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# Dissent In Parliament As Commission Claims EU Pharma Revision Will Improve Competitiveness and Access

by Ian Schofield

Proposals on regulatory data protection and transferable exclusivity vouchers to encourage antimicrobial R&D have received mixed reactions from the parliament's rapporteurs for the draft legislation.

Plans for the overhaul of the EU pharmaceutical legislation have begun what will likely be a long and tortuous legislative journey after Florian Schmidt of the European Commission formally presented the proposals to the European Parliament's environment and public health committee (ENVI) on 20 September.

The presentation covered all the key points of the revision, including plans to "modulate" regulatory data protection on medicines. However, it was notable that Schmidt did not specifically mention the fact that the commission is proposing to cut the default regulatory data protection (RDP) period by two years – a key concern raised on many occasions by the R&D-based pharmaceutical industry.

He insisted, though, that the revision would "strengthen innovation and competitiveness in medicines development in the EU" and that it aimed to "ensure that this innovation is brought… to the patients that need it."

The commission had "listened to the European Parliament and the member states before we made the final proposal. Now we are entering the phase of inter institutional negotiations," said Schmidt, who is deputy head of unit at the commission's health directorate (DG

***Key Takeaways***

- The European Commission has formally

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SANTE).

"Together, we believe we can deliver an ambitious reform that promotes access to medicines for all European patients by also strengthening our regulatory system so it remains innovation friendly, competitive and fit for the future."

The revision will be implemented by a new regulation and a new directive, currently in draft form, that the commission official presented to the ENVI and will be debated and amended by the parliament and the Council of the EU (representing EU ministers).

Under the "ordinary legislative procedure," the two institutions will attempt to reach agreement on the texts as soon as possible, but given the breadth and often contentious nature of the proposed reforms, this is expected to be a lengthy and complex process. (Also see "*EU Pharma Revision: Legislators Prepare For Long-Haul Debate*" - Pink Sheet, 25 May, 2023.)

presented the pharmaceutical legislative revision package to members of the European Parliament.

- The commission says the revision will "strengthen our regulatory system so it remains innovation friendly, competitive and fit for the future."
- Proposals to "modulate" regulatory data protection periods on medicines have met with mixed reactions among MEPs.
- The parliament's rapporteur for the draft regulation says he cannot support the proposal to introduce a "transferable exclusivity voucher" to encourage R&D into new antimicrobials.

## Streamlining Regulatory Procedures

Schmidt told the ENVI the reform had the following key objectives: to ensure a competitive regulatory framework and boost innovation in the EU, improve access to and availability and affordability of medicines, combat antimicrobial resistance, and "improve the environmental sustainability of the medicines we authorize."

On regulation, he said the ambition was to simplify and streamline regulatory procedures, resulting in "shorter authorization times" at the European Medicines Agency – from 210 days to 180 – while "maintaining our high standards for the assessment of quality, safety and efficacy." This included improving the EMA's processes and structures and "the amplification of the voice of patients in its main committee."

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The commission is also proposing to modernize the regulatory system with "enhanced

digitalization," including more use of real-world data in regulatory decision-making, and is envisaging "the possibility of adapted regulatory frameworks for novel types of technologies and treatments where existing rules may not be fit for purpose," Schmidt declared.

## Differences Over Data Protection

On RDP, the commission official said the plan was to have a modulated system so that the incentives "better reflect specific public health objectives." This would provide "an internationally competitive set of incentives for all innovative medicines" with "the possibility for add-ons," he declared.

"For example, we propose an add-on data protection period, which will be granted to those companies that launch their medicine in all EU member states. Other add-on protection periods are given for medicines addressing unmet medical needs, or that include comparative clinical trials."

But Schmidt did not mention that the commission plans to cut the basic RDP period from eight years to six, which means that some of these "add-ons" would simply be reinstating the lost RDP time.

