



# **PGEU CONTRIBUTION**

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## **THE EUROPEAN MEDICINES AGENCY ROAD MAP TO 2010 – DISCUSSION PAPER**

## Summary

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The Pharmaceutical Group of the European Community (PGEU) welcomes the opportunity to participate in this consultation.

On **Information on Medicines**, the PGEU strongly supports the aim of providing information that is easy to read and understand. It supports the concept of user testing. It also urges the Agency to take into account, when considering the format and content of its proposed database on all medicines for which Marketing Authorisations have been issued in the EU, the need to include information to help patients on long term medication to realise the potential implications of non-adherence and to help health professionals, in partnership with patients, to overcome adherence problems.

On **Pharmacovigilance**, the PGEU asks the Agency to promote to Member States, the benefits to protection of public health of formally including community pharmacists in pharmacovigilance systems.

On **Transparency**, the PGEU considers that the policy of the Agency should be that documents, including agendas and minutes of meetings, should be publicly available unless there are reasons for confidentiality that will withstand public scrutiny, for specific documents. We welcome the fact that, in future, the Agency will be able to publish details of applications for Marketing Authorisations that are withdrawn and, with reasons, details of application declined.

On **Communication**, we would welcome discussions with the relevant unit of the Agency, on how the PGEU, through its member organisations, could assist in ensuring the provision to community pharmacies in all Member States, with the minimum possible delay, of important information from the Agency, related to public health or safety.

On **Medicines for Children**, the PGEU welcomes the aim of new Community legislation to increase the development of medicines for children. A Statement of Principle of the International Pharmaceutical Federation on this important topic, which has the support of the PGEU, is attached.



## Introduction

The Pharmaceutical Group of the European Union (PGEU) represents the community pharmacists of 29 European Countries. The Members of the PGEU are the professional bodies and pharmacists' associations in EU Members States, EU candidate countries and EEA Member States.

Community pharmacists throughout Europe are committed to making a major contribution to improving public health by:

- Seeking to ensure that people derive maximum therapeutic benefit from prescribed medication dispensed in pharmacies;
- Providing high quality advice to ensure responsible self care, including self medication when that is appropriate;
- Encouraging healthy lifestyles through effective health promotion and health education strategies.

The PGEU welcomes the publication of the discussion paper and particularly appreciated being able to participate in the meeting between representatives of the Agency and Professional Associations and Learned Societies on 4 June 2004 and the Infodays organised both by the CPMP and by the CVMP, the most recent one held on 17 June 2004.

The EMA's Mission Statement is set out in Chapter 1 of the discussion paper. This encapsulates the balance that the Agency must strike between high quality evaluation of medicinal products and allowing timely access to innovative medicines. At all times, the interests of patients must be the first priority.

In general, the PGEU supports the initiatives designed to permit quicker access to the market of truly innovative medicines. This will, however, bring into even greater focus, the other aspects of the Agency's Mission Statement, pharmacovigilance and the provision of useful and clear information on medicines to users and health professionals. It is on these topics that the PGEU mainly wishes to comment. We do not, therefore, intend to comment Chapter by Chapter but rather by individual topic. This also reflects the fact that topics such as pharmacovigilance and information on medicines are mentioned in more than one Chapter.

## Information on Medicines

1. The PGEU welcomes the fact that, in due course, the Agency will provide a database containing information on every medicine for which a Marketing Authorisation has been granted in the EU, whether through the centralised procedure or by a national regulatory authority. It is intended that the database will be accessible electronically and it is, of course, essential that community pharmacists have access to it, if they are to be in a position to provide a service of the highest quality to those who seek advice in pharmacies.
2. Although it is true that people now seek information about medicines and medical treatments from many different sources, it is also true that they seek advice from their doctor or pharmacist on interpreting or clarifying the information, often conflicting, that they have obtained. The community pharmacist is the person from whom such advice is often sought, as the final link with the medicine user in the chain involving regulatory body, manufacturer and prescriber. It should also be borne in mind that when consideration is being given to information for "prescribers" of medicines in the human field, that they may nowadays include pharmacists and other health professionals, as well as physicians and dentists.
3. Reference is made in Chapter 2 of the Paper to the impact of an ageing population. One feature of that will probably be an increasing number of people taking medication for long-term conditions. As the World Health Organisation (WHO) identified in its 2003 Report "Adherence to long term therapies, - evidence for action", non-adherence to prescribed courses of medication is a major problem. The often quoted figure is that in developed countries, adherence among patients suffering from chronic conditions averages only 50%. Non adherence leads to failure of treatment, involving in some cases additional otherwise unnecessary costs for secondary care and in the worst instances severe disability and even premature death. One conclusion in the WHO Report was that "increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvements in specific medical treatments." As the WHO Report points out, the reasons for non-adherence vary, but often



encountering an adverse side effect is the trigger. The patient may decide to lower dosage, or cease taking the medicine, without discussing the consequences with their doctor or pharmacist. There is evidence that people make conscious decisions to cease taking medication, rather than just forgetting to do so. Information about medicines provided by the Agency should take this into account, with the inclusion of information, for both users and health professionals about the potential consequences of non-adherence and, where possible, on how best to deal with any of the side effects listed.

