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# Report on the second stakeholder forum on the implementation of the new pharmacovigilance legislation

On 17th June 2011 the European Medicines Agency held a stakeholder forum on the implementation of the new pharmacovigilance legislation with a broad cross-section of participants including industry, patient, consumer and healthcare professional representatives as well as representatives from national medicines regulatory authorities and the Agency itself. This was the second in a series of stakeholder meetings taking place during 2011 and 2012 when the Agency aims to raise awareness of the new legislation and promote the timely exchange of ideas, concerns and opinions during the implementation phase. These meetings are not intended to replace the public consultation on the implementation measures that the European Commission and the Agency will organise in due course.

The first meeting, held on 15th April 2011, aimed at obtaining feedback from stakeholders mainly in relation to the Agency's and Member States' technical contribution to the draft European Commission implementing measures. This second meeting allowed stakeholders to discuss with the Agency and Member States their expectations on various aspects of the implementation of the new legislation.

The objectives of this second meeting were to:

- give an update on the progress of the implementation.
- introduce topics of relevance to stakeholders and for which specific feedback was sought.
- discuss a range of topics particularly relevant to patients and healthcare professionals.

The meeting was structured as sessions and panel discussions in which the different parties presented their views and expectations. The morning session was co-chaired by Noël Wathion, Head of the Agency's Patient Health Protection Unit, and June Munro Raine, chair of the Pharmacovigilance Working Party and Director of the Vigilance Risk Management of Medicines Division at the Medicines and Healthcare products Regulatory Agency (MHRA). The afternoon session was co-chaired by Isabelle Moulon, Head of the Agency's Medical Information Sector, and Dolores Montero, Head of Pharmacoepidemiology and Pharmacovigilance Division at the Spanish Medicines Agency (AEMPS).

The meeting was opened by Andreas Pott, the Agency's Acting Executive Director, who welcomed all participants, stressed the importance of the new legislation, and confirmed the Agency's commitment to work closely with stakeholders and to establish the necessary mechanisms to guarantee their timely input during the implementation process.

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Noël Wathion, who followed Andreas Pott's introduction, spoke of the challenges ahead. In particular he addressed the impact of the current economic climate on the implementation process, the existing budgetary constrains and the possible delays in implementation. It was confirmed, however, that despite the difficulties, the Agency's plans for the implementation are on track.

Franck Diafouka, from the the Agency's Pharmacovigilance and Risk Management Sector updated participants on the working methodology and governance structure in place to deliver the provisions laid down in the new legislation. The overall planning and key deliverables were presented.

Fergus Sweeny, Head of EMA Compliance and Inspection described the current thinking on the minimum requirements for quality systems to assure the integrity of the pharmacovigilance systems, which are being proposed as part of the implementing measures and which will entail specific obligations for marketing authorisation holders, national competent authorities and the EMA. He also updated participants on the measures being proposed with regard to the content and maintenance of the pharmacovigilance system master file kept by the marketing authorisation holders. In addition to European Commission implementing legislation on these topics, guidance for both particulars will be included in the "Good Vigilance Practice" (GVP).

Dolores Montero and Roberto De Lisa from the Agency's Pharmacovigilance and Risk Management Section presented the new Pharmacovigilance Risk Assessment Committee (PRAC). They introduced its mandate, responsibilities and composition and described the way it will interact with other groups and committees such as the Committee for Medicinal Products for Human Use (CHMP) and the Coordination Group. They also spoke of the unprecedented level of transparency which is anticipated, with much of the committee's outcome will be made publicly available (minutes, agendas, etc).

Albert Van Der Zeijden from the International Alliance of Patients' Organisations (IAPO) complemented the discussion by bringing an overview of his experience as patient observer in the Pharmacovigilance Working Party (PhVWP). His view served to confirm the added value of having patients in such a group.

