Briefing paper | Non-Prescription Medicines

AESGP

Recommendations to strengthen Prescription-to-Non-Prescription Switch in Europe

To improve the consistency, efficiency, and accessibility of non-prescription medicines (NPM) across Europe, AESGP proposes action at national and EU-coordinated levels to eliminate disparities in switch procedures and make reclassification transparent, predictable, and efficient.

1 Simplify and increase transparency of switch pathways

EU Rx-to-NPM pathways require further simplification with clear, transparent procedural steps and applicant requirements.

2 Consider wider switch benefits in decision-making

Assessments must weigh risks against public health benefits like improved access, patient empowerment, and reduced healthcare system pressure.

3 Improve transparency and predictability for MAHs

Switch procedures should offer clear requirements, predictable timelines, and structured dialogue opportunities with regulatory authorities.

4 Publish clear national guidance in English

National medicines agencies should publish detailed guidance on switch procedures, fees, timelines, and data requirements, including English versions.

5 Strengthen dedicated switch expertise within agencies

Authorities need specialised non-prescription departments or assessors to support consistent evaluation and best-practice sharing.

6 Provide pre-submission advice and meetings

Agencies should offer early scientific/regulatory advice, exploring **Simultaneous National Scientific Advice** across Member States for MRP/DCP switches.

7 Maintain public registers of switch decisions

Authorities should publish databases of Rx-to-NPM switch outcomes and assessment reports to increase transparency and guide future filings.

8 Clarify the role of expert committees

Advisory committee roles must be clearly defined to deliver expert support while preserving predictable, evidence-based decisions.

AESGP

Unlocking switch innovation: 3 years of data exclusivity for better self-care

Prescription-to-non-prescription switch is an important self-care innovation. Enabling medicines to become safely accessible without a prescription expands treatment options for citizens, supports responsible self-care, and helps reduce unnecessary pressure on healthcare systems.

Why change is needed

High investment and data demands

Switch applications, particularly first-in-class, require substantial investment in clinical and non-clinical data, consumer research, actual-use studies, behavioural and real-world evidence to prove safe use without direct medical supervision.

Flawed EU exclusivity framework

The current EU framework provides insufficient incentives, offering only 1 year of data exclusivity. In practice, this limited period fails to protect against launch delays or swift competitive entry. Unsurprisingly, switch data **exclusivity has been granted only twice in over 20 years**.

Global competitive disadvantage

The scope of eligible data remains too narrow to reflect modern switch application requirements. Europe is less competitive, overall, than major markets like the US and Japan, which already provide **3 years of data exclusivity**.

Key policy actions

Extend switch data exclusivity from 1 year to 3 years

The EU should provide three years of data exclusivity for prescription-to-non-prescription switches. This creates a predictable incentive for investment, especially for complex, first-in-class switches requiring substantial evidence.

Broaden the scope of protected evidence

The scope of protected data should expand to include modern evidence types, such as robust real-world evidence, behavioural research, and actual-use studies that support the assessment of safe and effective non-prescription use.

A stronger exclusivity framework will foster innovative switch opportunities, increase self-care availability, improve investment predictability, and ensure timely access to appropriate non-prescription medicines.