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Environmental Risk Assessments To Loom Larger In EU Drug Reviews

by Ian Schofield

Among the many proposed changes to the EU pharma legislation to be negotiated by the EU institutions in the coming months are much tougher requirements for environmental risk assessments (ERAs).

The new ERA framework was proposed by the European Commission in April 2023 as part of its pharmaceutical reform package, with the aim of incentivizing companies to submit properly substantiated ERAs. A year later the European Parliament adopted a number of amendments on the ERA proposals that imposed even tighter conditions on companies. ERAs have been a standard requirement for new medicines since 2006.

Some of the proposals and the new requirements adopted by the parliament have been welcomed by the pharmaceutical industry, while others have come under fire for being too stringent and risking unforeseen consequences.

Lutz Bonacker of CSL Behring told the *Pink Sheet* that while the ERA had value as a way of reducing the industry's environmental footprint, "we strongly believe that the enforcement and implications of ERAs must be proportionate to its purpose and avoid unintended and disproportionate negative impacts on patients who could see access to these treatments limited on the grounds of environmental concerns."

Key Takeaways

- The European Parliament's amendments to the "pharmaceutical package" include stricter obligations on pharma firms in terms of environmental risk assessments.
- Key changes include widening the

Full ERA To Be Published, And

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Scope Extended

The pharma package comprises a draft directive and draft regulation, each of which contains a number of provisions on the purpose, content and evaluation of ERAs.

A key amendment introduced by the parliament in April was that when a marketing authorization was granted, the complete ERA would have to be published, rather than just a summary as had been proposed by the commission. It added that when publishing information on the ERA, any information of a commercially confidential nature should be deleted.

The parliament noted that according to the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, "the public has a right to obtain information on environmental matters, including on the ERA of a pharmaceutical product."

It also extended the scope of the ERA in terms of the product lifecycle. While the commission said that risk mitigation measures – those to avoid or limit emissions to the air, water or soil – should apply during the use and disposal of a medicine, the parliament said they should extend to the whole of the medicine's lifecycle, including the manufacturing stages.

The ERA should also have to state what techniques the company proposed to use to reduce discharges of medicines into the environment, particularly in the form of effluent from manufacturing.

Connected to this, the parliament said that compliance with relevant EU and member state legislation in terms of environmental protection at the manufacturing stage "should generally be considered as a relevant risk mitigation measure in terms of production," and that this should also apply to production in third countries with a level of environmental protection equivalent to that of the EU.

- scope of the ERA to include the manufacturing stage, and a requirement to publish the entire ERA rather than just a summary.
- The parliament said that any decision to revoke or refuse a marketing authorization on the grounds of an inadequate ERA must take account of the clinical benefits of the medicine, the needs of patients and any alternative treatments available.
- One industry executive believes that "by no means" should marketing authorizations be revoked or refused on the basis of an ERA.
- The pharma package is now awaiting the formal position of the Council of EU before negotiations begin between it and the parliament.

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The commission's original draft directive stated that if the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment "or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorization should be refused."

However, parliament said that "due consideration to avoid restricting patient access to such medicinal products should be given before any decision is taken on revocation." Any decisions to revoke or refuse a marketing authorization "shall take into account the clinical benefits of the medicinal products and the needs of patients, including alternative treatments available," it said.

New ERA Working Party Proposed

The parliament also put more emphasis than the commission on the need for a new ERA working party that could be consulted by the European Medicines Agency's human medicines committee, the CHMP, when carrying out centralized assessments of proposed ERAs.

It said the EMA "shall" (rather than "may") set up such a body, and that it should have "the scientific knowledge necessary to characterize and assess the risks, and the mitigation measures for such risks, related to the manufacture, use and disposal of medicinal products."

Also under the parliamentary amendments, member states would have to draft national plans for informing the public and health care professionals about the environmental risks associated with the "incorrect disposal of unused or expired medicinal products."

Concerns Over 'Potential Unintended Impacts'

Bonacker, who is CSL Behring's general manager of commercial operations, said he saw the ERA as a "valuable tool" for mitigating and reducing the potential environmental impact of pharmaceuticals. His company, like many others, had put in place "meaningful targets" as part of their sustainability strategies to reduce the environmental footprints of their products.

However, "we do have some concerns over the potential unintended impacts of the proposals adopted by the European Parliament, including on the stability of supply chains and availability of medicines," he told the *Pink Sheet*.

"There may be a variety of factors determining the extent to which environmental impacts can be managed or prevented, and these have to be carefully considered in collaboration with all stakeholders, including regulatory and licensing authorities," he said.

"By no means should marketing authorization of medicinal products be revoked or refused on the basis of ERAs," Bonacker declared. "This would be a regrettable consequence of environmental policies for EU citizens, which the EU should not allow."

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Bonacker was also concerned about the parliament's proposal to "expand the scope of ERAs and its potential consequences to the full lifecycle of medicines, including manufacturing processes."

This, he said, would have "negative consequences on an industry that still relies on and will continue to rely on globally integrated value chains, in order to ensure resilience of our manufacturing and supply chains, as well as competitiveness and economic viability of our products. We emphasise the need to balance environmental considerations with the imperative of patient welfare and reliable supply chains."

"We therefore call on legislators to adopt extended ERA measures that do not negatively impact innovation and ultimately access to patients."

Next Steps For The Pharma Package

Following the adoption of the parliament's amendments in April, the pharmaceutical package is now awaiting a formal position from the Council of the EU, which represents member state ministers. The council and parliament will then try to reach agreement on a final text.

The parliament's negotiations on the package are being led by its environment, public health and food safety committee (ENVI), which has a new chair and composition following the parliamentary elections in June.

At its 23 July "constitutive meeting," the ENVI chose Antonio Decaro of the S&D parliamentary group to chair the committee, which will hold its first ordinary meeting on 4 September. The new rapporteurs for the pharma package will also be chosen in the autumn, according to the ENVI secretariat. (Also see "*EU Pharma Reform, SPCs, Compulsory Licensing Among Parliament's 'Unfinished Business'*" - Pink Sheet, 22 Jul, 2024.)