Medicinal products for human use: pharmacovigilance of products

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The Committee on the Environment, Public Health and Food Safety adopted the report by Linda MACAVAN (S&D, UK) on the proposal for a directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. It recommended that the European Parliament's position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

A more robust risk assessment committee: Members propose increasing the powers of the Pharmacovigilance Risk Assessment Committee (PRAC) in relation to the coordination group. The coordination group is not a specialist body on pharmacovigilance. The PRAC should be the only body in charge of pharmacovigilance and risk assessment, in order to avoid undue duplication of roles.

The Committee for Medicinal Products for Human Use shall adopt an opinion which differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, only if there exist strong scientific and public health grounds for doing so. The Committee for Medicinal Products for Human Use shall explain these grounds in a justification to be annexed to its opinion.

Summary of Essential Information: the Commission had proposed this summary to be included in the Package Information Leaflet. However, the committee deleted this and inserted a clause specifying that for medicinal products included on the list referred to in Article 23 of Regulation (EC) No 726/2004, the statement, preceded by a black symbol which shall be decided on by means of delegated acts: "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."

For medicinal products not included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the following statement should be included: "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.

The report adds that it is important for healthcare professionals and patients to identify easily the most relevant information about the medicines they use. In order to facilitate such identification, the Commission should review the summary of the product characteristics and the package leaflet within 18 months.

Within 18 months of the entry into force of the Directive, the Commission shall present to the European Parliament and the Council an assessment report on how the summary of product characteristics and the package leaflet should meet the needs of patients and healthcare professionals. On the basis of this, the Commission shall issue proposals in order to improve the readability, layout and content of these documents.

The summary of essential information is deleted from the text.

Marketing authorisations and post-authorisation safety and efficacy studies: marketing authorisation may be subject to the requirement to conduct post-authorisation safety studies or post-authorisation safety

and efficacy studies where important questions relating to the efficacy of a product remain, or when scientific advances in the understanding of the disease or in the clinical methodology would significantly change previous efficacy evaluations. For this purpose, the Commission shall provide guidelines. The Commission shall also, based on data received from the Agency and Member States, produce a report focusing on the concept of clinical effectiveness, on studies and data required and on methodologies for assessing it.

The competent authorities shall have the power and appropriate resources to immediately suspend or revoke the marketing authorisation in the event that the conditions included in the marketing authorisation are not fulfilled by the relevant deadline.

Renewal of marketing authorisation: the committee deleted the words « insufficient exposure to the product » as a criterion for restricting renewal to a five-year period. It states that the words introduce a degree of uncertainty especially for products, such as orphan drugs, for which exposure is unlikely to ever be sufficient (sufficient exposure is a very difficult threshold/ benchmark to achieve). The new proposal should not regress on improvements introduced by the previous revision of the medicines legislation which aimed at reducing the number of renewal procedures.

Reporting of adverse drug reactions: Member States must take all appropriate measures to encourage patients, doctors, pharmacists and other health-care professionals to report suspected adverse reactions to the national competent authority; these measures shall include training for health professionals and a public information campaign for patients. Patients' and consumer organisations shall be involved in providing information to patients and in developing public information campaigns in cooperation with regulatory bodies.

Member States must also:

- facilitate direct patient reporting through the provision of alternative reporting formats in addition to web-based formats;
- ensure that the public is given important information in good time on pharmacovigilance concerns relating to the use of a medicinal product through publication on the web portal and through other means of public information as necessary;
- pensure that any biological medicinal product prescribed, dispensed, or sold in their territory which is the subject of a report on a suspected adverse reaction is identifiable by, where available, the name of the MAH, the INN, the name of the medicinal product and the batch number, using the standard forms and procedures developed in accordance with Regulation (EC) No 726/2004 and taking due account of the developments within the EudraVigilance system.

Reporting of suspected adverse reactions due to medication errors should be on a 'no blame' basis, and should be legally privileged.

Transparency and medicine safety: each Member State shall set up and maintain a national medicines web-portal, including a dedicated medicine safety web page which shall be linked to the European medicines web-portal. Member States must provide:

- 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);
- for each medicinal product which Member States have authorised, the most up-to-date electronic version of the summary of the product characteristics and any conditions established, together with any deadlines for their fulfilment;
- assessment reports for medicinal products authorised in accordance with this Directive (and where applicable the link to the EPAR summary).

Reporting pharmacovigilance data: the Eudravigilance database should simultaneously and electronically notify the relevant Member States of reports submitted by market authorisation holders. From this perspective, and in order to achieve the objectives referred to above, Member States should not impose any further requirements on marketing authorisation holders in respect of the prompt and regular reporting of suspected adverse reactions. The Eudravigilance database and the national database should be fully interoperable.

The proposed new requirement for pharmaceutical companies to report all non serious suspected adverse reactions (including non-medically confirmed consumer reports) will have a massive impact on the workload of both the industry and regulatory authorities since the majority of cases are non-serious unconfirmed consumer reports. The committee states that certain holders of authorisations will be exempt.

Concerning suspected adverse reactions reported by patients, Member States may decide whether those are reported directly or via healthcare professionals.

Reporting by healthcare professionals should be particularly encouraged in cases where their contribution is essential in order to understand the significance of the adverse reaction and of adverse reactions derived from medication errors. To facilitate this type of reporting and to protect the citizen, access to data contained in patients' medical files should be accessible to healthcare professionals.

Data protection: the Directive should apply without prejudice to Directive 95/46/EC and Regulation 45 /2001/EC on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The purpose of safeguarding public health constitutes a substantial public interest which justifies the processing of identifiable health data as long as this is processed only when necessary and the parties involved assess the necessity of processing such data at every stage of the pharmacovigilance process.

Guidelines on good pharmacovigilance practice : the Commission, in cooperation with the Agency, Member States and stakeholders, shall prepare detailed guidelines on good record-keeping practices for pharmacies and others that dispense or administer medicinal products, to ensure retention of records necessary for filing a pharmacovigilance report or to provide information needed by a marketing authorisation holder conducting an evaluation of an adverse event and to facilitate follow-up investigations by the marketing authorisation holder and national competent authorities.

Environmental supervision and protection: Member States shall appoint one or several national authorities to monitor adverse environmental effects of medicinal products on public health or the environment. If one of these authorities identifies an environmental risk that is higher than that indicated in the evaluation or if it finds new adverse environmental effects, it shall forthwith transmit all findings to the European Medicines Evaluation Agency and to the competent authority. The Agency shall, upon receiving such information, assess whether the risk-benefit balance remains favourable when taking into account the new findings. This must not lead to the withdrawal of the authorisation for drugs necessary for treating life-threatening or serious diseases."