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## Global Forum on Competition

# COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

**Contribution from Ms Sabine Vogler**

**-- Session III --**

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# LIBERALIZATION IN THE PHARMACY SECTOR

**-- Contribution from Ms Sabine Vogler [*] --**


## Summary

1. Liberalization in community pharmacy usually comprises one or more of the following components: liberalization of the establishment rules for new pharmacies, liberalization of ownership and liberalization of OTC medicines' sale outside pharmacies.

2. Based on case study examples from a few European countries with a liberalized pharmacy sector, the paper discusses whether, and how, liberalization in the pharmacy sector impacts medicine prices and availability of medicines in terms of access to pharmacies and further dispensaries as well as of medicines' supply in pharmacies.

3. In the European countries with publicly funded health care, liberalization in community pharmacy is not likely to impact prices of medicines that are (co-)funded by public payers because prices of these medicines continue to be regulated at all levels. Lower prices could therefore only be expected for non-regulated non-reimbursable OTC medicines but no reduction in OTC medicine prices was confirmed by empirical evidence.

4. In general, accessibility of medicines increases after liberalization in the pharmacy sector because numerous new pharmacies and OTC dispensaries are usually established. However, liberalization tends to favour urban populations which already had good accessibility since new pharmacies and further dispensaries are typically established in urban areas and not in rural remote areas. Indications for a distortion of competition were found when some market players, e.g. wholesalers, gained market dominance. They were incentivized to align their product range to the supply of the owners which limited the availability of less frequently requested products.

5. Policy-makers are recommended to take action to prevent or lessen unwanted effects in order to ensure equitable accessibility and sustainable competition in a liberalized environment.


## 1. Aim and methodology

6. The aim of this paper is to discuss the impact of liberalization in community pharmacy on medicine prices and accessibility of medicines. Supporters of liberalization argue that increased competition following liberalization is likely to lead to improved accessibility of medicines for patients thanks to the opening of more pharmacies, and to a reduction in medicine prices [1-5]. Voices in favour of more regulation have expressed concern about a possible decline in quality of pharmacy services, about

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limited accessibility for vulnerable groups and remote areas as well as unbalanced market power after liberalization [6-8].

7. The analysis in this paper is based on experiences from European countries which liberalized the pharmacy sector. A literature review was performed as of December 2013, which also considered grey literature. This paper particularly draws from studies and evaluations performed by national authorities, including Competition Authorities.

## 2. Components of liberalization in community pharmacy in Europe

8. In several high-income countries, such as most European countries, the community pharmacy sector is a highly regulated area. Regulations determine the qualifications of pharmacists and further staff working in a pharmacy, the criteria for opening new pharmacies, and the requirements for owning and running one or more pharmacies and their affiliations. The remuneration of pharmacies for supplying patients with medicines at the expense of the public payers is frequently regulated on a statutory basis, and provisions exist with regard to the supply chain, the kind of products a pharmacy may offer, its equipment, its opening hours, the time it takes to supply a medicine to patients, etc.

9. In this context, liberalization in community pharmacy usually refers to one or more of the following components: 1) liberalization of the establishment rules for new pharmacies, 2) liberalization of ownership of pharmacies, and 3) liberalization of the sale of medicines, usually Over-the-Counter (OTC) medicines, outside pharmacies. In Europe, the picture related to these three components is as follows:

- Ad 1): Most European countries apply statutory provisions to regulate the **establishment of new pharmacies**. Typically, demographic criteria (e.g. minimum number of persons that will be supplied by the pharmacy) and geographic criteria (e.g. minimum distance to existing pharmacies) are taken into consideration. Usually, these regulations relate to the whole country but specifications at regional levels are possible. In Spain, for instance, national regulation requires a minimum distance of 250 meters to the next pharmacy and a minimum number of 2,800 supplied persons, and, in addition, the Autonomous Communities (regions) have been allowed to adjust these criteria for their own peculiarities [9]. Besides such statutory regulation (i.e. based on a legal basis), internal requirements of a pharmacy association might also be in place though this is rather rare (the Dutch pharmacy association used to apply its own establishment policy accompanied by sanctions but following legal proceedings sanctions were abolished in 1987 and any establishment restrictions were forbidden in 1998). There are no establishment rules in Germany, Iceland (abolished in 1996), Ireland, the Netherlands, Norway (abolished in 2001), Sweden (abolished in 2009) and UK. Ireland did not use to have establishment regulation but in 1996 such rules, which applied geographic and demographic criteria, were introduced. Following an OECD report [10], which recommended their abolishment, the establishment criteria were removed in 2002. Though England never applied statutory establishment rules in general, the ‘control of entry’ test restricts market entry of those pharmacies which aim to dispense prescriptions at the expense of the National Health Service (NHS) – which determines the viability of a pharmacy. Following a report [4] of the Competition Authority, the Office of Fair Trading (OFT), the ‘control of entry’ test was abolished in 2005, except for four categories of pharmacies, and in September 2012, it was partially introduced, with the removal of three of the four exceptions [11].

