

Medicinal products for human use: pharmacovigilance of products

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On the basis of progress reports, the Presidency informed the Council of the **state of play in the negotiations** on two parts of the "pharmaceutical package": preventing falsified medicines from entering into the legal supply chain of medicinal products and the strengthening and rationalising of the current pharmacovigilance system.

Under the Swedish Presidency, the preparatory bodies of the Council pursued their work with high priority on these two parts of the package.

1) Concerning the [draft directive on preventing the entry into the legal supply chain of falsified medicinal products](#), the working group reached tentative agreement on a number of technical aspects, including:

- the definition of "falsified medicinal products";
- the proposed definition of "trading of medicinal products" has been changed to "brokering of medicinal products" and amended, thereby clarifying which actors in the supply chain should be subject to the responsibilities of brokers. The proposed introduction of obligations for brokers aim to reinforce the traceability of medicinal products;
- a clarification of the relationship between the proposed new provisions in Directive 2001/83/EC and Community legislation on intellectual property rights.

Other elements of the proposal still need further discussion, notably with regard to the strengthening of controls of non active substances used in pharmaceuticals (excipients) and the proposed safety features aiming to render falsification more difficult.

The proposal includes provisions requiring the accreditation of third party auditors of Good Manufacturing Practices and Good Distribution Practices. A majority of delegations object to accreditation, since they maintain that such a system could result in a transfer of responsibility from manufacturers and importers as well as make enforcement by national competent authorities more difficult. The Presidency has therefore proposed to delete the provisions regarding accreditation from the text. Some delegations have expressed an interest in the possibility of establishing third party accreditation at a national level.

2) Concerning the proposals for a regulation and a [directive](#) on strengthening the EU system for the safety monitoring of medicinal products ("pharmacovigilance"), the working group reached tentative agreement on a number of questions including:

- a clarification of the relation between the proposed new provisions in Directive 2001/83/EC and Regulation (EC) 726/2004 on the one hand and the Community legislation on protection of personal data on the other hand;

- a strengthening of the role of the Pharmacovigilance Risk Assessment Committee (PRAC) in relation to the Committee for Medicinal Products for Human Use and to the Coordination Group set up by Article 27 of Directive 2001/83/EC (CMD), including an obligation for these last two bodies to explain any differences in opinion compared to the PRAC;
- a change in the composition of the PRAC and in the method for nominating the PRAC members so that all Member States will be represented;
- the inclusion of a requirement for the Agency, in collaboration with the Member States and the Commission, to draw up functional specifications for the Eudravigilance database which will take account of the role and experience of national competent authorities for pharmacovigilance. The new reporting obligations to Eudravigilance will not apply until these specifications are met and to this end a transitional period is envisaged;
- the legal status of CMD opinions and how they are implemented in Member States. Here, text redrafting proposals are under legal scrutiny.

The Working Party has continued to discuss other central provisions of the proposals, mainly in relation to the Community Procedure and Referrals, the Recording and Reporting of adverse reactions, the Periodic Safety Update Reports and the Post Authorisation Safety Studies.

A number of issues still require further examination, such as the recording and reporting of adverse reactions and the proposed list of medicinal products for human use under intensive monitoring.

At this stage, all delegations have a general scrutiny reservation on the entire proposal while the Danish, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.

3) With regard to the third part of the "pharmaceutical package", the proposals for a [regulation](#) and a [directive](#) concerning information for the general public on medicinal products, the Presidency recalled the strong concerns of many Member States. The Commission made it clear that it is prepared to show flexibility in order to find a common basis for the future negotiations.