4. The Agency's "focus on the needs and expectations of patients and users of medicines" is referred to in Chapter 3.2 and the aim of providing information that is easy to read and understand in Chapter 4. In this regard, community pharmacists know from experience that the current "patient information leaflets" made available in packs of medicines, leave much to be desired. The wording is often complicated and sometimes appears to be presented in a manner designed to protect the legal position of the holder of the Marketing authorisation, rather than to inform the user. The PGEU supports the aim of providing easily understandable information and the concept of user testing to ensure that the objective is achieved, and asks the Agency to actively involve community pharmacists in such revision. The package insert is not only a crucial information tool for the patient, but it is also a daily working tool for the pharmacist.
5. It should also be noted that research suggests that written information, however clear and easy to read, when related to medicines, is not the total answer. Personalised advice from the pharmacist at the time a medicine is dispensed, when the attention of the individual is focused on the treatment rather than a diagnosis, supported by printed information, is the best combination to achieve the desired result. The PGEU would suggest that in any information about medicines, aimed at users or potential users, provided by the Agency, there should be explicit advice to discuss the information with their doctor or pharmacist.

## Pharmacovigilance

6. Chapter 3 refers to the increased role of the Agency in pharmacovigilance and the Agency's "Vision" in Chapter 4 refers to the aim of providing for "better protected" patients and users of medicines. As in all other cases where "users of medicines" are mentioned, medicines available without prescription should not be overlooked. There have been a number of instances in the past when products used for medicinal purposes, previously thought to be safe to be taken without medical prescription, have been shown to have serious adverse effects. In addition, Attachment 5 makes it clear that pharmacovigilance must be pursued "throughout the lifecycle of a medicinal product ...to further strengthen public health protection." Nowadays the "lifecycle" of a medicinal product may start as one used only in a hospital setting and perhaps to be prescribed only by specialists, then become a "normal" prescription-only medicine for use in general medical practice, then become a medicine available from pharmacies without prescription and finally, and unfortunately in the opinion of the PGEU, be available for sale in non-pharmacy outlets. At each step, a larger population than previously is exposed to the effects of the medicine and new adverse effects not seen at an earlier stage can occur. There must therefore be, as stated in Attachment 5, "continuous and adequate monitoring of the safety of medicinal products, once put on the EU market."
7. In some EU Member States community pharmacists are formally included in the system for reporting suspected adverse reactions to medicines. This is a logical situation since people discuss any difficulties they are having with their medicines when presenting a prescription or collecting a repeat supply. Such discussions should become even more frequent if people are encouraged to do so, not least to improve adherence, as suggested above. Unfortunately, pharmacists are not included in pharmacovigilance systems in some Member States at present. This is a weakness. We suggest that the Agency should promote with the regulatory authorities in those EU countries where they are not at present included, the concept of officially including pharmacists in the pharmacovigilance scheme. Any solution which could contribute to strengthening the current system should be encouraged to ensure that the EU put in place an "adequate" system, as stated in Attachment 5, to protect the health and safety of EU citizens.



## Transparency

8. Attachment 6 deals with this topic. The PGEU contributed to the public consultation by the Agency on transparency initiatives and supported virtually all the proposals in the document. Our general response to the questions posed in Attachment 6, is that the starting point should be complete openness unless there are reasons, which will withstand public scrutiny, for confidentiality. Thus we consider that the proceedings of the bodies mentioned towards the foot of this Attachment and the documents before them, should generally be available publicly. It would be preferable for the Agency to be proactive in this respect rather than face inevitable court action to secure disclosure.
9. We would also agree that information on ongoing applications should be disclosed along the lines suggested in the fourth bullet point. We understood, from a presentation on 4 June 2004, that in future the Agency will be able to publish details of applications for Marketing Authorisations that are withdrawn and, with reasons, information on applications declined. That, in our view, will further strengthen the confidence of EU citizens in the work of the Agency.

## Communication

10. We support the proposal in Attachment 6 that the Agency should develop, in close collaboration with national regulatory authorities, a European Communication Strategy. This, as stated, is particularly important in the field of communications on post authorisation safety data. We understood, however, from a comment made by the Executive Director of the Agency on 4 June 2004, that at present, although in some EU countries important information can be conveyed to health professionals within 24 hours, this can take up to 14 days in others. Here we wish to repeat a comment we made in our contribution to the Agency's Consultation on Transparency Initiatives. PGEU member associations have regular contact with the community pharmacies in 29 European countries. With adequate support, we could develop a dissemination strategy, using PGEU member organisations, to ensure necessary important information reached these pharmacies in the shortest practicable time. At present, we inform member associations of Agency press releases and EPARs and leave it to them to decide how best to convey the information to their members. This will no doubt continue to be the right approach for some Agency documents. However, in specific cases, where there was urgency, we could develop a fast track system. This could also have the effect of raising the profile of the EMA with EU community pharmacists. We would welcome the opportunity to explore possible collaboration in this area with the relevant unit within the Agency.

## Medicines for Children

11. Mention is made in Chapter 3.1 of new Community legislation that aims to increase the development of medicines for children and the implications this has for the Agency. The "off licence" use of adult medicines for children is something that is of concern to pharmacists worldwide. A statement of Principle on Pharmaceutical Research in Paediatric Patients was adopted by the Council of the International Pharmaceutical Federation in 2000. This statement, a copy of which is attached, has the support of the PGEU.

**END**

Enclosures:

1. International Pharmaceutical Federation (FIP) statement of principle, "Pharmaceutical research in paediatric patients"

