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EU Pharma Reform Proposes Cuts In Regulatory Protections & Faster Drug Approval Times

by Ian Schofield

Proposals for the overhaul of the EU pharmaceutical legislation will make medicines more widely available, accessible and affordable while supporting innovation and boosting the “competitiveness and attractiveness” of Europe’s pharma industry, the European Commission claims. The research-based industry thinks otherwise, saying cuts in regulatory protections will undermine R&D.

The European Commission’s long-awaited package of proposals for overhauling and modernizing the medicines legislative and regulatory framework was finally released on 26 April, comprising a new draft Regulation and Directive alongside two initiatives to help tackle antimicrobial resistance.

As widely expected, the package includes cuts in the regulatory data and market protection periods for new drugs, albeit with the possibility to build up additional years of protection by, for example, launching the product in all EU markets or targeting major unmet medical needs. (Also see "*EU Prepares To Release Major Pharma Legislative Overhaul*" - Pink Sheet, 25 Apr, 2023.)

The cuts have not gone down well with the R&D-based pharmaceutical industry, which said the commission’s proposals would “undermine research and development in Europe" while failing to address patient access to medicines.

Also in the package are a new temporary emergency marketing authorization for future health crisis-related medicines, and a transferable exclusivity voucher intended to encourage R&D into new antimicrobials.

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While a proposal to streamline the structure of the European Medicines Agency by cutting the number of scientific committees was expected, one surprise in the draft Regulation is a planned reduction in the regulatory review time at the EMA from 210 days to 180.

The commission would have 46 days to make a decision on marketing authorization following an EMA recommendation, compared with 67 days at present.

This move, the commission said, would "help to reduce the current average of around 400 days between submission and market authorization."

Other proposals in the package include earlier regulatory and scientific support for "promising" new medicines to facilitate their rapid approval, the use of regulatory sandboxes to test new regulatory approaches for novel therapies, and some "future-proofing measures" to ensure the EU drug regulatory system can "keep pace with scientific and technical progress."

There will also be more action on medicines shortages, with stronger monitoring requirements for the EMA and national authorities, and greater obligations on companies in terms of earlier reporting of supply chain disruptions and maintaining shortage prevention plans.

Requirements regarding the environmental impacts of medicines will be strengthened, and there will be more transparency of public funding of R&D into new medicines.

The commission said the proposals would make medicines more available, accessible and affordable while supporting innovation. They would also boost the "competitiveness and attractiveness of the EU pharmaceutical industry, while promoting higher environmental standards."

The proposals will now be discussed by the European Parliament and the Council of the EU, the commission noted. "The discussions will start as soon as possible, but we cannot predict the timing for adoption at this stage."

Data Protection & Market Exclusivity Cuts

For the pharmaceutical industry, the regulatory streamlining and other plans will be welcomed but somewhat overshadowed by the proposals for changes to regulatory and market protections.

The commission is proposing to reduce the statutory regulatory data protection period from eight years to six, to be followed by two years of market exclusivity. However, on top of this guaranteed eight-year period, companies could gain an extra two years for launching the product

in all EU member states, an additional six months each for addressing unmet medical needs or producing the results of comparative clinical trials, and an extra year for a new indication of an authorized product.

This would give a maximum of 12 years' potential protection compared with 11 years today, the commission observed. "The additional regulatory protection of two years if medicines are launched in all member states is expected to increase access by 15%. This means that 67 million more people in the EU could potentially benefit from a new medicine."

For orphan drugs, the standard period of market exclusivity would be cut from 10 years to nine, with the possibility of building up additional protection for addressing high unmet medical needs (one extra year), launch in all member states (one year) and a new indication for an approved orphan drug (up to two years). This would give a maximum of 13 years of market exclusivity, compared with 10 years today.

According to the commission, the "combination of the existing intellectual property rights and the new regulatory protection periods" will "safeguard the EU's competitive edge in pharmaceutical development, one of the most protective world-wide."

Plans Would 'Undermine R&D'

The European pharmaceutical industry federation, EFPIA, would beg to differ.

"Delivering faster, more equitable access to medicines, avoiding and mitigating shortages as well as ensuring that Europe can be a world leader in medical innovation are goals we share," said its director general, Nathalie Moll.

"Unfortunately, today's proposals manage to undermine research and development in Europe while failing to address access to medicines for patients."

"The approach set out in the pharmaceutical legislation, penalising innovation if a medicine is not available in all member states within two years, is fundamentally flawed and represents an impossible target for companies," Moll continued.

She said the "vast majority" of delays in access to new medicines were known to occur after a company had filed for pricing and reimbursement and was awaiting a decision. "Fixing the tenfold variation in access to new medicines across the EU requires all partners to urgently get round the table and address the real issues rather than unworkable EU-level legislation that is destined to fail."

EFPIA president Hubertus von Baumbach said that while the revised legislation was meant to improve Europe's competitiveness, "the net impact of policies set out across these proposals, in

their current form, puts European competitiveness at risk: overall, it weakens the attractiveness for investment in innovation and hampers European science, research and development."

In order to "truly realize a patient-focused EU life science ambition, it is vital that a comprehensive competitiveness check is conducted on the impact of the revised pharmaceutical legislation," von Baumback said.

Moll said that over the coming months, EFPIA was committed to working with members of the European Parliament, the Council of the EU and other stakeholders "to ensure the revised pharmaceutical legislation and patent package meets the needs of patients, our healthcare systems, member states and Europe's life science sector."

If changes are not made, she said, the legacy of this commission would be for Europe to be "simply consumers of other region's medical innovation, and European patients waiting longer than ever for the latest advances in care."

In similar vein, Vas Narasimhan, CEO of Novartis, said that the US, China and Japan were "outpacing the EU in terms of biopharmaceutical investment. Actions like this only make Europe less competitive for high innovation industries like the biopharmaceutical industry. I don't think it'll serve its intended purpose."

He said the changes to data protections would "erode investment over the medium to long term and continue to damage the ecosystem here in Europe. So I'm hopeful that European legislators will be thoughtful, understand the implications of these policies, and hopefully correct them prior to their approval or implementation."

'Priority For Health Needs'

By contrast, the European Public Health Alliance welcomed the proposals, saying that "people's health needs must be given clear priority over profits for the pharma industry. We call on the European Parliament and Council to ensure this balance between incentives and obligations is indeed achieved by the final regulations."

Yannis Natsis, director of the European Social Insurance Platform, felt that offering industry extra regulatory protection for conducting comparative trials was not justified. "It continues to puzzle me how we feel the need to reward pharma with longer monopolies for what should be common sense standard: conducting comparative trials," he tweeted. "Most patients are completely unaware of the fact that most new drugs are approved on the basis of non-inferiority trials. This means that pharma needs to only prove that a new product is not worse (!!!) than standard treatment."

The Pink Sheet will be exploring the implications of the various aspects of the pharmaceutical reform

package over the coming days and weeks.