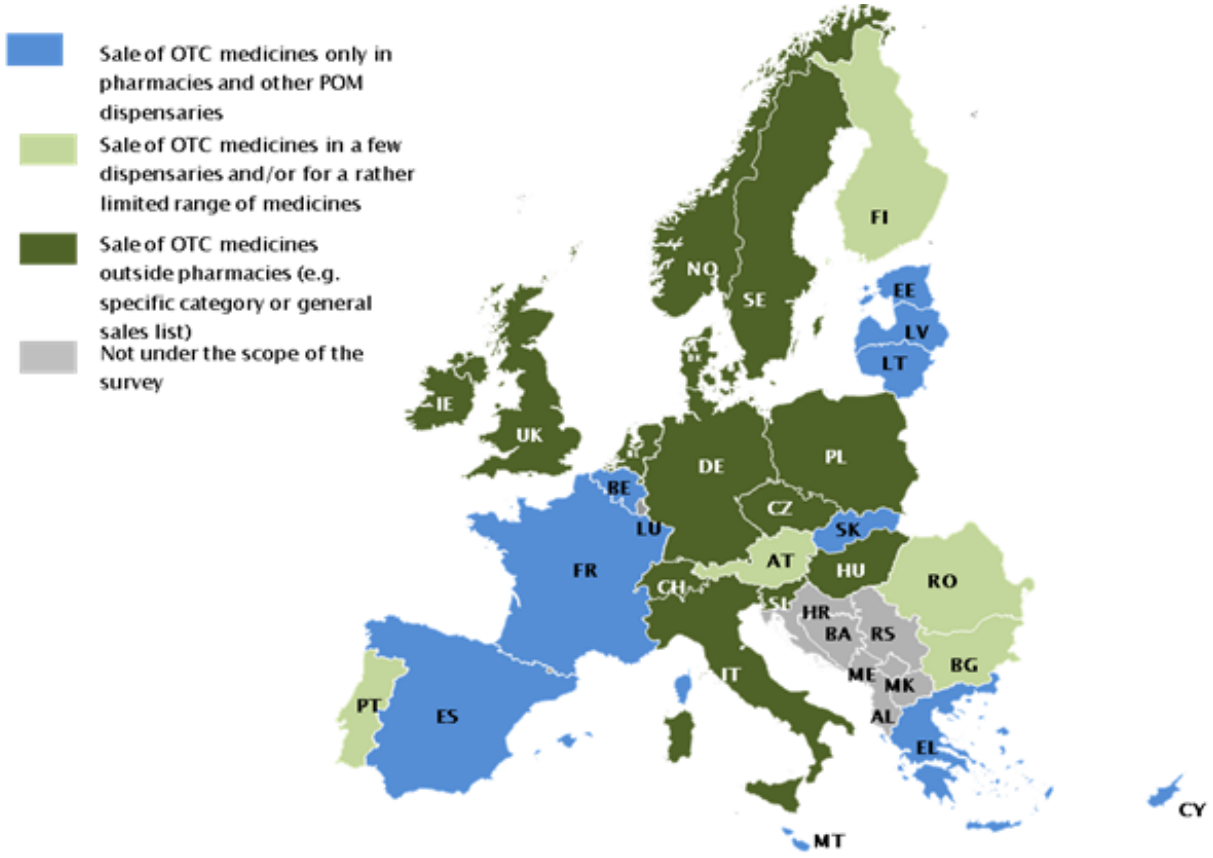
- Ad 2): The **ownership regulation** relates to the question who is allowed to own a private community pharmacy. In regulated environments only pharmacists may own a pharmacy (though some co-ownership of non-pharmacists to some limited extent can be allowed, as observed in Austria and Spain), whereas any individual or legal entity may, in principle, own pharmacies in a

