EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Biotechnology and Food Supply Chain

MULTISTAKEHOLDERS WORKSHOP ON THE PHARMACEUTICAL INDUSTRY

Amsterdam, 22 March 2016

MINUTES

Welcome and Introduction

The meeting was severely affected by the terror attacks which took place in Brussels in the morning of the same day. Some of the participants including both stakeholders association and countries' representatives were not able to attend. Furthermore one of the speakers was also unable to attend therefore one of the agenda items was not presented.

The participants who managed to arrive in Amsterdam for the workshop were welcomed by the Chair Mr Carlo Pettinelli, Director of Consumer, Environmental and Health technologies Directorate at DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW). The Chair called for one minute of silence in memory of the victims of terror attacks.

This was the third Multistakeholders meeting organised by GROW, as a response to the requests of stakeholders who see these meetings as an opportunity to meet and exchange views with MS representatives. It is noted that pricing and reimbursement decisions regarding pharmaceuticals are a national competency but at the same time many economic operators or other organisations such as patients, health professionals, insurers and industry are all affected by these decisions.

DG GROW reiterated its commitment to further support the multi-stakeholders dialogue in line with stakeholders' desire for open minded discussions on a broad spectrum of aspects relating to access to medicines, to research and innovation, to the competitiveness of our industry as well as sustainability of health systems. The fact that issues related to pricing and reimbursement of pharmaceuticals is relevant to Directive 89/105/EEC (Transparency Directive) was also highlighted. The agenda of the meeting was developed in collaboration with the Presidency, some MS, industry associations and other Commission services.

DG GROW also confirmed their intention to continue supporting the rotating Presidencies of the Council in organising the meetings of the Network of Competent Authorities responsible for Pricing and Reimbursement (CAPR) – subject to the necessary budgetary decisions.

Selected topics

1) The BENELUX collaboration on reimbursement of medicines – Mr R. De Ridder, Director General of Healthcare Department INAMI, Belgium.

This collaboration materialised as a result of a protocol signed by the Ministers of Health of the three countries. It is based on a need expressed many times in various cases, such as in the Working Party on Public Health at Senior Level, meetings of the CAPR, meetings of multistakeholders workshops, the Process on Corporate Responsibility in the Field of Pharmaceuticals, a call made by Belgium in an Informal Health Council to make innovative medicines more accessible in the EU, Council Conclusions during the BE & IT Presidencies and the Commission Staff Working Document on the Pharmaceutical Industry. This collaboration concerns HTA, horizon scanning, exchange of information on pharmaceutical markets, prices, information from registries and joint negotiations. There is a structural exchange of information and testing through pilots and it was clarified that this collaboration is not a joint procurement. Procedures are compatible with national legislations. Possible deliverables of the pilots are common assessment reports, common negotiations and common registries. Managing expectations and communication issues are an important aspect of the BENELUX collaboration. There is great interest and expectations from many parties but it is still early stages as pilots are ongoing. Terms of reference of this collaboration are currently being prepared.

2) EU Health Program – Study on enhanced cross-country coordination in the area of pharmaceutical product pricing – Ms S. Vogler, Gesundheit Österreich GmbH / Austrian Public Health Institute.

The study was commissioned by the European Commission (DG SANTE), through the EU Health Program with the aim to examine EPR (external price referencing) in Europe, explore possible coordination mechanisms at EU level and to develop possible improvements to these EPR schemes; another aim was to analyse how DP (Differential Pricing) schemes could possibly be designed and used in EU countries. The study also addressed possible constraints of EPR and DP. The speaker as one of the authors of the study clarified that any opinions expressed represent only the authors. The study was elaborated further to various activities including a written survey with competent authorities,, a written stakeholder review followed by a stakeholder meeting, as well as several simulations. Based on the study's findings, EPR is a key pricing policy for EU countries considered to contribute to cost containment of pharmaceutical expenditure but does not always ensure access to medicines for patients or transparency of procedures. The study developed policy recommendations for the improvement of EPR, the main of which are to consider using "real prices" after discounts, perform regular price reviews, consider purchasing power or GDP when selecting reference countries and enhance collaboration between countries for the exchange of prices and other information.

