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EU Proposes To Chop EMA Committees, Drop Five-Year Renewals

The EMA, Not The Commission, Would Decide On Orphan Designation

by Ian Schofield

The EU's legislative revision proposals include stripping down the European Medicines Agency's committee structure, abolishing the five-yearly marketing authorization renewal requirement, and doing away with the "sunset clause" that requires a product to be launched in at least one EU country within three years of approval.

Among the many wide-ranging proposals for the overhaul of the EU medicines legislation that are due to be published at the end of this month is a radical restructuring at the European Medicines Agency that will see the number of its scientific committees reduced from six to two.

The two committees that would remain are the Committee on Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC). The CHMP's role includes assessing and making recommendations on EU marketing authorization applications for new drugs under the EU centralized procedure.

The expertise of the other four scientific committees would be retained and organized into working parties and a "pool of experts" that would give input to the CHMP, the PRAC and the EU Heads of Medicines Agencies' Co-ordination group for mutual recognition and decentralized procedures – human (CMDh). These four committees are the CAT (advanced therapies), the COMP (pediatric medicines), the PDCO (orphan medicines) and the HMPC (herbal medicinal products).

The working parties would support the work of the two committees, ensuring a "continuous link" between the experts from national EU regulatory agencies and the EMA. There would also be greater representation of patients and health care professionals on both the CHMP and the

PRAC, including in the areas of rare and pediatric diseases.

Freeing Up Resources

According to the proposals, which were recently leaked and are not the final version, the aim of the simplified EMA structure is to free up the resources of the EU regulatory network so that it can focus on new activities such as early scientific support for promising new drugs – and for repurposing of older ones – as well as on activities related to a "more lifecycle approach" to medicines authorization.

The committees and national authorities are facing an increasing number of regulatory procedures that require additional resources to make sure rapporteurs and assessors remain available to carry out assessments within the stipulated timeframes, the commission says. The current structure of the agency means that "in some cases up to five scientific committees are involved in the assessment of one product."

Moreover, new challenges are arising from the assessment of "innovative and complex" medicines, while capacity constraints observed during the COVID-19 pandemic risk becoming more frequent.

There have been calls for changes to the EU regulatory procedures for some time, with speakers at last year's Drug Information Association Europe conference, for example, expressing concern over the complexity of the system and duplication of processes. (Also see "*Top EU Regulator Attacks Complexity & Duplication In European System*" - Pink Sheet, 14 Apr, 2022.)

Renewals And Sunset Clause May Go

As part of the drive to reduce the regulatory burden, the commission is proposing to abolish two key provisions of the current medicines legislation: renewals of marketing authorizations (MAs) and the so-called "sunset clause." To support the move, it cites a May 2022 report by the Technopolis Group that found the sunset clause was "ineffectual" and the five-year renewal requirement "inefficient."

At present, MAs are subject to one renewal after five years, a process intended to make sure that the product's benefit-risk balance is still positive, taking into account any additional information on the product gathered since its approval, such as pharmacovigilance data.

Under the commission's proposals, MAs would be granted for an unlimited period, although in certain cases the commission could require a one-time renewal on safety grounds, on the basis of a scientific opinion from the EMA.

The sunset clause requires companies to place a product on the market in at least one EU member state within three years of marketing authorization. The MA ceases to be valid if this

does not happen or if a product is removed from the market for three consecutive years.

While the draft proposals suggest removing this clause, there would be a new kind of marketing requirement linked to data exclusivity.

The commission says that under its proposals, if a new product was launched in all EU member states within two years of approval, it could gain an extra year of regulatory data protection (RDP). However, this is cold comfort for innovators, given that the commission is also planning to reduce the default period of RDP from eight years to six. (Also see "*EU Data Protection Reductions Would 'Irretrievably Sabotage' Pharma Industry*" - Pink Sheet, 15 Feb, 2023.)

Orphan Designations

Under another regulatory streamlining proposal, the EMA, rather than the commission, would have responsibility for adopting decisions on orphan drug designation. At present, the agency's COMP committee examines applications for orphan drug status, and issues an opinion that is then sent to the commission for a decision. The proposed change is "expected to facilitate and expedite the designation procedure, while ensuring a high level of scientific expertise," the commission says.

As a whole, the various measures on simplification will "support innovation, future proofing and reduction of the regulatory burden" and "strengthen the competitiveness of the pharmaceutical sector," the commission asserts.

The EMA declined to comment on the proposals given that they have not yet been officially published.

The legislative revision package, which includes a new draft Regulation and Directive, is scheduled for publication on 29 March.