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

Consumer, Environmental and Health Technologies
Biotechnology and Food Supply Chain

MINUTES OF THE EXPERT GROUP FOLLOW-UP ACTIVITIES RELATED TO CORPORATE RESPONSIBILITY IN THE FIELD OF PHARMACEUTICALS[1]; MULTISTAKEHOLDERS MEETING ON PHARMACEUTICALS
12TH SEPTEMBER 2017

1. Introduction

The Chair welcomed the participants and reminded them of the previous Multistakeholders meeting which took place on 22nd March 2016.

2. Nature of the meeting

The Chair announced that the meeting would follow the model of cooperation developed under the Process on Corporate Responsibility in the field of Pharmaceuticals https://ec.europa.eu/growth/sectors/healthcare/competitiveness/corporate-responsibility_en

The Commission intends to continue facilitating the exchange of information between competent authorities responsible for pricing and reimbursement and other relevant stakeholders in a non-regulatory environment since the participants recognise an added value in these meetings. Moreover, the Council[2] recently underscored the importance of a continuing open and constructive multi-stakeholder dialogue.

3. List of points discussed

The following points were presented:

- Transparency Committee – short update by DG GROW

The Commission informed the participants on the meeting of the Transparency Committee (TC) which had taken place in the morning of the same day. The TC is a consultative committee pursuant to Directive 89/105/EEC (Directive relating to the transparency of measures regulating the pricing of medicinal products of human use and their inclusion in the scope of national health insurance system), which aims to discuss issues related to the implementation of the Directive..

[1] http://ec.europa.eu/transparency/regexpert/index.cfm

[2] http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/

Following up to questions sent to the Commission both by Member States and individual stakeholders in particular in relation to the scope of the Directive, the Commission initiated a discussion within the TC in an effort to seek legal clarity.

It was recognised that there have been many developments regarding pricing and reimbursement policies and instruments, both at political and technical level, since the adoption of the Directive in 1989, and that these developments raise questions as regards their relation with the scope of the Directive. Topics discussed at the TC meeting were procurement in the health sector, managed entry agreements and the publication of prices.

- EU Procurement Law in the Health Sector – update of ongoing activities by DG GROW

The Public Procurement (PP) legislation refers to the process by which public authorities such as government departments or local authorities purchase work, goods or services from companies. In order to create a level playing field for all businesses across Europe, EU law sets out some minimum harmonised PP rules. EU rules on PP specify how to buy goods regarding rules and procedures and not what to buy. The presentation, given by a Commission representative, focused on the health sector although PP rules are applicable in other sectors as well.

Purchasing medicinal products is a complex issue since different procedures are actually applied, for example the Transparency Directive, managed entry agreements and others. In this respect the issue of PP in the health sector has gained importance in many MS due to its economic importance and it is recognised as a strategic tool that can contribute to more sustainable health systems. The main objective of PP legislation is the opening of the market for competition and equal treatment. On the website http://ted.europa.eu/TED/main/HomePage.do which is dedicated to European PP there is information and publication of calls for tenders from across the EU. It seems that in the health sector there is room for improvement as regards the application of the EU public procurement rules (resulting in low publication rates in TED) and lack of competition.

Contracting authorities have a considerable margin of discretion with regard to drafting the tender specifications and to some extent also on the different types of public procurement procedure that can be chosen; it is recommended to use other criteria than the lowest price. It was also clarified that contracting authorities e.g. hospitals can actually speak to the industry before organising a public procurement procedure. The advantages of central or joint procurement were underlined. Problems or legal irregularities observed: discriminatory tender specifications or award criteria not linked to the procurement subject. More information is needed regarding the implementation of PP rules in the purchasing of medicines and participants were asked to provide such information if they have it also in writing after the meeting.

- IPR – Intellectual Property Law relevant to medicines – update of ongoing activities by DG GROW

A Commission representative updated participants on the ongoing DG GROW work related to intellectual property law specifically for the part relating to pharmaceuticals. For pharmaceuticals there are specific IP rights, for example the SPC (Supplementary Protection Certificate), market protection, data exclusivity, etc.

The Commission Communication on the Single Market Strategy of October 2015 announced the Commission's intention to "explore a recalibration of certain aspects (not limited to the pharmaceutical sector) of patent and SPCs protection", and an update of the scope of the EU research and so-called Bolar patent exemption. In addition, in June 2016 the Health Ministers' Council EPSCO invited the Commission to inter alia analyse the impact on innovation and access to medicines of existing specific pharmaceutical IPR in the EU. Furthermore, the European Parliament through an initiative related to access to medicines supported this invitation of the Council to the Commission. The Commission reminded the participants of the published roadmap[3] as a follow up to the SPC-related initiatives under the Single Market Strategy and in addition informed about the current formal evaluation of the existing SPC framework and assessment on the merits of a unitary SPC title for the EU, a SPC manufacturing waiver for export purposes and update of the Bolar scope. DG GROW are currently working on several studies which examine the specifics of the legal and economic SPC framework, but are also preparing a public consultation with specific questions on pharmaceuticals in the context of the SPC-related initiatives of the Single Market Strategy. Participants were invited to participate if they wish and provide input. Industry representatives expressed their support to the ongoing work and their willingness to contribute to the public consultation.