Regarding DP – having different prices for different countries – which is based on the concept of ability and willingness to pay, there is no experience in Europe as it has never been used in any EU country as a governmental policy. Experience on DP concerns its use by international agencies such as UN, Global Fund, GAVI, etc. It was clarified that it is not considered a cost containment tool. There are mixed opinions on whether prices should be published or not. The introduction of DP would require major political will and would also need to address other parameters such as parallel exports. The study recommended that MS could consider combination policies (EPR & DP), i.e. using DP traits in EPR schemes and explore policies beyond the scope of the study.

Overall, it was concluded that dialogue between MS but also with stakeholders should continue as more evidence is needed in relation to pricing policies.

3) Update on Commission Expert Group STAMP (Safe and Timely Access to medicines for Patients) – Ms H. Lee, DG SANTE, Unit B5

Unfortunately the speaker was not able to attend due to the Brussels terror attacks. The Chair reiterated that this was not the first time that we had this topic on the agenda as it was deemed important to update the multistakeholders meeting on the developments in STAMP. Without prejudice to any national competences it was identified that there is a need for closer collaboration between pricing and reimbursement and regulators in order to facilitate faster access to medicines. The relevant European Commission services are in close collaboration on this topic.

4) The value of generic medicines – Mr M. Van Baelen, Medicines for Europe (formerly EGA).

Medicines for Europe is a European pharmaceutical industry association specialising in generics medicines, biosimilars and value added medicines who presented their vision for better healthcare in Europe based on their products. The speaker explained that taking into consideration current challenges such as slow growth rate, ageing population and very expensive new products, their aim is to provide high quality medicines, improve health outcomes and the sustainability of health systems.

Some generics are also used against cancer. Value added medicines are improvements of existing molecules and Medicines for Europe created a specific sector group in their association dedicated to these medicines. They also underlined the increased importance of biosimilar products with over 14 EU countries having manufacturing sites for biosimilars and over 60 countries worldwide making them available for patients. They stated that their products improve access to medicines and that generic competition increases access further. There are differences in generics uptake between countries according to the national relevant policies. Uptake is also affected by policies such as level of patient co-payment and generic substitution. The role of community pharmacists was underlined in particular when generic substitution is allowed in an individual system.

PGEU, the Pharmaceutical Group of the European Union representing community pharmacists raised the issue of unused medicines by patients when they are reimbursed by the health system and they asked that it is addressed in the future since it affects pricing and reimbursement policies.

5) Challenges regarding vaccinations – Mr J. L. Sion, DG SANTE Unit C3

European Commission supports Member States in the elaboration of their national vaccination policies. There have been some reports on vaccines shortages, especially shortages of vaccines containing a-cellular pertussis and vaccines against tuberculosis. The European Commission and Member States discussed options for policy interventions and actions to address current vaccines shortages inter alia in the remit of the HSC (Health Security Committee). HSC is an advisory committee to the European Commission, where MS are represented at high level from Ministries of Health and facilitate coordination in cases of health related crisis.

The issue of vaccines shortages in EU has been discussed at expert level in the HSC. It was found that enhanced stakeholder dialogue would increase the effectiveness of measures aiming at mitigating the risk of vaccines shortages. In this respect MS should consider strengthening dialogue with the industry, define collaboration with national advisory groups and other stakeholders and encourage investments in vaccines production.

Unfortunately, Vaccines Europe industry association were not able to attend the Workshop due to reasons described above, therefore it was not possible to hear their views on this topic.

The Chair encouraged the participants of the workshop from competent authorities to liaise with their colleagues at national level who are members of HSC in order to learn more and exchange views on this topic.

Conclusions and follow-up

The Chair thanked the participants for their interest and attendance, especially under the difficult circumstances of terror attacks in Brussels.

All presentations and other relevant documents are accessible for the participants through the dedicated platform of CIRCA.

Exchange of knowledge and information is essential and many interesting topics and information were raised by the speakers and shared with the audience, such as development of a multi-domain collaboration and how this could be enlarged by themes, objectives or participants. The common denominator in all presentations was the usefulness of having representatives from all countries in the presence of stakeholders as some ideas and some concepts are still under elaboration, so there is an added value in analysing different approaches for same problems.

The European Commission is in close contact with future Presidencies and will communicate in due time if and when there will be a follow up Multistakeholders Workshop meeting.

The stakeholders associations and the Dutch Presidency expressed their appreciation for the organisation of the meeting and thanked the European Commission for their support in the multistakeholders collaboration in the area of pricing and reimbursement of pharmaceuticals.