liberalized pharmacy sector. Some countries, though liberalized, excluded specific stakeholders from ownership: in Iceland, Ireland, Norway and Sweden doctors are not allowed to own a pharmacy due to a possible conflict of interest as prescribers, and manufacturers are excluded from pharmacy ownership in Iceland, Norway and Sweden [12,13]. Usually, in European countries with a liberalized pharmacy sector, private community pharmacies still need to be managed by a pharmacist. Another dimension of pharmacy ownership is regulation relating to multiple ownership, i.e., whether it is permitted to own more than one pharmacy. Whereas a limited number of branch pharmacies, under the supervision of a community pharmacy, is not understood as 'multiple ownership' and is also permitted in regulated countries, multiple ownership is allowed in liberalized environments. Usually pharmacy chains have been established within short time after liberalization occured. The number of pharmacies in a chain varies across the countries: In England, the biggest pharmacy chain comprises nearly 2,000 pharmacies (18% of all pharmacies), the second large one around 1,400 pharmacies (13%) and nine further chains between 100 and 500 pharmacies [14]. Limitations on the number of pharmacies in a chain are possible but rare: In Norway, the number of pharmacies in a chain is to 40% of all pharmacies following an intervention of the Competition Authority after one group organised more than 80% of the pharmacies after liberalization [13].

- Ad 3): The permission of the **sale of OTC medicines outside pharmacies** is another element, which may accompany, and follow a few years after, the liberalization of establishment and ownership rules in community pharmacy. In addition, in the last decade there has been a trend to allow OTC medicines' sales outside pharmacies even in those countries which have establishment and ownership regulation in place. In 10 of 28 European countries there is a pharmacy monopoly on the sale of OTC medicines, whereas in the other 18 countries OTC medicines may be sold outside pharmacies. However, the extent of OTC medicines which may be sold outside pharmacies varies among the countries. In Austria, Bulgaria, Finland and Romania a limited range of OTC medicines may be sold outside pharmacies; so this is rather close to a pharmacy monopoly for OTC medicines. In countries where OTC sale is permitted outside pharmacies this is either done by specific OTC dispensaries such as in Denmark, Norway or Portugal, or in general stores such as supermarkets, groceries, drugstores or petrol stations. Even if a larger amount of OTC medicines is permitted for sale outside pharmacies, a distinction between pharmacy-only OTC medicines and those permitted for 'general sale' usually is in place [15-20]. Figure 1 provides an overview about the permission of OTC medicines' sale outside pharmacies in European countries.

10. In the European arena, countries which changed from a strongly regulated system in community pharmacy to a liberalized one were Iceland (1996: liberalisation of establishment and ownership regulation, no permission of OTC medicines' sales outside pharmacies), Norway (2001) and Sweden (2009) – the latter two with full liberalization related to all three presented components.

**Figure 1: Sale of OTC medicines outside pharmacies in 28 European countries**




Specifications regarding sale of OTC medicines in a few dispensaries and/for a rather limited range of medicines:

**AT**: Drugstores: sale of a rather limited range of OTC medicines

**BG**: Drugstores: sale of a selected range of OTC medicines. Vending machines (owned by pharmacies or drugstores): less than a dozen of OTC medicines

**FI**: Pharmacy service outlets: service points for a range of OTC medicines under the supervision of a pharmacy in rural areas; retailers and vending machines for Nicotine Replacement Therapy (NTR) products if OTC

**PT**: Specific OTC dispensaries: sale of OTC medicines in these OTC dispensaries; **RO**: Drugstores: sale of OTC medicines

Source: [20]

11. In addition to these reforms which were initiated at national level, the European Commission challenged existing regulations on establishment and ownership in several European Union (EU) Member States, and launched infringement procedures. Following a European Court of Justice (ECJ) ruling on 19 May 2009, the European Commission announced on 23 November 2011 the dropping of all charges against Member States regarding the pharmacy sector [21]. The ECJ ruled that, while restrictions on ownership and operation of pharmacies constitute a restriction on freedom of establishment and the free movement of capital, these restrictions can be justified, and the EU Member States' national legislation may restrict pharmacy ownership and operation to persons having the status of a pharmacist [22].

