 990 985	2 000 705 (40%)
Cetirizine	4 646 962	484 645 (10%)
Total	54 207 557	11 178 228 (21%)

*Savings from generic substitution are expressed in absolute terms and as a percentage of public expenditure on originator medicines.

DISCUSSION

This study carried out a descriptive analysis of policy toward generic medicines and proposes the avenues to support the further development of a competitive and sustainable Polish generic medicines market (Table 2). The Polish generic medicines market is mainly driven by supply-side measures relating to intellectual property rights, pricing, reference-pricing, and reimbursement of generic medicines. Few demand-side measures are in place to incite physicians to prescribe, pharmacists to dispense, and patients to use generic medicines.

With respect to market access, entry of generic medicines should be allowed once all intellectual property and data exclusivity periods of originator medicines are exhausted. Also, as compared with other European countries, the 180 days needed to gain pricing and reimbursement approval in Poland delays market entry of generic medicines and appears to be unnecessarily long in the case of a generic medicine that has the same quality, safety, and therapeutic efficacy as the originator medicine (17). For instance, the time delay for a generic medicine to obtain reimbursement approval in 2006 was 14 days in Denmark; 30 days in Bulgaria, Norway, Spain, and Sweden; 45 days in Finland, Ireland, and the Netherlands; and 60 days in Hungary and Turkey (6).

There is a need to develop a competitive generic medicines market with transparent information about generic medicine prices. This is not currently the case in Poland, where discounts are offered in the distribution chain. Therefore, Poland needs to consider moving away from competition by discount to competition by price. Such a system would be transparent and easy for all market actors to understand, and would ensure that prices paid by the National Health Fund and patients reflect value for money (18). This could be achieved by replacing "maximum margins" by "fixed margins," thus making it impossible to offer discounts in the distribution chain. Such a policy has already been implemented in France, which regulated the size of discounts awarded in the distribution chain to a current maximum level of 17% (5).

TABLE 2. The Polish generic medicines market: current policy and recommendations

Item	Current policy	Policy recommendations
Market access	– Limited availability of originator medicines prior to end of communism in 1989 – Absence of product patents until the early 1990s – Short data exclusivity period of originator medicines – Simplified registration procedure for generic medicines – Introduction of Supplementary Protection Certificates prolonging patent period	– Allow market access once all intellectual property and data exclusivity periods are exhausted
Pricing and reimbursement	– Low level of medicine prices – Pricing and reimbursement approval process of 180 days following marketing authorization – System regulating prices of generic medicines – Imposition of several price cuts – Introduction of maximum distribution margins, enabling the practice of discounting – Implementation of reference-pricing system	– Move from competition by discount to competition by price by imposing fixed margins – Raise reference prices as a temporary measure to boost market entry for medicine classes with few generic medicines
Incentives for physicians	– Physician awareness of patient co-payments – Prescribing by name of originator medicine, name of branded generic medicine, or international non-proprietary name of generic medicine – Long-term, positive experience with generic medicines – Possibility to forbid generic substitution by pharmacists	– Assist generic prescribing by means of electronic prescribing systems, medicine databases, audit and feedback on prescribing data, prescribing guidelines and formularies, or substitution lists –Demonstrate size of possible savings arising from generic medicines use
Incentives for pharmacists	– Generic substitution by pharmacists is allowed – Financial disincentive to engage in generic substitution – Requirement to inform patients of availability of generic medicines	– Increase regressive effect of pharmacist remuneration scale (ie, increase percentage remuneration for lower priced medicines and reduce percentage remuneration for higher-priced medicines)
Incentives for patients	– Financial incentive to demand generic medicines in the context of a reference-pricing system	– Raise patient awareness of generic medicines by launching information campaigns – Stimulate demand for generic medicines by reducing co-payment on generic medicines

With respect to the reference-pricing system, setting the reference price at the level of the cheapest medicine has generally led to low medicine prices, but may inhibit market entry of generic medicines companies and may force patients to buy more expensive medicines. Therefore, for reference groups with few generic medicines, setting the reference price at a higher level (for example, the average price of the lowest-priced medicines that have a combined market share of at least 30%) can be introduced as a temporary measure to boost market entry of generic medicines until the reference group market reaches a more mature level of development. This minimum level could, for instance, be set at a generic medicines market share by volume of 40% for the reference group. Once this level of development has been attained, the reference price can be reduced to the price of the cheapest medicine within the reference group (5).