Monika Benstetter, an external communication officer at the Agency and Doris Stenver, chief medical officer of the Danish Medicines Agency (DKMA) gave a first insight into the current proposal for public hearings in the context of the new legislation. Public hearings were presented as an opportunity to obtain feedback and information from stakeholders during the assessment of medicines. Further work is ongoing to define criteria on when to hold public hearings and to define a process for participation. The views of patients, consumers, healthcare professionals and industry were presented, and a panel discussion followed afterwards. Overall there was positive reception of the proposal. Ideally public hearings should be meaningful for the general public and be built upon realistic expectations. The possibility of establishing a mechanism capable of capturing existing public interest in holding a public hearing was highlighted, as well as a mechanism which would ensure that the programme of each hearing addresses those questions and issues which are of much relevance to the stakeholders.

Peter Arlett, Head of the Agency's Pharmacovigilance and Risk Management Sector, moderated the session on direct patient reporting and introduced Tony Avery of the University of Nottingham, who presented the results of a research project which evaluated the pharmacovigilance impact of patient reporting to the yellow card system in the United Kingdom. This overview was complemented with other existing national experiences on direct patient reporting (Denmark and United Kingdom) as well as reporting experiences from patients and consumers.

It was agreed during the panel discussion which followed that the value of direct patient reporting has been sufficiently demonstrated by the various research projects and pilots. Current evidence points to the need to increase awareness among patients of the opportunity they have to report adverse reactions directly, which is done infrequently at the moment. The role of patients' and healthcare

professionals' organisations was highlighted here. It was also concluded that patient reporting should be seen as a complement to the reporting made by healthcare professionals but not as a substitute; moreover, it is considered as an opportunity to strengthen the patient/healthcare professional relationship. Industry representatives also supported the principle of direct patient reporting.

The last session covered the new developments of Eudravigilance and its access policy. Sabine Brosch from the Agency's Pharmacovigilance and Risk Management Sector and Sarah Morgan, Head of Pharmacovigilance Risk Management at the Medicines and Healthcare products Regulatory Agency (MHRA), moderated the session. They updated participants on the enhanced functionality of the database introduced in the context of the new legislation. This includes, among others, simplified rules for reporting by marketing authorisation holders, patients and healthcare professionals, exchange of information with the World Health Organisation (WHO) and the European Monitoring Centre for Drugs and Drug Addictions (EMCDDA), etc. Mechanisms in place will ensure that accurate and reliable data is held in Eudravigilance. As regards the access policy, information will be made publically available in a phased manner, giving priority to medicines authorised through the centralised procedure while a second phase will give public access to information on non-centrally authorised medicines.

Representatives of patients, consumers, pharmacists and the pharmaceutical industry gave their views on the expectations that they have on the database, and highlighted the interest and relevance of the ongoing initiatives.

In the context of Eudravigilance development and medicinal product identification and in accordance with Article 57(2) of Regulation (EC) No 726/2004, Sabine Brosch updated participants on further progress on this area. The Agency will make public a format for the electronic submission of information on medicinal products for human use by 2nd July 2011. This format will be used from this date by the marketing authorisation holders with all products notified by July 2012. The format of the Eudravigilance Medicinal Product Report Message (EVPRM) will serve as the initial format. The Agency will update the format by the end of 2014, taking into account the ongoing international harmonisation and technical and scientific progress. Additionally training, information days, as well as specific tools will be made available to help stakeholders with their submissions (with particular consideration for SMEs).

The co-chairs of the afternoon session concluded the meeting, which was acknowledged to have been rich in feedback and ideas. The feedback received will be used to progress the implementation of the legislation. Participants were informed that further meetings and interaction with stakeholders on the new legislation are planned for 2011 and 2012. Additionally, the Agency will make use of all available channels (e.g. PCWP, HCP WG, Eudravigilance User Group, etc).

The agenda, list of participants, slide presentations and session videos will be made available on the EMA website.

The co-chairs thanked the speakers and participants for their contribution.