PINK SHEET
CITELINE REGULATORY

06 Jul 2022 | **Analysis**

Access In Jeopardy If Generics Excluded From EU Centralized Procedure

Industry Body Urges European Commission's Pharmaceutical Committee To Abandon Idea

by David Wallace

Recent suggestions by the European Commission's Pharmaceutical Committee that generics could be excluded from the centralized procedure for marketing authorizations would create barriers to access and put extra pressure on the European regulatory network overall, Medicines for Europe believes. The association has urged the authorities to abandon the idea.

The European Commission's Pharmaceutical Committee must "abandon the idea of closing access to the centralized procedure for generic medicines," off-patent industry association Medicines for Europe has urged, in the wake of recent suggestions that marketing authorizations for generics could be excluded from the process and handled exclusively through the mutual recognition and decentralized procedures.

According to minutes from the committee's 11 May meeting (*see sidebar*), discussion took place over whether generics manufacturers should continue to have the choice of taking their products through either the centralized procedure, which is overseen by the European Medicines Agency, or the mutual recognition or decentralized approval procedures, which are conducted at national level.

"Discussions during the Pharmaceutical Committee regulators' workshops highlighted that in practice the vast majority of generic medicinal products apply for authorization via mutual recognition/decentralized procedures, thus creating a well-functioning system overseen by the co-ordination group for mutual recognition and decentralized procedures – human," the minutes state.

PINK SHEET
CITELINE REGULATORY

"The committee will exchange views whether the scope of the central authorization procedure can be updated to optimize the system and reduce administrative burden as well as allow the the [EMA's] committee for medicinal products for human use to focus on more complex applications."

The pharmaceutical committee said that while some EU member states maintained that applicants should continue to have a choice of procedures, others felt that generics should be transferred "to national level."

Meanwhile, others wanted "a more nuanced approach," for example transferring "simple" generics to the MRP/DCP procedures and keeping complex generics within the centralized procedure.

EU Targets Generics, Inspection Shortfalls & Environmental Assessments

By Ian Schofield

29 Jun 2022
As the European Commission prepares to publish its proposals for overhauling the EU pharmaceutical legislation at the end of the year, member states have been discussing a range of technical and legal issues such as the scope of the centralized approval procedure, the use of electronic product information and the shortage of inspection capacities.

Read the full article here

But responding to these suggestions, Beata Stepniewska – deputy director general of Medicines for Europe and the association's head of regulatory affairs – described the potential move as "a very disappointing attitude that needs to be corrected."

"We very strongly call on the European Commission and Pharmaceutical Committee to abandon the idea of closing access to the centralized procedure for generic medicines," she emphasized.

> ***"Reducing access to the centralized procedure will have the opposite effect to increasing access to generic medicines, as envisaged in the European Commission's Pharmaceutical Strategy."***

"We have reviewed with great concern the report of the meeting of the Pharmaceutical Committee on possible restriction of the centralized procedure for generic medicines," Stepniewska confirmed.

She suggested that "solving the problem of the CHMP way of working and lack of resources in the context of marketing authorization of generics as 'insignificant' and 'unworthy' of access to the centralized procedure shows a very negative CHMP perception of the value and importance of broad and timely patient access to generics, highlighted in the Pharma Strategy as one of the key objectives." (Also see "*European Parliament Urges Increased Role For Generics And Biosimilars*" - Generics Bulletin, 25 Nov, 2021.)

Rather than eliminating generics from the centralized procedure, Stepniewska argued, "the access to two procedures, the CP and the DCP, should co-exist, serving the improvement of patients' access to medicines rather than restricting and delaying access."

Ongoing work on the revision of the EU marketing authorization system "should focus on improving and streamlining both, the CP and DCP procedures," she suggested, "leaving the marketing authorization holder free to choose the procedure according to product/patient needs/company presence on a given market."

Smaller Countries At Particular Risk Of Limited Access

Essentially, Stepniewska summarized, "reducing access to the centralized procedure will have the opposite effect to increasing access to generic medicines," as envisaged by the Pharma Strategy.

"Although marketing authorization alone does not automatically guarantee access to medicines," she acknowledged, "the mere existence of a valid marketing authorization in a given country is already an important prerequisite for placing a product on the market."

In particular, she highlighted, a centralized marketing authorization "automatically offers marketing authorizations in all countries of the EU, which significantly increases the chances of marketing the product also in smaller countries, which are not always identified as concerned member states in the decentralized procedure."

And addressing the potential for the CHMP to focus on more complex and innovative applications while excluding generics from the centralized procedure, Stepniewska said this was "discriminatory for generic medicines producers."

"The latest revision of the veterinary legislation went in the opposite direction by extending the scope and access to the CP to all types of products, instead of restricting the scope," Stepniewska highlighted. "If the workload of the CHMP is the main reason of the exclusion, the effort should go into improvement of the CHMP decision-making process to make it efficient in view of resources involved, instead of closing the door for generic medicines applications via the CP."

Moreover, Stepniewska suggested, pushing generics towards the decentralized procedure would

not lessen the overall pressure on European regulators.

“Restricting access for generics to the centralized procedure will put additional pressure on the DCP and will not result in any savings in resources in the EU regulatory network, but will actually have the opposite effect,” she described.

“One member state will have to take up the role of reference member state anyway – and the other countries, concerned member states, will be asked to analyse the RMS assessment report, which engages even more resources than the CP.”