## 3. Impact of liberalization on medicine prices

12. In most European countries the medicine prices are regulated, at least the prices of reimbursable and/or prescription-only medicines [23,24]: The state determines, frequently at a statutory basis, the prices of medicines that are fully or partially covered by public payers. At the ex-factory price level, a common method to set the price is external price referencing (international price comparisons) [25]. All components of a medicine price (ex-factory price, distribution remuneration) are usually subject to regulation [26]. Even after liberalization in community pharmacy, pharmacy margins continue to be regulated in OECD countries [12,16,27-29].

13. An impact of liberalization on medicine prices can therefore be only expected for areas where there is free pricing of medicines (liberalization of pricing). In European countries, this would be OTC medicines which are usually not reimbursed [30].

14. Price studies on OTC medicines are rare. Table 1 provides an overview of the methodology and findings of relevant OTC price analyses in Europe.

15. The existing price surveys in this field could not confirm a decrease in OTC medicine prices after liberalization in community pharmacy, and competition on prices was found to be limited [29,31-36].

## 4. Impact of liberalization on availability of medicines

16. Availability of medicines can be defined as easier access to pharmacies and further dispensaries due to shorter distances and in terms of opening hours as well as relating to the range of products and services offered and the time it takes to supply a medicine to patients.

17. After liberalization of establishment and ownership rules an opening of numerous new pharmacies was observed. In case of liberalization of OTC medicines' sale a large number of OTC dispensaries tended to be established. Hundreds and thousands of retailers, which sell OTC medicines, are estimated to exist (e.g. around 8,000 OTC retailers in the Netherlands, around 6,000 retailers in Norway and: around 950 retailers in Denmark [12]).

**Table 1: OTC price studies related to liberalization in community pharmacy**

| Study | Methodology | Findings |
|---|---|---|
| Econ Analyse AS 2004 [33] | Analysis of pharmacy retail price data in Norway provided by the Medicines Agency. | No clear effect on pharmacy retail prices following liberalization though lower purchase prices were expected due to vertically integrated wholesalers and pharmacy chains. No indication for price competition. |
| Vogler et al. 2006 [29] | Collection of the pharmacy purchase prices of the least and most expensive versions of 4 comparable OTC presentations from 1995 till 2005 (as of 1 January) in 6 countries (Ireland, the Netherlands, Norway, Austria, Finland, Spain), data access via national pharmacy associations. | In none of the six countries clear price reductions for at least 2 of the selected OTC could be observed. |
| Verbraucherzentralen Nordrhein-Westfalen, Rheinland-Pfalz und Sachsen [Consumer Associations of North Rhine-Westphalia, Rhineland, and Saxony] 2006 [36] | Primary data collection of pharmacy retail prices of 5 OTC medicines in 837 pharmacies (thereof 343 pharmacies supplied price data) in three regions in Germany | On average, 4.5% of the medicine prices had changed. 91% - 97% of the pharmacies applied the price suggested by the manufacturer.<br>Note: Similar findings in updated surveys as of 2007 [37] and 2008 [38], however the 2008 report concluded that price competition has started in some pharmacies. |
| Stargardt, Schreyögg 2007 [31] | Primary data collection of pharmacy retail prices of 5 OTC medicines in 256 pharmacies in Germany in 2006 (2 years after liberalization). A probit regression model was used to identify factors that increased the likelihood of price changes. | 23.1% of the participating pharmacies had modified the price of at least one of the 5 OTC medicines. In total, only 7.5% of the prices differed from their pre-liberalization level. A higher density of pharmacies was found to have a negative impact on the likelihood of a change in prices. |
| Statens Legemiddelverk [Norwegian Medicines Agency] 2010 [32] | Primary data collection of pharmacy retail prices of 78 medicines, thereof the 10 most frequently sold OTC medicines, in 13 pharmacies, 24 OTC dispensaries and 4 internet pharmacies in Norway. | Price differences were found between the OTC dispensaries, but no substantial competition on the price between pharmacies. The average difference between the lowest and highest prices in all pharmacies was 9.9%. Between the three major pharmacy chains, the average price difference 3.8%. The largest price difference between pharmacies was observed on generic versions of common medicines. |
| Danmarks Apotekerforening [Danish Pharmacy Association] 2012 [35] | Analysis of pharmacy retail prices from 2000 (year before liberalization of OTC medicines' sale) till the first half of 2012 in Denmark, for the total of the market and the non-pharmacy OTC medicines. | Overall, pharmacy retail prices decreased by 42 percent in the survey period (2000 – 2012), however prices of non-pharmacy OTC medicines increased by 23%. |
| Tillväxtanalys [Swedish Agency for Growth Policy Analysis] 2013 [34] | Analysis of the pharmacy purchase prices and pharmacy retail prices for all medicines and OTC medicines from January 2008 and October 2012 and comparison of the pharmaceutical price index to inflation in Sweden. | Overall price decreases (10% measured in pharmacy retail price and approximately 30% measured in pharmacy purchase price) in the survey period, but increase in the prices of OTC medicines which followed inflation. |

