Lithuanian Free Market Institute

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# Greater flexibility is the path towards better access to medication and innovation

A position paper on the EC's initiative on the evaluation and revision of the general pharmaceutical legislation

The European Commission has launched an initiative on the evaluation and revision of the general pharmaceutical legislation with an overall aim to ensure a future-proof and crisis-resistant regulatory system.[1] The revision is intended to ensure access to affordable medicines, to foster innovation, including in areas of unmet medical need, to improve security of supply and address shortages, to promote technological development and to reduce red tape.

The steps towards more flexibility in the regulatory framework are welcomed and much needed as for any economic agent the ability to act in general determines the ability to adapt to evolving circumstances, such as by pursuing permanent technological development or responding to a random crisis. It determines the ability to innovate, to develop and to meet the demand of individual patients by creating patient-centred systems. In complicated and sensitive product chains such as the pharmaceutical industry and healthcare, this ability is crucial as in no other area.

Therefore, any policy changes simplifying legislation and creating regulatory attractiveness with the aim to reduce regulatory approval times and regulatory costs, utilizing digital technology and the use of electronic product information, clearing space for competition, providing for a single assessment process across Member States and employing other advantages of the single market look promising.

Although healthcare is not a common policy field in the EU, closer integration could ease some of the worrying problems across the Member States. The challenge of meeting the demand for healthcare is common for European nations as their populations are aging, expectations about healthcare quality and accessibility are rising, and a shortage of financial resources is calling for more efficacy and efficiency. A chronic lack of medical personnel across the EU calls for a broader view than simply a focus on financial adequacy in seeking solutions. Safety requirements that cannot be compromised and new goals relating to the Green Deal and Circular Economy only reinforce the ambitiousness of the goals set out in the Initiative and the extent and depth of changes that need to be made to achieve those goals.

The Initiative points out that companies market medicines differently across Europe and access can therefore vary considerably across the Member States. This is mainly caused by the conditions that member states offer for suppliers. Some of those conditions are objective, such as the size of the market, while others, such as local regulations, are purely subjective. Analysis of the Lithuanian pharmaceutical market suggests[2] that the environment can be made unattractive for business entities when the single objective the governments pursue is to secure the lowest prices at any cost. A more integrated approach towards flexibility in the pharmaceutical regulation framework is likely to have a positive impact on easing national regulatory regimes.

Local language labelling is a requirement that objectively makes small markets less attractive for producers. Leveraging digital technologies and the use of electronic product information could remove the extra cost of printing different labels and so increase the attractiveness of small markets. However, it is important to note that regulations should be flexible enough to ensure these outcomes.

However, the goal of putting in place tailored incentives for attracting investments for certain unmet needs looks doubtful. Tailored incentives are unsustainable in that they program lagging behind with innovation, resource misallocation and the need for routine changes in the incentive mechanisms. Tailored top-down incentives at best will address existing problems, but they will fail to make the

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Evaluation-and-revision-of-the-general-pharmaceutical-legislation

[2] https://www.llri.lt/wp-content/uploads/2020/09/Ar-vaistu-rinkos-reguliavimas-tarnauja-vartotojui.pdf

system crisis-proof, as is the aim. Systems become crisis-proof only if the incentives stem from the industry itself and if the regulatory framework is flexible enough to facilitate swift response and adaptability.

It is important to note that the Initiative does not address some essential and pervasive problems facing the pharmaceutical sector such as a decreasing role of the market and unrealistic expectations of the consumers.

First, the pharmaceutical sector, just like the whole healthcare sector, is suffering from the rigidity and inertia caused by the dominant role of administrative-political actors and procedures. Although the main agents are private pharmaceutical companies, other important players are numerous regulators and the state acting as the main purchaser on behalf of the population. This undermines the potential of competition (as only fragments of competition come at play) and to foresee the actual demand. Therefore, some wanted products and solutions are missing. And this is not a market failure – it is the failure of market restrictions. The market has to be sufficiently unrestrained to match supply with demand.

Politicians, who de facto manage the process, seek to maximise the current or short-term benefits for the public or certain population groups, e.g. by supplying free medicines or significantly reducing patient co-payments. When such goals and measures are pursued without taking into consideration their long-term effects, the industry's development is compromised and more sustainable ways of financing and long-time behaviourial changes in society are dismissed. This causes, among other things, a decline in investments, late technological response to already existing diseases/threats, and poor crisis management.

Another serious, yet not clearly identified problem is that the sector is suffering from mounting expectations. Everyone expects the most modern treatment and medication, and this Initiative also calls for the newest medicines and the highest quality treatment now and for everyone. This is simply not possible. Unrealistic targets and promises lead to tensions and cracking in the value creating process, because these objectives are pursued at the expense of its various participants. Consequently, companies try to protect themselves by increasing prices and terms, making quality compromises, or simply staying away from those lines of business which are subject to more onerous regulations.

COVID-19 vaccine examples are worth to be taken into consideration. The gravity of the reaction to minor numbers of serious side effects shows that the fruits of technology are expected to be perfect and reactions to any deviations (though anticipated and reported) are disproportionately strong. It suggests how deeply rooted the illusion about impeccable solutions is. There is a clear need to talk openly about possible and even expected side effects of all medicines and technologies and to moderate expectations.

Thirdly, lessons from the pandemic show financial means are not the main bottle neck, in healthcare or in the economy. The main bottle neck is the process of resource allocation – from idea, to technology, human capital, raw materials, production, logistic solutions to the beneficiary. This is particularly relevant in the healthcare and pharmaceutical sectors because here market forces are extremely fragmented and dominated by administrative and political decisions. The more administrative solutions, the lesser the speed, adaptability and efficiency.

If everything is continued on the same path of creating unrealistic expectations, demanding a hundred-percent guarantee, increasing the mandates of regulatory institutions, constraining agreements, keeping high market entry thresholds and relying exclusively on public financing, the need to update the whole framework will re-emerge in several years. Processes inevitably adjust and slip out of tight regulatory framework. The current pharmaceuticals regulatory system is too massive and too rigid to adapt to the dynamics of the sector. If the aim is to make the regulatory framework future-proof and crisis-resistant, it calls for greater flexibility so the industry can enhance adaptability and efficiency in meeting growing public demands.