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AESGP Annual Meeting: OTC Antifungals, Antivirals Could Become Rx In EU

by [David Ridley](#)

The European Commission shocked participants at this year's AESGP Annual Meeting by warning that OTC antifungals, like treatments for athlete's foot, and OTC antivirals, like cold sore creams, could soon become prescription-only within the region, under proposed revisions to the EU pharma legislation. There is hope, however. The proposals are still open to feedback from industry, the AESGP points out, and even if this proposal becomes law, member states can waive this prescription requirement under certain conditions.

OTC antifungals, like treatments for athlete's foot, and OTC antivirals like cold sore creams could soon become prescription-only within the European Union, according to the European Commission.

New "prudent use" rules proposed by the Commission as part of its reforms to EU pharmaceutical legislation include placing OTC antimicrobials under prescription status within the region, revealed the EC's Olga Solomon at the AESGP's Annual Meeting in Paris, France on 23 May. To tackle antimicrobial resistance (AMR), the Commission has come up with a set of targets for reducing overall antimicrobial consumption by 20%. (Also see "[EU Reforms Include 'Prudent-Use' Targets For Cuts To Antibiotic Consumption](#)" - Pink Sheet, 3 May, 2023.)

The new prescription criteria, which also includes medicines with active substances that are bioaccumulative or toxic – raised "huge concerns" for [Bayer Consumer Care](#)'s head of regulatory affairs, EMEA, Christine Eising.

AESGP Welcomes EU Pharma Revision But Warns Of 'Unintended Negative Consequences'

During the first session of the meeting – “EU Pharmaceutical Law review: what opportunities for self-care?” – Eising argued that the proposal was “counter-productive” in terms of the EC’s other goals of expanding access to medicines.

Quick treatment is “absolutely mandatory” for minor conditions like cold sores which can soon spiral out of control, Eising pointed out. “If I have to go to the doctor when I get a cold sore it will be spreading round my face,” she noted.

“We believe the EU pharma review is key to keeping us competitive with other jurisdictions, and to keep up with innovation,” Eising concluded. “However from an OTC perspective, we feel like we need to work on this more, and we would be very happy if we could have further discussions to ensure access.”

Surprise!

Judging by the reaction of the audience, industry had not expected the relevant clauses in the proposed regulation and directive to include OTC antifungals and antivirals.

AESGP director general Jurate Švarcaite told the EC’s Solomon that the expanded scope was “a surprise to us.”

“We thought AMR was more about antibiotics rather than antifungals and antivirals.”

“Was it intentional to capture everything?” Švarcaite asked Solomon in the Q&A.

“Yes it was. But that doesn’t mean it was easy,” replied Solomon, who is head of the EC’s DG Sante unit - Medicines: Policy, Authorization And Monitoring.

“In order to be future proof, making something now that would be sustainable over time, we said we need to cover everything,” Solomon explained.

Solomon did, however, offer an olive branch to industry. “There are provisions in the legislation to keep flexibility, so member states can waive the Rx status depending on pack size, strength etc.”

After the session, Švarcaite emphasized this point on social media. Responding to a post by HBW

By [David Ridley](#)

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European self-care industry association AESGP says it supports the revision of the EU pharmaceutical legislation “in principle,” but has concerns that some of the proposals “may have unintended negative consequences.”

[Read the full article here](#)

Insight on LinkedIn about the proposed reverse switch of OTC antimicrobials, she said:
“Important to note that the final decision will be made in national markets based on case-by-case assessment of each antimicrobial.”

OTC Savings

The news came as AESGP published research showing that self-care saves Europe’s healthcare system €36bn (€39bn) a year – a saving that could potentially rise to more than €54bn if more, not fewer, medicines are made available OTC.

Pointing to the potential cost of reverse-switching popular OTCs like Bayer’s Canesten antifungal range, the research found that, without self-care, doctors would have to work an extra 2.4 hours each day.

“In the face of unprecedented times that require health systems to adapt,” Švarcaite said, “the promotion of self-care in Europe ensures the efficient and sustainable use of health system resources and guarantees that people have full and reliable access to health care while feeling empowered to take care of themselves whenever possible.”