The Polish reference-pricing system groups medicines on the basis of active substance, pharmacological class, and therapeutic class. As equivalence criteria for selecting a group of interchangeable medicines are broadened from active substance to pharmacological class and, ultimately, to therapeutic class, heterogeneity of medicines within the same group increases (19). On the one hand, a reference-pricing system by therapeutic class may lead to the prescription of a less effective medicine within the group if it allows the patient to avoid a co-payment. On the other hand, a reference-pricing system by active substance or pharmacological class may suffer from re-allocation of demand away from a reference group to patented medicines with a similar therapeutic indication that do not fall under the reference-pricing system (so-called "re-allocation of demand"). The European experience shows that re-allocation of demand has happened to some extent in, for instance, France and Italy (5).

In Poland, demand-side measures targeting physicians, pharmacists, and patients are largely absent. To the extent that the generic medicines market share by volume can be further increased, this may be achieved by assisting physicians in generic prescribing by means of instruments such

as electronic prescribing systems, medicine databases, audit of and feedback on prescribing data, guidelines offering advice on which medicines to prescribe, formularies providing a limitative list of medicines that can be prescribed, or substitution lists that report originator medicines that can be replaced by generic medicines (5). Furthermore, the financial disincentive for pharmacists to dispense generic medicines can be removed by increasing the regressive effect of the pharmacist remuneration scale. In other words, there is scope to increase the percentage remuneration for lower-priced medicines and reducing the percentage remuneration for higher-priced medicines. Finally, Poland may wish to raise patient awareness of generic medicines by launching information campaigns, and to stimulate patient demand for generic medicines by reducing co-payment on generic medicines. The latter policy has been introduced in Portugal, where a 10% decrease in the co-payment on generic medicines between 2000 and 2005 and the exemption of low-income pensioners from co-payment since June 2009 appears to have stimulated the generic medicines market (5,20).

The analysis in this study demonstrated that substantial savings could be gained from increased substitution of generic for originator medicines by Polish pharmacists. Caution needs to be exercised when using these estimates, as this exercise was carried out for illustrative purposes and the findings give an idea of the order of magnitude of savings from generic substitution, but do not represent exact data. Also, generic medicines markets evolve rapidly with new generic medicines being introduced over time. Therefore, data relating to 2004 may no longer reflect the current market situation. However, the selection of best-selling active substances is unlikely to change greatly over time (21). One additional limitation of the simulation exercise needs to be noted. An active substance may contain medicines in different forms, strengths, and package sizes. The analysis did not account for differences in form, strength, or package size between individual products, but substituted generic for originator medicines at aggregate level.

In the absence of studies evaluating the impact of policy measures, this study mainly analyzed measures in terms of the incentives that they put in place for different stakeholders, such as industry, physicians, pharmacists and patients. The analysis may be biased by focusing on studies published in English, but this is usual practice in literature reviews. The study was limited to examining implemented policy measures, although reforms in the Polish pharmaceutical sector are ongoing (22-24). There is a need for decision makers and researchers to make sure that the introduction of new measures governing generic medicines is accompanied by an evaluation of their impact on the multiple goals that the Polish health care system aims to attain.

In conclusion, Poland has a mature, high-volume, low-value generic medicines retail market. The establishment of the reference price at the price of the cheapest medicine in combination with pricing regulation and the low level of medicine prices in Poland has contributed to a low-value generic medicines market. This high-volume market has benefited in the past from the limited availability of originator medicines and a short data exclusivity period, even though there are no incentives for physicians to prescribe generic medicines and a financial disincentive for pharmacists to dispense generic medicines. To develop a competitive and sustainable market, Poland needs to consider moving away from competition by discount to competition by price. This could be achieved by replacing maximum distribution margins by fixed margins. Also, Poland may wish to raise reference prices as a temporary measure to boost market entry for medicine classes with few generic medicines.

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