RAPS EURO Convergence 2025 Brussels

INTERNATIONAL
DRUG DEVELOPMENT

1 EU General Pharmaceutical Legislation (GPL) revision

Significant attention was paid to the upcoming reforms and their potential impact on pharmaceutical development and market authorization processes

Impacting the current 20 year old framework,

Understanding these shifts is crucial for future strategies

Amending Variations Regulation (EC) 1234/2008, the new regulation is applicable from **01.01.2025.**

2 EU Variation Regulatory Reform

In a nutshell:

- IA annual updates
- Supergrouping
- Worksharing procedures mandatory or voluntary
- Biologicals: risk-based decrease in cat.

Implementation of “Guidelines on the details of the various categories of variations” expected **Q2 2025**

Expect a 2nd revision once the GPL is revised

From **AI in regulatory** compliance and its use by NCAs to the implications of the **EU AI Act** , the integration of artificial intelligence in our field is rapidly evolving

It's vital to understand both the opportunities and the regulatory hurdles.

Do not miss the boat as the pace of **this change is fast** !

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- EMA and FDA experiences assessing AI models in view of regulatory submissions
- Use of AI for regulatory decision-making shows great promise, but also carries risks

3 The Rise of AI in Regulatory

4 The new HTA Regulation

Is applicable **since January 2025**

It is applicable to medicines and medical devices/IVDs.

It creates synergies between HTA bodies and regulators through:
Joint Clinical Assessments (JCA) & Joint Scientific Consultations (JSC)

The first step applies to MAAs for a new cancer medicine or an advanced therapy medicinal product.

It will cover all new medicinal products in 2030.

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The **Critical Medicines Act** has been proposed by the EC in March 2025

The **ESMP platform** of the EMA was launched in Feb 2nd 2025 and becomes mandatory.

5 Medicines Shortages

It is now necessary for pharmaceutical industries to have **a standardized risk-based approach for shortage prevention** and mitigation plan combining patient criticality and supply chain vulnerabilities.

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