Commission To Look Into 'Skyrocketing' EU Drug Prices, Availability, and Patient Access

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- **NEWS**
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Executive Summary

The European Commission, at the request of member state health ministers, is to run an analysis of the effect of incentives such as data exclusivity and supplementary protection certificates on drug prices, availability and access to medicines. Ministers have also given their backing to further voluntary cooperation initiatives among countries to rein in what they see as the very high prices of some medicines.

EU incentives for innovative drug research, and their possible impact in terms of high prices, reduced access to medicines and limited availability in some member states, are to be the subject of an "evidence-based" analysis by the European Commission.

At the request of EU health ministers, the commission will look at the effects of incentives such as data exclusivity, market exclusivity and patent term extensions on innovation, pricing, and access to medicines, including generics. The ministers say they are concerned about cases of "very high and unsustainable price levels" hindering patient access to effective and affordable medicines.

In a set of conclusions adopted at the June 17 meeting of the Council of the EU, entitled "strengthening the balance in the pharmaceutical system in the EU and its member states," ministers urged countries to press on with voluntary cooperation initiatives on pricing and reimbursement and to see how far such projects could contribute to greater affordability and better access to medicines.

The council also expressed concern that the growing trend towards earlier drug approvals in smaller populations might encourage companies to seek "very high prices" for products whose added value was not always clear, and wanted specific reassurance on the effects of incentives on the orphan drugs market.

Several member states, it said, felt that the EU pharmaceutical system, which involved a "complex set of interactions between marketing authorisation and measures to promote innovation, the pharmaceutical market, and national approaches on pricing, reimbursement and assessment," might be "imbalanced."

Dutch health minister Edith Schippers told a June 17 press conference that the conclusions sent "a strong political message on the way the current pharmaceutical system is working, and that the council had identified "important challenges" such as "low access to essential medicines due to high prices, shortages, and products being withdrawn."

Health commissioner Vytenis Andriukaitis welcomed the council's conclusions and said that in order to carry out the analysis requested by the council, "I count on input from the member states, and I want to strengthen our cooperation."

In response to the conclusions, the industry bodies, Medicines for Europe and the European Federation of Pharmaceutical Industries and Associations, have come up with some proposals of their own for taking forward the discussion on the impact of incentives on access and pricing, and said they would work closely on this with the other stakeholders including the commission and the member states.

Dutch Impetus

The council's proposals have been developed under the impetus of the Dutch presidency of the council, which organized a meeting in March where Schippers said that "skyrocketing" prices of some new drugs

threatened the sustainability of healthcare systems in Europe and that it was important to ensure the best use was made of early access schemes "without compromising safety."

In their conclusions, the health ministers said that while the pharmaceutical sector had the potential to be "a major contributor" to innovation, health and the life sciences, new medicines being developed and marketed could pose "new challenges" to patients and health systems, particularly regarding assessment of their added value, the financial sustainability of health systems and patient access.

Access to medicines is "endangered by very high and unsustainable price levels"

They said were concerned about "an increasing number of examples of market failure in a number of member states" where access to medicines was "endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances."

In the area of orphan drugs, the council said the commission should continue its efforts to streamline the legislation and if necessary consider a revision of the regulatory framework and incentives for orphan medicines. The incentives, it said, had to be proportionate to the goal of encouraging innovation and improving patients' access to innovative medicines while avoiding the creation of circumstances that might encourage "inappropriate market behavior of some manufacturers and/or hamper the emergence of new or generic medicinal products."

Evidence-Based Analysis

Urging the commission to carry out an "evidence-based analysis" of the impact of the various incentives on innovation and on the availability and accessibility of medicines, it said particular attention should be paid to the purpose of supplementary protection certificates (SPCs), the use of the "Bolar" patent exemption (which allows generics firms to conduct R&D activities necessary for approval during the patent period of the originator), data exclusivity for medicines, and market exclusivity for orphan drugs.

