



EU Pharmacovigilance Legislation Clears Legislative Hurdle, Approaches Final Form

The proposed EU pharmacovigilance legislation has cleared a significant legislative hurdle on April 26-27, 2010. The ENVI Committee has adopted compromise amendments as a result of the language that was inserted into the draft PV directive, forming the 'ENVI Position'.

History

Previously, *Rapporteur McAvan* had issued a draft report after reviewing the EC proposals which received approximately 240 comments/amendments, in addition to the 56 amendments that she proposed in the draft report.

Then, *Rapporteur McAvan* and her five shadow rapporteurs (one shadow per political grouping within the European Parliament) reviewed the approximately 300 amendments together and drafted new compromise amendments to the EC proposal that incorporate several amendments/direction of those amendments within the most relevant article of the proposed text. The ENVI Committee voted on the 270 amendments that emerged as a result of this process.

Key Amendments to Directive

The following seven compromise amendments to the Directive were adopted (key impact is also highlighted):

Article 11 (3)(a) - Intensively monitored products will be subject to the addition of a black symbol with the following text: 'This medicinal product is **subject to additional safety** monitoring. All suspected adverse reactions should be reported to your **doctor, pharmacist, healthcare professional, or to** <name and web-address, **postal address and/or telephone number** of the national competent authority>'.

Article 21a – A marketing authorization may be granted to conduct a post authorization safety and efficacy study if important efficacy questions remain or if advances in the understanding of the disease would significantly change prior efficacy evaluations.

The Commission shall provide guidelines and criteria on the concept of clinical effectiveness.

Article 59(1) - The proposal for Summary of Essential Information on the Summary of Product Characteristics and the Package Information Leaflet will be deleted. The Commission will have 18 months from the date that the legislation comes into force to come forward with a proposal to revise the Package Information Leaflets, and the Summary of Product Characteristics.

Article 102 – Pertains to reporting by patients and affirms the concept of 'no-blame' reporting. Patients can report directly to a national competent authority in both electronic and non-electronic media. A public campaign will be undertaken for reporting and HCPs will receive training as well. While reporting cannot be done anonymously, ADR reports cannot be used in legal proceedings against a health professional.

Article 105 - The national competent authorities will be responsible for the management of funds intended for pharmacovigilance activities, in order to guarantee their independence.





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Article 106 - Each Member State shall set up and maintain a national medicines web-portal, **including a dedicated medicine safety web page**. On the page, the Member State needs to make public:

(1) risk management systems **and a user-friendly summary of these systems**, for medicinal products authorized in accordance with this Directive

(1a) the most up-to-date electronic version of the leaflets of the medicines available on the national market in the national language (and where applicable the link to the Agency's EudraPharm database);

(1b) the most up-to-date electronic version of the summary of the product characteristics and any conditions established in accordance with Articles 21a, 22 and 22a, (including the PASS and efficacy studies referred to above) together with any deadlines for their fulfillment, for each medicinal product which they have authorized;

(1c) assessment reports for medicinal products authorized in accordance with this Directive (and where applicable, the link to the EPAR summary)

Key Amendments to Regulation

The following two changes to the Regulation were adopted:

Article 24(2)(3a) states that: **'The Agency shall work together with all stakeholders, including research institutions, health professionals and patient and consumer organizations, in order to define the "appropriate level of access" to the Eudravigilance database.'**

Article 26(10)(a) of the Regulation states that there will be a consultation with multiple stakeholders including industry, prior to and during subsequent reviews of the European medicines safety web-portal.

Next Steps

All amendments to the Directives and the Regulations will be consolidated into the EVNI Position, which will go to the European Parliament likely in June 2010. After this vote, the Parliament Position goes to the Council for review along with *Rapporteur McAvan*. At the conclusion of this review, Council will adopt the Council Report. Upon approval by the Council of Ministers, the position will need to be translated into the 22 official languages of the EU for review. The legislation can then be published in the Official Journal, to be effective 18 months from that date.

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