PGEU GPUE
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PGEU POSITION PAPER

On

The effects of deregulation of distribution channels for non-prescription medicines in Europe

PGEU firmly believes that the regulation of pharmaceuticals distribution is one of the most effective means of rationalising access to medicines, ensuring patients safety and protecting public health.

According to the principle of subsidiarity enshrined in the Treaty of the Functioning of the EU, [I] [II] Member States are competent for the organization and delivery of health services. As such, many European countries chose to regulate the distribution of non-prescription medicines (NPMs) allowing it only in community pharmacies to protect public health while, in recent years, others decided to allow it also via other distribution channels.

Pharmaceuticals are very special products[III] because of their therapeutic effects, their vital role for people health and because of the inherent risks related to their use and potential misuse[1] [2] [3]. Pharmacists have legal obligations to ensure the medicine is suitable for the patient before dispensing it and to report any adverse reaction to the competent authorities (pharmacovigilance)[4] [5] . These rules do not apply in most cases for non-pharmacy distribution channels.

Initial expectations of the deregulation of the distribution channels for NPMs were to increase accessibility and to reduce prices due to increased competition. However, there is no conclusive evidence[6] [7] that these goals have been achieved in practice. PGEU considers that patient safety and quality of services should be prioritized over any other policy objective in reforms affecting pharmaceuticals distribution.

1.1. Patient safety and quality of service

NPMs can have side-effects and interactions with other medicines, food supplements and herbal preparations. NPMs also bear a high risk of being misused or abused. In many countries, non-prescription medicines as common as paracetamol or ibuprofen dominate the list of agents involved in people poisoning[8] [9] [10].

Professional pharmacists counselling[11] plays a key role in ensuring a more rational and safer use of NPMs. Pharmacists also have legal obligations to report adverse reactions to regulatory authorities contributing to the EU pharmacovigilance system and improving the knowledge about the safety of

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[I] Article 2(5) TFEU states "in certain areas (which fall under Member States' competence, such as the protection of human health) and under the conditions laid down in the Treaties, the Union shall have the competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in these areas.

[II] Article 168 (7) of the TFEU clearly recognises that "**Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care**. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them".

[III] Directive 2011/62/EU, recital 22: "[...] **the Court of Justice of the European Union [...] has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods.** The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the TFEU and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since that level may vary from one Member State to another, Member States must be allowed discretion as regards the conditions for the supply on their territory of medicinal products to the public."

medicines on the market. In addition, community pharmacies must comply with several regulations to ensure accessibility of NPMs and their safe dispensing to patients, concerning, for example, the establishment of pharmacies, staff qualifications (including continuous professional training), stock and ambiance control, high traceability standards, continuity of care beyond standard opening hours, risk assessment before dispensing of NPMs to patients. In the non-pharmacy distribution channel, few of these regulations apply [12]. Moreover, community pharmacies are an entry point to health system and an important venue to promote public health messages and raise awareness on health-related issues.

1.2. Accessibility

While reforms deregulating distribution channels for NPMs are likely to increase the number of access points with the new shops opening and existing retailers extending their product range by offering selected NPMs, this does not translate into an overall increase in accessibility. Non-pharmacies tend to be opened in locations that already enjoy good accessibility, (i.e. urban areas), whereas few if any non-pharmacy outlets are started in rural, remote areas. One explanation for this trend of "urban clustering" in the non-pharmacy distribution channel is linked to the business expectations of the retailers: some of them might consider non-pharmacies outlets not to be financially viable in rural areas[13]. In addition, trends have been found for the non-pharmacy market to concentrate around few market players[14], for example some market players gained market dominance and promoted their own product brand, limiting availability of less frequently requested products on their outlets shelves.[6] Furthermore, the pharmacy distribution channels offer a wide range of non-prescription medicines to patients, whereas non-pharmacies hold a predominant market position for a few selected products. Community pharmacies are required by law to ensure community care by being accessible on the basis of the planning criteria in place (guaranteeing supply of medicines also in remote areas) and beyond standard opening hours.

1.3. Prices

In countries where reforms of distribution channels were implemented, there is little evidence that shows an overall reduction in prices after the deregulation[15]. In some countries prices even increased.[16] [17]Literature shows that it is not possible to establish an uncontroversial link between deregulation and cost containment for consumers[18]. Still, in some countries prices differences can be observed between non-pharmacy and pharmacy channels. Those typically concern comparably few products since non-pharmacies offer a small range of non-prescription medicines. Despite price differences for single products, patients consider community pharmacies as their preferred distribution channel because of pharmacists' expertise and advice and the wide range of products and services offered[19]. Furthermore, it should be considered that pharmacists are an important source of data collected in routine practice to help national governments design public health policies.

2. Conclusions

Member States organise their healthcare systems on the basis of local needs and national strategies aimed at ensuring a certain level of safety and quality in health services. The countries who deregulated distribution channels for NPMs are characterized by differences in income levels and in their healthcare and pharmaceutical systems, geographic location and culture. These countries also differ in terms of the organization of the community pharmacy and non-pharmacy sectors. Despite

the differences, similarities related to the deregulation of distribution channels for NPMs allow to highlight the following key conclusions:

1. There are increasing concerns[20] about the risk of NPMs abuse in the non-pharmacy distribution channels after deregulation.
2. Community pharmacists have the professional expertise and proper setting to provide high quality advice to patients for the safe and rational use of NPMs and to promote public health.
3. The deregulation of distribution channels for NPMs was not accompanied by an adequate impact assessment. As a result, there is lack of evidence on effects of those reforms.
4. The non-pharmacy distribution channels are characterised by lower levels of regulations and lack of data collection.
5. Deregulation has led to an increased number of access points but not to an overall improved accessibility of NPMs.
6. A decrease in NPM prices after the deregulation is not confirmed by empirical evidence. In some countries a price increase has been observed. Price competition concerns a limited range of products.

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