It gave the commission to the end of 2016 to prepare a timetable and methodology for conducting such an analysis.

The member states and the commission, the council said, should explore possible synergies between regulators, health technology assessment bodies and payers to help ensure timely and affordable access to medicines, particularly where products reach the market through accelerated assessment, exceptional circumstances authorization and conditional approval.

Cooperative initiatives should also be encouraged among member states "that share common interests" in relation to pricing and reimbursement and to look at areas where such voluntary cooperation might contribute to better affordability and access, the council said.

These initiatives could include "joint horizon scanning" in order to anticipate the arrival of "new, expensive, innovative medicinal products that might potentially affect current policy and practice," proactive exchange of information among member states at the pre-launch phase, voluntary joint price negotiations, and mutual recognition of HTA reports and/or joint HTA reports.

It stressed, though, that that it was "fully member states' competence and responsibility to decide which medicinal products are reimbursed and at what price, and that any voluntary cooperation on pricing and reimbursement between member states should remain member states driven."

Schippers said that these measures were needed because the EU legislation has "all kinds of top-ups, for example for orphan drugs." She said that in practice "if you have a pharmaceutical product and you limit your indications you can make use of these top-ups, then once on the market you can add indications, you may have 20 years of full use of the system and no competition at all."

Are these top-ups in favor of innovation, or "do they hinder new generic products on the market?" she wondered. She said innovation was extremely important as "we have severely ill patients waiting for new medicines that may cure them," but on the other hand it was important to ensure timely entry of generics to the market, "then we can put money into R&D for new medicines."

Noting that Austria was planning to take part in the price negotiation coalition launched last year by the Benelux countries (Belgium, the Netherlands and Luxembourg), Schippers said that other countries had also expressed interest in joining. "I really think we have made progress so far – we are now busy negotiating one price with one company," she declared.

Industry Reactions

Industry gave the proposals a cautious welcome. EFPIA (the European Federation of Pharmaceutical Industries and Associations) said it recognized the challenges facing member states from rising healthcare demand as a result of an aging population and understood their wish to share information and cooperate on issues relating to the long-term sustainability of healthcare systems, "such as the use of pan-European relative efficacy assessments." But it highlighted the council's conclusion that drug pricing and reimbursement were strictly a member state competence.

"In the future, we believe we can contribute to more sustainable healthcare systems by developing new pricing models, such as outcomes-based or value-based contracts," it said, noting that this approach had begun in a number of countries and required partnering with patients, healthcare providers, payers and industry.

"In that respect, EFPIA underlines 'the importance of a continuing open and constructive multi-stakeholder dialogue between the pharmaceutical industry, patient organizations and other stakeholders', as stated in the Council conclusions." It said it also supported the council's recognition that "a strong IP framework is important for supporting and promoting access to innovative safe, effective and quality medicinal products" in the EU, and that it would contribute to the commission's proposed analysis.

Generics And Biosimilars

Medicines for Europe, which represents makers of generics, biosimilars and "value added" medicines, said it would "engage rapidly with health ministers across Europe" to implement the conclusions.

Its director general, Adrian van den Hoven, said member states had "now understood the importance of stimulating competition in pharmaceuticals

after patent expiry to help rebalance a market heavily impacted by the introduction of new highly priced patent protected medicines. Our members are ready to drive this agenda forward to ensure better access for better health."

The association proposed a number of ways to strengthen the balance of the system, such as introducing specific uptake measures for generics, biosimilars and value added medicines, and including its products in horizon scanning so that the member states could better plan for such measures immediately after patent and exclusivity expiries.

It also said the EU should quickly adopt an SPC manufacturing waiver so as to allow generic manufacture for export during the SPC period, remove "patent linkage systems" and address "other unwarranted restrictions to competition after patent or exclusivity expiry."

The EU and member states should engage in joint dialogues with Medicines for Europe and EFPIA to develop "sustainable partnerships for better access to medicines" while respecting the different roles of the EU and member states in this domain, it added.