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Systemic, Not Topical Antimicrobials Should Be Prescription-Only, Says EU Rapporteur

by [David Ridley](#)

Topicals should not be included in the proposed prescription-only requirement for antimicrobials, including antifungals and antivirals, suggests EU rapporteur Pernille Weiss in her response to the European Commission's planned overhaul of the EU pharmaceutical legislation.

Only systemic antimicrobials should be prescription-only, says the European Parliament's rapporteur for the draft directive that is part of the planned overhaul of the EU pharmaceutical legislation.

Targeting the part of the draft directive that would move all antimicrobials, including OTC antifungals, like treatments for athlete's foot, and OTC antivirals, such as cold sore creams, to prescription-only status within the European Union, rapporteur Pernille Weiss said that she "wishes to ensure continued patient access antimicrobials not for systemic use."

To this end, Weiss, who is MEP for the center-right European People's Party, suggests an amendment to Article 51 of the [draft directive](#), which concerns "products subject to medical prescription," changing point (e) which states "is an antimicrobial" to "is an antimicrobial of systemic administration."

"The [draft report](#) takes a less strict approach to the prescription status of antimicrobials and proposes a differentiated regulation whereby only antimicrobials that are of systemic administration and antibiotics must be prescription-only," explained lawyer Els Janssens.

There is no definition in the report of "systemic administration," noted Janssens, who is counsel in commercial law, litigation and healthcare regulatory issues at law firm Baker McKenzie. "In

our general understanding medicines of systemic administration are those that affect the whole body, as opposed to topical medicines that act locally.”

Welcomed By Industry

The amendment was welcomed by the Association of the European Self-Care Industry, which has been critical of the move since it was announced out of the blue at the association’s Annual Meeting in May this year. (Also see "[AESGP Annual Meeting: OTC Antifungals, Antivirals Could Become Rx In EU](#)" - HBW Insight, 24 May, 2023.)

“Putting all antimicrobials on prescription would not be effective to curb antimicrobial resistance and would add pressure to healthcare systems,” commented AESGP director-general Jurate Švarcaite.

“It is sensible that some antimicrobials, such as antibiotics and products taken orally that have a systemic effect, should be prescription-only,” Švarcaite continued.

“However, it does not seem wise to put a prescription status on other products, such as anti-herpes ointments, dandruff shampoos, athlete's foot creams, and vaginal thrush products.”

Health System Overload

Self-care antivirals and antifungals help people to “take timely action” and “avoid aggravation of the condition, which could result in a requirement for higher dosages and longer-term usage,” Švarcaite pointed out.

“This time-sensitive availability reduces the burden on national healthcare systems and prevents escalation of the infection or its transmission,” she told HBW Insight.

For example, in 2022, just under 50m packs of topical antifungals for nail, vaginal or oral fungal infection were sold in Germany, Austria and the Netherlands combined, the AESGP explained in a recent published position paper.

This total represents the potential number of additional medical consultations needed if these medicines were subject to a medical prescription, the association noted. (Also see "[AESGP: Rx Status For Antifungals And Antivirals Risks Health System Overload](#)" - HBW Insight, 22 Aug, 2023.)

The point was also made by the Dutch central government, De Rijksoverheid, in a letter to the Dutch parliament. (Also see "[German Regulator, Dutch Government Criticize EU's OTC Antimicrobial Reverse-Switch Plans](#)" - HBW Insight, 28 Jun, 2023.)

Describing the proposal as “undesirable,” the government said it recognized the need for measures to reduce AMR, but is of the opinion that making all antimicrobials subject to

prescription would place a too greater burden on the country's healthcare system as well as on patients and consumers.

The proposal has also come under fire from consumer healthcare industry associations across Europe, such as BAH (Germany), Netrofarm (the Netherlands), NèreS (France), IGEPHA (Austria), ASSGP (Switzerland), as well as global switch expert Natalie Gauld. (Also see "[“Totally Unacceptable” – Industry, Experts React To EU OTC Antimicrobial Reverse-Switch Proposal](#)" - HBW Insight, 26 Jun, 2023.)

Next Steps

Weiss' report will be subject to debate at the EU parliament's next Environment, Public Health and Food Safety (ENVI) committee meeting, which should take place at the beginning of November, explained Janssens' colleague Olha Sviatenka.

"After one or more meetings, the committee should eventually adopt a consolidated report and this report would then be subject to the EP's plenary vote," continued Sviatenka, who is associate in healthcare regulatory issues at Baker McKenzie.

The European Council will also examine the Commission's proposals in parallel to parliament. "Given the sensitivity and breadth of the topics covered in the package we expect a heated debate both in the EP and in the Council," Sviatenka said.

Once the European Parliament's Committee and the Council have finalized their position on the proposal, informal negotiations with the aim of reaching a first reading agreement on the proposal are then expected to begin.

Bad Timing?

Janssens said the timing for approval of the new legislation is currently "unclear."

"The sensitivity of the measures contained in the proposals and the divergence in views that we are already seeing around them show that this will be a very complex legislative process," Janssens noted.

"The parliamentary elections in June 2024 will only bring added pressure to the timings and negotiations," she added.