## **Pharmaceutical Industry Workshop**

## Innovation and Competitiveness of Pharmaceutical Industry in Europe

The importance of the pharmaceutical industry to the growth of the European Union lies in its substantial R&D investments (estimated at EUR 27,500 million in 2011) as well as the 660,000 jobs it provides. In addition for every job in the sector, three to four additional jobs are created in up-stream or down-stream sectors. In terms of performance, the industry is considered a top performer within the European economy, with exports accounting for up to 66% of output. Challenges arise mainly in the form of regulatory requirements, the costs of R&D and budget cuts affecting inputs crucial to the industry.

**Prof. Joanna Chataway**, of RAND Europe, spoke on the pharmaceutical industry and public-private partnerships (PPPs). The complexity of the pharmaceutical industry and the regulatory framework affecting it have shown how outdated the traditional model of government involvement is, which is supposed to be limited to funding activities. Numerous forms of public-private partnerships have since materialised, the most important of which is the Innovative Medicines Initiative (IMI), a EUR 2 billion PPP involving the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) and which aims at fostering a collaborative environment for innovation in the industry. However, one relevant aspect has thus far remained untouched by PPPs: public opinion. Given the public's general sensitivity towards the industry, it is important to enhance the image of pharmaceuticals as a positive driver of health, employment and research.

It was argued that negative perceptions by the public, through their impact on policy makers, posed a severe cost both to industry and the public itself, as pharmaceutical advancements and the resulting availability of treatment may be stalled or even halted. As such, there is a clear benefit in improving the public image of PPPs. When asked about the reservations towards PPP, an industry representative stated that these were mainly to be found on the side of policy makers. It was agreed that the main steps to take are the communication of successful forms of PPP to the public and clarification of the roles of public and private players willing to engage in PPPs.

Richard Torbett, Chief Economist of EFPIA, spoke on access to medicine and the position of the industry in growth strategies. As with many sectors, the pharmaceutical industry has witnessed an increased price convergence as a consequence of the formation of the Internal Market. The general use of international reference pricing for medicines is an important element in this respect. Nevertheless, the special position of medicines has prompted economists to question the need or usefulness of price convergence. It was argued that access to medicines might be more effective as a policy target, as a number of elements (including the willingness to pay, health literacy and delivery systems) make a difference in price desirable at times. In a broader sense, it was acknowledged that the pharmaceutical industry has an important role as a lever for growth. The opportunities posed by the presence of industry inputs as well as the rapidly ageing population and the need for better access to treatment, make the inclusion of the pharmaceuticals in the European growth effort not only useful, but necessary. In order to allow the EU to remain one of the

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three main locations of the global pharmaceutical industry (the others being the USA and Japan), a triple focus on health, financial sustainability and growth/competitiveness was important. Exploiting synergies and reducing costs to the industry were considered vital in this respect.

Thomas Heynisch, Deputy Head of Unit, DG Enterprise and Industry, European Commission, explained the role of the Commission in promoting pharmaceutical competitiveness. The key elements of the Commission's commitment are the progress towards a single market in pharmaceuticals, dealing with the challenge of globalisation, pursuing a high level of public health protection and fostering an environment favourable to innovation. DG Enterprise has undertaken a set of legislative and non-legislative measures to follow up on these policy goals. The main pillar of legislative action is the Directive on transparency on the pricing and inclusion of medicines which is currently under review. It aims to facilitate free movement without infringing the competence of Member States in pricing and reimbursing medicines. This is done by requiring time limits for pricing or reimbursement decisions, an obligation to provide applicants with a statement of reasons in the case of a decision and an obligation to provide legal remedies for the applicant. Non-legislative actions include the spuring of momentum between stakeholders in the context of the Pharmaceutical Forum (2005-08) by providing recommendations on access, expenditure control and rewards for innovation. In 2010, a stakeholder process on corporate responsibility in the industry was launched and included the issue of access to medicines, exploring non-regulatory ways of addressing the access challenge. In addition, the Commission has indicated its intent to explore new areas of action along the lines of a comprehensive approach to counter distortions of the internal market, provide a review of the regulatory framework and work towards a level-playing field in global markets.

Xavier Hormaechea, Director of Public Affairs at UCB, examined how to incentivise businesses and the role of institutional actors. In 2010, the Belgian pharmaceutical company UCB started the construction of a Centre of Excellence for the pharmaceutical industry at a research and production facility located in Braine-L'Alleud (BE). The project brought EUR 70 million worth of investments to the region, and was facilitated by incentives provided by the Walloon regional authorities, including tax breaks on the R&D activities which make an important part of the new site's activities. In addition to fiscal incentives, the access to highly skilled labour as well as the geographic position and the location of existing plants were mentioned as key elements in the firm's deliberations and its decision to keep its new activities in Belgium. However, an important element of friction between institutional priorities and actions was identified. Whereas the pharmaceutical industry has a role to play in promoting growth, it is often affected by budget cuts relating to crucial inputs such as R&D, production sites and educational inputs such as specialised Ph.D. programmes. The highly layered structure of institutional decision making was also mentioned as an obstacle to the growth of the industry. In this respect, it was suggested that the current crisis should be used as an opportunity to address these key challenges in order to make lasting changes to the benefit of industry, consumers and society as a whole.