The European pharma industry federation EFPIA has attacked the proposals on data protection on a number of occasions, saying they would significantly reduce European intellectual property rights "while adding complex incentives for additional IP protection which in practice makes it impossible to achieve these incentives." (Also see "*Pharma Revision Will Hasten EU's R&D Decline, Says EFPIA's New Presidency Team*" - Pink Sheet, 26 Jun, 2023.)

A number of life science lawyers agree that the pan-EU launch requirement for recouping some RDP protection, in particular, appears "unworkable" and "very onerous and unrealistic." (Also see "*EU's Plans for Regulatory Data Protection 'Unworkable'*" - Pink Sheet, 12 May, 2023.)

Dissent was also evident among the ENVI rapporteurs, who will be preparing reports on each of the drafts with proposed amendments and guiding them through the legislative process.

Timo Wölken, rapporteur for the draft regulation, gave his backing to the RDP proposal. He said it "shouldn't be a surprise that I'm very much in favor of getting rid of the one-size-fits-all approach and moving towards a modulation of regulatory protection."

He said it was "a mistake to think that we will generate more research and development within the EU just because of longer protection periods," and it was "misguided" to suggest that the move to modulation would endanger overall EU competitiveness.

"Where a company does R&D does not influence the duration of protection within the EU.

Hence, EU companies can benefit in other jurisdictions either way, providing they sell their products there – something that even the impact assessment of the commission has underlined."

By contrast, Pernille Weiss, rapporteur for the directive, suggested it might be better to consider approaches other than RDP modulation. She noted the concern already raised by EFPIA and others that such a system would be "extremely difficult to manage across Europe, in that [companies] don't know how long their data protection will last."

It has been pointed out that launching products in all member states by a specific deadline would be difficult or impossible because of factors such as the different pricing and reimbursement systems at member state level.

Weiss wondered whether the commission had "contemplated other options" because it "obviously has to be realistic in its approach."

One of the shadow rapporteurs for the regulation, Tomislav Sokol, agreed that a modulated approach could "help address inequitable access" to medicines across the EU, but that smaller companies might find it more difficult to "adjust to the modulation of incentives linked to market launch, as they often lack the capacity to serve all member states in a timely manner."

## Shortages And Affordability

Schmidt also outlined some of the other measures in the package, such as proposals to prevent and tackle drug shortages by requiring companies to maintain shortage prevention plans and notify potential shortages earlier. He added that the commission "may adopt implementing acts, for example to impose contingency stock requirements on marketing authorization holders, wholesale distributors, or other relevant entities."

On ways of improving the affordability of medicines, the commission official noted that pricing and reimbursement systems were a member state competence, but that the commission was proposing "several measures under the EU pharmaceutical legislation that will support member states in their efforts to ensure sustainability of health care systems."

These included measures to facilitate timely market entry of generics and biosimilars to increase competition and reduce prices and to "strengthen the position of member states in their price negotiations with pharmaceutical companies. For example, we propose to improve transparency on public funding that companies have received for their medicine development."

In addition, encouraging the conduct of comparative trials (which is one criterion for winning added RPD protection) will "support member states in taking evidence-based decision on pricing and reimbursement" and will "also be useful in other contexts, for example, for the development of clinical treatment guidelines."

## Antimicrobial Vouchers

Another key proposal from the commission is to offer a "transferable exclusivity voucher" to encourage the development of innovative antimicrobial drugs, Schmidt noted. This would give a company with a promising product a year of added RDP, which could be used for any other drug in its portfolio or sold on to another company.

But Wölken was not impressed by the idea. "We know that much of the innovation in antibiotics is driven by small and medium sized companies, which are struggling to find investors. So it is not these actors, but rather the big players who would then profit from longer data protection," delaying generic access, he said.

"This is not even to mention the uncertainty and unpredictability and cost for national health systems. I just cannot support a voucher that, after it has been sold to another company, does not include a guarantee of supply. If it is kept, there needs to be additional wording which guarantees the availability of novel antibiotics on the market."