EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Resources Based, Manufacturing and Consumer Goods Industries
Food and Healthcare Industries, Biotechnology

MULTISTAKEHOLDER WORKSHOP ON THE PHARMACEUTICAL INDUSTRY

Rome - Wednesday, 22 October 2014

MINUTES

COMMISSION STAFF WORKING DOCUMENT: PHARMACEUTICAL INDUSTRY – A STRATEGIC SECTOR FOR THE EUROPEAN ECONOMY

Remarks and discussion

The participants were welcomed by the Chair Mr Gwenole Cozigou, Director of Resources Based, Manufacturing and Consumer Goods Industries Directorate at DG Enterprise and Industry. This was the first meeting of the group after the finalisation of the activities under the "Process on Corporate Responsibility in the Field of Pharmaceuticals".

In particular, the workshop was the first opportunity for a joint meeting between the competent authorities responsible for pricing and reimbursement of pharmaceuticals and other relevant public and private stakeholders, after the adoption of the Commission Staff Working Document (SWD) – Pharmaceutical Industry: a strategic sector for the European economy – in June 2014, as a starting point for future discussions. It is envisaged to have a more comprehensive approach and an as wide as possible representation from all sectors on how to ensure sustainable provision of effective and safe pharmaceuticals focusing not only on cost containment but also on patient's access, innovation and industrial competitiveness in Europe.

The participants and contact list will be revisited in view of the scope in order to ensure an appropriate wide and balanced representation in any follow up activities. At this point in time the Commission had invited the ex-members of the above mentioned group. The only change was the participation for the very first time of a representative from the Unions – IndustryAll.

Having in mind the divergence in health systems in Europe, governed both by European and national legislative frameworks, and in light of previous and ongoing Commission activities, a new discussion should be launched based on the identification of priority topics of mutual interest.

The participants of the workshop were asked to react not only during the meeting but also in writing in the following days. All the proposals received will be shared with the group. Based on the input, the Commission will prepare a short paper reflecting the main elements and priority ideas worth exploring further. This paper will form the basis for internal discussions in the Commission with a view to next actions.

It was underlined that this workshop was not the event mentioned under Next Steps of the SWD, as such event will be organised in 2015.

A short presentation of the SWD followed. It touched upon the political context of the initiative, the importance of the sector in terms of productivity and growth, drivers and challenges for the industry, European responses and possible next steps based on volunteer collaboration.

EFPIA, AESGP, EUROPABIO, Sweden, EPF, GIRP, INDUSTRYALL, The Netherlands, PGEU, Slovenia and Italy welcomed the initiative. During the round table discussion various topics for the future Commission initiatives were expressed, for example on the importance of maintaining and further elaborating the multistakeholders dialogue and cooperation, extending the dialogue to include regulators, increase the focus on the needs of patients and encourage their more active participation, potential consequences of pricing and reimbursement decisions on shortages, encourage more transparent behaviour in the sector, take into account the needs of SMEs, especially as regards access to finance, and others.

The Chair invited the participants to send their contributions of ideas also in writing.

PRESENTATIONS ON SELECTED TOPICS

The Commission had invited some presentations on selected topics related to previous or ongoing initiatives that are relevant to the discussion and that could potentially stimulate the exchange of ideas. Under no circumstances the selection of these topics restricts any follow up activities or formation of working groups.

An example of Life Sciences Strategy: UK experience

The UK was invited to present their experience on the "Strategy for UK Life Sciences" which was published in December 2011. Mr. D. Kullman from the Office for Life Sciences informed that this joint office had been recently created from the Department of Business, Innovation and Skills and the Department of Health. Some of the activities of this office are to increase the impact of the life sciences industries on economic growth and improve patient outcomes, create a globally competitive research and commercial environment, support the uptake of clinically effective and cost-effective products and process to improve patient care and decommissioning, determine metrics to evidence the impact of these activities, coordinate and communicate industry – facing activities. In addition, a dedicated Minister for Life Sciences has been appointed. Through this project private investments (£ 2 billion) have been attracted which contribute to growth.