18. In Norway and Sweden a substantial increase in the number of newly established pharmacies was observed, particularly shortly after liberalization: In Norway, between January 2001 and March 2004, a total of 128 new pharmacies (a 32% increase) was established which may be compared to an increase of 71 pharmacies between 1991 and 2000 [13,33,39]. Sweden saw an increase of 330 pharmacies (approximately 36 percent) from the introduction of the reform in 2009 till September 2012 [40]. The increase in the number of pharmacies was an intended aim of the reform. Nonetheless, in European comparison the number of inhabitants served per pharmacy continues to be high in Norway and Sweden though in Denmark it is considerably higher [12].

19. An increased competition due to an increase in the number of pharmacies may eventually even lead to the closure of pharmacies. This happened in the Spanish Autonomous Community of Navarra, which had liberalized establishment rules [41].

20. However, new pharmacies tended to be established in urban areas, whereas no or few pharmacies were opened in rural localities with an existing pharmacy in place. In Sweden, 67% of the new 330 pharmacies are located in areas of very high accessibility (defined as urban areas of at least 60,000 inhabitants), 28% in areas of high accessibility (i.e. at least 30,000 inhabitants), 6% in areas of medium accessibility (at least 3,000 inhabitants) and no pharmacies in areas of low accessibility (i.e. at least 1,000 inhabitants) and very low accessibility (i.e. 200 inhabitants) [40]. In England, there were indications for a clustering of new pharmacies around existing pharmacies after the liberalization of the 'control of entry' test: before the 2005 reforms, 54% of the openings occurred in a distance of more than 1 kilometre to the nearest pharmacy; in 2012, the corresponding share was 14% (compared to 57% within 500 metres and 29% within 500 metres and 1 kilometre to the nearest pharmacy) [11,14]. These developments might have led to the change in September 2012 with the removal of some of the exemptions for the 'control of entry' test.

21. A similar trend on 'urban clustering' could be observed for OTC dispensaries: In Sweden, only 4% of the new OTC retailers are located in areas of low or very low accessibility [40]).

22. A policy to prevent the risk of closure of pharmacies in less attractive places or even support rural pharmacies is to provide financial incentives: In England, rural pharmacies are subsidized under the Essential Small Pharmacy Local Pharmaceutical Services scheme (ESP LPS) [42], and in Denmark a tax equalization scheme is in place to support pharmacies with lower turnover [43]. In Norway, for several years an agreement between the state and pharmacy chains provided that in case of closure of a pharmacy in a rural area the pharmacy chain had to take over this pharmacy or establish a new one. Though accessibility in the remote areas did not increase, no rural pharmacy was closed in Norway [13,33,44].

23. There are indications that the opening hours of pharmacies usually improved after liberalization, as evidence from Iceland, Norway and Sweden confirms. [13,33,34]. On average, opening hours increased from 42 to 53 hours per week [34].