- Alternative approaches to pricing and reimbursement of pharmaceuticals by INAMI, Belgium

The representative of Belgium from INAMI presented a discussion document with the title "*Outcomes based pricing and reimbursement of innovative medicines with budgetary limitations*" which was elaborated with the contribution of professor L. Annemans from Ghent University also attending the meeting. http://www.riziv.fgov.be/fr/themes/cout-remboursement/par-mutualite/medicament-produits-sante/remboursement/medicaments-innovants/Pages/default.aspx#.WaVCPK2B2i4.
Access to medicines is a complicated issue and the paper makes an effort to outline the various uncertainties that define the best financial outcomes and access market to innovations while taking into consideration the individual characteristics of health systems and competences in the specific policy area. Some common standards are being developed for data collection and analysis, in some cases there are early dialogues between regulators, manufacturers and payers but the discussion paper outlining a series of key recommendations calls for further reflections on the subject. The speakers inquired if there is a broad willingness to engage in a wider multistakeholders discussion, which would be the appropriate platform and what kind of information they would be interested in discussing and sharing – without duplicating any other initiatives.

Some of the participants already expressed some interest for cooperation but further reflection may be inquired regarding the format or platform of collaboration, which indicators can be used in addition to pricing, methodology and other practical aspects.

The Commission announced that they take note of the initial interest expressed. In addition the European Commission's expert panel assesses pricing models for innovative medicines, access to healthcare and performance of primary care http://ec.europa.eu/newsroom/sante/newsletter-specific-archive-issue.cfm?newsletter_service_id=327&newsletter_issue_id=4617 and in particular their opinion on innovative payment models for high cost innovative medicines will be

[3] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf

finalised in November 2017. The Expert Panel opinion will identify the gaps of current payment models, provide the methodological framework and explore possible synergies between various bodies in the EU and the Member States. A public hearing is going to be organised on the 25th October 2017.

- Payers' role in early access to medicines and repurposing of existing medicines by DG SANTE

A Commission representative from the Health and Food Safety DG (DG SANTE) provided an update on the activities of STAMP – the expert group on safe and timely access to medicines for patients https://ec.europa.eu/health/documents/pharmaceutical-committee/stamp_en with a focus on issues raised at STAMP of particular interest for pricing and reimbursement representatives.

STAMP facilitates information exchange among Member States, examines national initiatives and explores ways to use existing EU regulatory tools more effectively. Although the discussions in STAMP are limited to regulatory issues it was noted that access to medicines depends on many different factors one of which is pricing and reimbursement decisions. Some of the issues therefore that have been discussed in STAMP can be relevant to the bodies responsible for the pricing and reimbursement of medicinal products.

These are repurposing of existing medicinal products (new indications for off patent products in new marketing authorisations and extensions of existing marketing authorisations with variation applications), the project PRIME (Priority Medicines) which was launched by the European Medicines Agency (EMA) to support the development of medicines for unmet medical needs and includes early dialogues between EMA and interested pharmaceutical developers but also the issue of conditional marketing authorisations for medicines intended to address unmet medical needs. In addition, in the margins of STAMP an ad hoc Synergy Group with representatives of the HTA bodies, the medicine regulatory bodies, EMA and EUnetHTA has been created aiming for further facilitation for access to medicines.

The Commission invited the competent authorities for pricing and reimbursements to give their perspectives regarding the above mentioned activities related to the earlier access to medicines for patients and engagement in these discussions. Industry representatives in general support these schemes of earlier access and at this point no representative of competent authority for pricing and reimbursement had asked for the floor. Other stakeholder's representatives expressed their concerns on these schemes and called on the Commission to increase the dialogue and the involvement of civil society in the discussions. The Commission thanked the participants for their interest in the work of STAMP, noting that the group's mandate is to identify ways to optimise the existing EU regulatory tools. Therefore the group is composed of Member States representatives whilst representative organisations are invited to participate on an ad hoc basis for specific agenda items when relevant.

4. Conclusions

The Chair closed the meeting by thanking all the participants and in particular all the speakers. Access to medicines is a multifaceted issue and, as there are mixed competences at EU level, any exchange of information or collaboration can be relevant.

5. Next steps

The Chair invited all members of the group to send feedback to the Commission on their interest for continuation of such meetings and of possible topics for discussion for the future.

6. List of participants

Members: Austria, Belgium, Czech Republic, Germany, Denmark, Greece, Spain, Finland, France, Hungary, Lithuania, Latvia, Luxembourg, Malta, Netherlands, Poland, Portugal, Sweden, Slovenia, UK, Norway, Iceland, AIM (International Association of Mutual Benefit Societies), AESGP (Association of the European Self-Medication Industry), BEUC (The European Consumer Organisation), CPME (Standing Committee of European Doctors), EFPIA (European Federation of Pharmaceutical Industries and Asociations), EPF (European Patients' Forum), ESIP (European Social Insurance Platform), EUROPABIO (The European Association of Bioindustries), GIRP (European Healthcare Distribution Association), HOPE (European Hospital and Healthcare Federation), MFE (Medicines for Europe) and PGEU (Pharmaceutical Group of the European Union).

Observers: EUCOPE (European Confederation of Pharmaceutical Enterpreneurs), Professor L. Annemans