Pharmaceuticals – Cost efficiency and sustainability

One representative from the Netherlands Mr. H. Hurts, (also current Director of the Medicines Evaluation Board in his country and previously Chair of the group "Cost

effective use of medicines"), was asked to share some of his experiences on this topic. Mr. Hurts clarified that the document "Medicines in Europe: 10 Strategic Observations" is reflecting only personal opinions based on his work experience and not the official national position. His presentation focussed on finding a balance between regulation on the one hand and focus on behavioural aspects on the other hand. There may be an over-appreciation of what can be achieved with regulatory instruments, he argued. Much of the regulation (old and new) may have become too complex, too detailed and with too much focus on procedures instead of real issues. Mr. Hurts went through examples in the fields of (a) marketing authorisation, (b) health technology assessment and (c) pricing and reimbursement. He called upon physicians, pharmacists and patients to take up more responsibility for cost effective use of pharmaceuticals. Patient organisations, to his opinion, can be clearer and demanding about the behaviour that patients may expect from their physicians and the pharmaceutical industry. The industry would help itself by starting to be more transparent about pricing, reasonable profit and behaving reasonable overall. Concerning regulators he called for avoiding over-regulation and to use the existing legislative framework with flexibility. The European Commission can, to his opinion, contribute greatly by trying to bring balance between patient safety, quicker access for patients to innovations and developments in science and research in a comprehensive approach for future regulation.

Pricing and reimbursement policies

Mr. J. De Cock, from NIHDI (National Institute for Health and Disability Insurance), Belgium, made an intervention on pricing and reimbursement issues. He reiterated three major questions which were also relevant during the Belgian Presidency back in 2010: how to ensure access to valuable medicines for EU citizens, how to reward valuable innovation and how to promote cost effective and rational use of pharmaceuticals. Convergence of access does not always equal convergence of prices. Access is affected by various factors and in some Member States early access schemes have been put in place. The relation between parallel trading and pricing in other countries based on external reference pricing is not always transparent. He pointed out the need to increase mutual understanding on how prices are determined and investigate concepts such as "fair pricing", improve data management and transparency. One way forward might be to create a "coalition of the willing" by launching pilots among interested parties who are willing to mutual recognise HTA assessments and engage in joint agreements as regard purchasing of pharmaceuticals. He considered it essential to bring together the policies concerning science, healthcare and industry in a comprehensive manner. A dialogue between various stakeholders is needed to explore flexible and innovative solutions. Progress can be achieved through collaboration rather than through legislation. He proposed to establish a link between the technical assessments and political decisions regarding pharmaceutical expenditures.

Pilot project Orphans – follow up

Mr. R. De Ridder from NIHDI (National Institute for Health and Disability Insurance), Belgium, who has co-chaired the working group on "Mechanism for coordinated access for orphan medicinal products" under the Process on Corporate Responsibility in the Field of Pharmaceuticals, gave un updated on a pilot project which was launched in 2013 to bring together interested parties in order to tackle delays and disparities concerning orphan products. The collaboration was based on a non-legislative, a non-binding and a non-regulatory approach with the objective to create shared understanding for pricing and reimbursement discussions in the various countries while keeping in mind that pricing

and reimbursement decisions are a national competency. The MEDEV (Medicines Evaluation Committee) – fostering cooperation between the statutory health insurance institutions in Europe – has taken the project forward and is preparing to launch the second pilot. The first pilot concerned a paediatric indication and phase II, III development. The specific objectives concerned the real life test of the "Transparent Value Framework" – agreed criteria on which values could be assessed – streamline and simplify the process, test hypotheses in the different phases and identify strengths and weaknesses. This pilot was built on an agreed agenda and needs and expectations of various stakeholders, protocol design, collaborative opportunities (EUnetHTA, EMA early dialogue), explored scenarios for volume price agreements all based on trust. Future pilots concerning other products have already been identified and the idea is to broaden the scope on promising treatments for high unmet needs. The widening of the scope may concern early dialogue, managed entry agreements, common pricing and procuring mechanisms, conditional reimbursement and others. In case of interest for future pilots, participants were asked to contact MEDEV at aschuurman@zinl.nl.