24. Liberalization of ownership rules in community pharmacy was observed to result in horizontal mergers and coalitions between pharmacies (pharmacy chains) and to vertical integration [12,13,29,45]. In Norway, pharmacies got vertically integrated with three wholesale groups which got a dominant market position [13,33,45,46]. The Norwegian Competition Authority expressed concern about the oligopolistic structure which had developed [8,47]. This distorted competition and impacted the accessibility of the medicines: vertically integrated pharmacies were observed to align their product range to the supply of the owners, and less frequently requested medicines were less available in pharmacies [29]. A focus in the product range was also reported from OTC dispensaries in Denmark which suggests again limited availability of less frequently requested medicines: Despite a growth in OTC medicines sales of 54% from 2001 to 2011, the availability of OTC medicines only increased for a few top-selling medicines, and four

medicine groups account for 85% of the sales of OTC retailers in Denmark [35]. In Sweden pharmacies were criticized in public debate for their share of body and beauty products in their product range while fewer prescription-only medicines were reported to be on stock [48]. There are indications from Sweden that the provision to supply the patient with 24 hours with a prescribed medicine could not be met in recent times [49,50]. However, it cannot be assessed whether this is an outcome of liberalization. In general, the time it takes to supply a medicine to patients is particularly connected to the logistics of the distribution system.

25. In countries that are, in general, regulated in the pharmacy sector the extent of regulation related to the availability of medicines is also higher [12]. However, across different countries no sufficient data could be collected on the average number of different presentations in stock in a pharmacy, so no conclusions on the actual availability of medicines in pharmacies can be drawn. Medicine shortages have become an increasing challenge in European countries in recent years, for various reasons (e.g. production failures, disruption in the supply chain, impact of pricing policies) [51,52]. However, liberalization in the pharmacy sector has never been reported to be a reason for shortages.

26. These experiences following liberalization in community pharmacy highlight the complexity of policy measures that can substantially influence competitive behaviour. It should be acknowledged that based on own experiences and lessons learned from other countries policy-makers in liberalized and less liberalized countries implemented measures to avoid distortion of competition (e.g. limit on the number of pharmacies held by one market player), to ensure an even spread of pharmacies across the country (e.g. financial incentives for pharmacies in remote areas) and to ensure availability of medicines in a pharmacy (e.g. provision to keep a minimum amount of medicines on stock, a rule to fill prescriptions within a specific time) [12,29].

## 5. Conclusions and lessons learned

27. Liberalization in the pharmacy sector is frequently connected to certain expectations, particularly to decrease medicine prices and pharmaceutical expenditure and to increase accessibility of medicines.

28. There was no evidence from the studied countries – all of them with a publicly funded health care and pharmaceutical system – about price competition of the non-regulated OTC medicines. A consistent decrease in the prices of OTC medicines was not confirmed. A reduction in overall pharmaceutical expenditure in these countries is thus also unlikely since pharmaceutical expenditure is largely influenced by prescription-only medicines that are publicly funded and whose prices continue to be regulated in liberalized markets; furthermore, factors such as increased medical need due to an ageing population, high-priced new medicines and consumption volume impact expenditure.

29. Accessibility of medicines was observed to increase in countries whose pharmacy sector had been subject to liberalization because several new pharmacies and further dispensaries, usually OTC retailers, tended to be established and opening hours of pharmacies were extended. The positive overall effect suffers, however, from some limitations since the new pharmacies and OTC dispensaries are usually established in urban areas, which already had a good presence of pharmacies before the reform. Accessibility of medicines in rural areas was not found to have improved; however, in the surveyed countries it has not decreased either, due to ‘safeguard’ policies to ensure provision with medicines in the remote areas. In general, liberalization tends to favour urban populations, particularly less vulnerable and less seriously ill patients who aim to obtain better access to non-funded OTC medicines. Another unintended effect of liberalization, which limits a successful increase in accessibility of medicines and distorts competition, is the possible establishment of oligopolies of a few vertically integrated pharmacy chains which might be incentivized to align the product range to their suppliers and focus on offering more frequently asked medicines.

30. The observations were made in European countries which have a high level regulation in community pharmacy in several areas (e.g., relating to qualifications of staff working in pharmacies, public service obligations for pharmaceutical wholesale). Nonetheless, the lessons learned are also relevant for countries with a less regulated or non-regulated pharmacy sector since distortion of competition due to unbalanced market power in the pharmacy sector and an uneven accessibility of medicines might also be observed in these markets.

31. Independently from the extent of regulation in community pharmacy, policy-makers are recommended to monitor and evaluate the impact of the policy measures and, wherever required, to take action in order to ensure equitable accessibility of medicines, enhance sustainable competition and avoid negative implications to the detriment of patients, particularly vulnerable groups.

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