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Summary - Benefit-risk communication to medicines users

How can regulators best meet the information needs of patients and healthcare professionals?

On 17 September 2014, the EMA convened a workshop to look at how we communicate benefit-risk to medicines users, attended by representatives of patients, consumers and healthcare professionals, academic researchers, representatives of regulatory authorities, members of EMA scientific committees including the chairs of the Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC), members of EMA staff and representatives of the Agency's Management Board.

The objectives of the workshop were to review the current practice in communicating benefit-risk, to examine recent initiatives into how research can help inform best practice, to discuss the role of communications in risk minimisation and to explore how they can aid patients and healthcare professionals in making decisions throughout the therapeutic journey.

The European Medicines Agency continues to work to incorporate the voices of medicines users in the regulatory process. As part of this work, it has organised three workshops involving representatives of patients and healthcare professionals together with members of EMA staff and scientific committees and other interested stakeholders. The first of these, held in September 2013, looked at how to involve the patients' voice in the evaluation of benefit-risk throughout the product lifecycle. This was followed by a workshop in February 2014 exploring methodologies and standards for the evaluation of benefit-risk and this third workshop in the series explored communication on this topic.

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