PINK SHEET
CITELINE REGULATORY

06 Mar 2024 | **News**

Cut In Data Protection Looms Large As EU Vote On Pharma Revision Nears

by Ian Schofield

All eyes will be on the European Parliament's ENVI committee later this month when it votes on the planned overhaul of the EU pharmaceutical legislative framework, including a highly controversial proposal to cut regulatory data protection for originator drugs.

The next major milestone for the European Commission's wide-ranging proposals for overhauling the EU pharmaceutical legislation is likely to be 19 March, when the European Parliament's environment and public health committee (ENVI) is scheduled to vote on the plans.

The so-called "pharmaceutical package" – consisting of a draft regulation, a draft directive and recommendations on tackling antimicrobial resistance – was launched almost a year ago in April 2023 but so far has only reached the parliamentary committee stage.

The revision is intended to ensure access to high quality, safe, effective and affordable medicines, support a "future-proof and crisis-resistant pharmaceuticals system," foster innovation and enhance security of supply, "while adapting to new scientific and technological developments and reducing regulatory burden," according to the parliament.

In the package are a number of controversial proposals, not least a two-year reduction in the baseline eight-year period of regulatory data protection (RDP) for originator drugs, albeit with the possibility of recouping protection periods under certain circumstances.

The R&D-based industry federation EFPIA is up in arms over this idea, saying that if it is passed, there will be "not only a reduction in European competitiveness, but a significant reduction in patients' access to medicines."

Other divisive ideas in the package include a "regulatory sandbox" for testing out new regulatory approaches to drug evaluation, and a "transferable exclusivity voucher" (TEV) system to

encourage the development of new antimicrobials.

Interesting Vote Ahead

Click here to explore this interactive content online

The ENVI is the lead parliamentary committee for the package, and its vote this month will be keenly followed by all interested parties, not least because of stark differences over the RDP proposal among the rapporteurs for the legislation.

The rapporteur for the draft regulation, Tiemo Wölken, is in favor of the modulated RDP idea, while Pernille Weiss, who is steering the draft directive, is firmly against it and has even proposed raising the baseline RDP period to nine years, an idea supported by the R&D-based industry. Wölken, meanwhile, is vehemently opposed to both the regulatory sandbox and the TEV proposals. (Also see "*Splits Over Data Protection Could Hamper EU Pharma Revision*" - In Vivo, 13 Nov, 2023.)

If the ENVI vote goes ahead on 19 March, and if the parliament can table it quickly enough, the package will go to a plenary session on either 10-11 April or 22-25 April, where the parliament will adopt its position on the proposals, a spokesperson for the parliament told the *Pink Sheet*.

However, the next stage of the legislative process – negotiations with member state ministers at the Council of the EU – will have to wait until after the parliamentary elections in June.

Following the elections, the new parliament will need to confirm that it is happy with the position adopted by the current legislature. While this is usually the case in these circumstances, the spokesperson said, there is a chance that the new parliament will choose to reopen the dossier and appoint a new rapporteur and negotiating team to begin talks with council, which will also need to adopt its own position on the package.

“This happens to all files for which Parliament closes its first reading and [which] need to be followed up after elections.”

“We won't know details until later in autumn,” the spokesperson added, noting that Hungary takes over the presidency of the council in the second half of this year.

The elections will also mean a pause for other pieces of draft legislation currently going through the EU legislative machinery, including the two proposals on supplementary protection certificates for human medicines. (Also see "*EU Parliament OKs Legislation To ‘Reduce Cost & Burden’ Of Patent Extensions*" - Pink Sheet, 28 Feb, 2024.)