



Press Release

Ensuring Access to Medicines for Patients: Pharmaceutical industry associations release ‘Principles for Communication of information on Quality and Manufacturing Potential Supply Disruption’

(20th January 2015 – Brussels) – AESGP, EFPIA, EGA, and PPTA are pleased to announce today’s release of the joint principles for “Communication of information on quality and manufacturing potential supply disruption”. This document forms part of the industry response to the EMA (European Medicines Agency) call for voluntary and proactive action, to provide European patients with continuous access to medicines.

There can be multiple causes to medicines shortages, including issues relating to quality and manufacturing. In cases where a disruption to the manufacturing process of a medicine arises, Marketing Authorisation Holders (MAHs) are obligated to timeously notify Competent Authorities (CAs). This document addresses such communications, and complements the output from the professional organisations ISPE & PDA on the prevention of such supply disruptions – *see enclosed summary report*.

This ‘Principles’ document introduces a harmonised approach to the communication of information by MAHs, meeting the complex and divergent data requirements across national CAs and EMA. This is expected to facilitate coordinated action between CAs; it will further enable CAs to gather standardised data for the identification and analysis of the causes, while considering mitigation strategies. This ‘Principles’ document constitutes a first and concrete step in the right direction and was warmly welcomed by the EMA and national CAs.

AESGP, EFPIA, EGA, and PPTA believe that more can be achieved within the EMA initiative, particularly on reporting and notification mechanisms beyond manufacturers, which should form the next key milestone of the EMA initiative for 2015. This necessitates an integrated solution involving all stakeholders in the supply chain, illustrated in the recent report commissioned by DG Sanco¹.

The pharmaceutical industry is fully committed to working with these stakeholders, to mitigate factors that could contribute to supply disruptions, and to provide European patients with continuous access to the medicines they need.

¹ http://ec.europa.eu/health/files/committee/73meeting/73plus/study_report.pdf



About AESGP

The Association of the European Self-Medication Industry (AESGP) is the official representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe.

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About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the research-based pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA provides the voice of 1,900 companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world

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About PPTA

The Plasma Protein Therapeutics Association (PPTA) is the global representative of source plasma collection centers and manufacturers of medicinal therapies derived from that plasma, as well as their recombinant analogs.

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