Mr. De Ridder underlined the need to take forward lessons learned from the projects to a more strategic level.

Managed Entry Agreements: future synergistic approaches and avenues for improvement in Europe

Italy, a frequent user of Managed Entry Agreements (MEA), presented its perspective on future European collaboration in the field. Mr. G. Tafuri from AIFA (the Italian Medicines' Agency) who participated in the relevant group under the Process on Corporate Responsibility, mentioned that MEAs are considered to be an important tool in the decision making process for competent authorities on reimbursement decisions. Regarding future cooperation it is important to share experiences, improve coordination on MEAs between Member States and training programmes especially for the smallest EU markets. It was proposed to create a European Network on MEAs with collaboration with other networks like the one on HTA or with the Euripid Database, assess the impact of MEAs on cost containment and patients' access and integrate MEAs in the HTA process. A common framework could be envisaged to generate real life evidence across different EU Member States, inter-linked patient registries or a single pan-European registry platform, and comparable real life evidence. All these can support decision making for pricing and reimbursement in those fields where limited data is available, like for orphans, personalised medicines or for smaller EU markets. Overall, there is a need to create more synergies for the MEAs with other EU ongoing initiatives, like the adaptive licencing and the patient registries. MEAs need to be integrated into the long term process starting from the horizon scanning activities, to HTA assessment and to pricing and reimbursement including post marketing studies and surveillance.

European Registry on Ethics

The Commission recalled the work that has been concluded under the Platform on Ethics and Transparency which led to the adoption of the Guiding Principles for ethical behaviour in the pharmaceutical sector. These Guiding Principles deal with a variety of issues and they have been agreed on a voluntary basis by all different stakeholders of the Process on Corporate Responsibility in the Field of Pharmaceuticals.

Without any intention of reopening the discussions already concluded, the Commission proposed an operational follow up: to create a public European registry gathering the

names of competent authorities and other stakeholders who adhere to these Guiding Principles, with the idea to open up the scope and include national, regional and local stakeholders.

EFPIA, EPF and BEUC welcomed the idea in principal and the exact operational follow up will be determined at a later stage.

New developments in the uptake of biosimilars in EU

Due to intense discussions between the industry associations, IMS–Health had decided to cancel their participation and presentation. Therefore the topic was removed from the agenda.

CONCLUSIONS

During the workshop various topics were identified by some of the participants as potential topics for further exploration, the main of which are:

- the importance of maintaining the multistakeholders dialogue without repeating work / discussions which have already taken place but developing them further and operationally;
- the inclusion of representatives of regulatory agencies in EU level discussions on topics related to pricing and reimbursement;
- an increased focus on patients and payers' needs;
- aspects concerning SMEs, i.e. access to finance and reduction of regulatory burden;
- support to the sustainability of innovative industry in order to enable them to come up with new medicines by keeping patients in the centre of attention;
- unintended consequences of the application of external reference pricing – to be followed up by a pilot;
- rational use of medicines;
- demographic changes;
- recognition of medicines shortages, not necessarily of new and expensive medicines;
- implications in non-European markets of policy decisions taken in the EU;
- long-term commitment of the industry.

The Chair announced that the Draft Minutes of the meeting would be send by the following week.

He invited the participants to send their input on ideas for priority topics in writing – including those mentioned above – by the end of November 2014 to:

ENTR-FOOD-AND-HEALTH-IND-BIOTECH@ec.europa.eu

All the contributions will be shared with all the participants of the workshop. The Commission will prepare a short paper based on the participants' contributions as a basis for the organisation of future meetings.