EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

STAMP 6/31
Summary record

STAMP Commission Expert Group
13 – 14 March 2017
6th meeting

Summary Record

The Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) held its 6th meeting on 13 – 14 March 2017, in Brussels, chaired by Unit B5 - *Medicines: policy, authorisation and monitoring* of Directorate General Health and Food Safety. Representatives from 23 Member States and the European Medicines Agency (EMA) participated in the meeting.

13 MARCH 2017

REPURPOSING OF ESTABLISHED MEDICINES/ACTIVE SUBSTANCES *AD HOC* SESSION WITH INVITED STAKEHOLDERS

A half day *ad hoc* session had been arranged to discuss certain aspects of repurposing of established medicines/active substances. In addition to the STAMP members, representatives of patient, consumer, industry, not-for-profit organisations, health technology assessment and pricing and reimbursement bodies had been invited. The list of the invited external participants is attached.

The STAMP expert group had discussed the issue of repurposing of established medicines/active substances in its 4th and 5th meetings. These discussions had mainly

focused on drug repurposing for new indications for well established (off-patent) medicines in areas of unmet medical need that could offer additional therapeutic options to patients. It was considered helpful to extend the discussion to involve stakeholders who have relevant experience of repurposing established medicines/active substances and to benefit from the attendees experience to identify opportunities and barriers to repurposing of established medicines. The aim of the session was to have a brainstorming around possible options and solutions to support the introduction of:

- new indications for off-patent medicines in new marketing authorisations;
- extension of indications for existing marketing authorisations (variation applications).

A background document (STAMP 6/29) was circulated to the participants prior to the meeting. The brainstorming was organised through small groups of 6-10 participants discussing the following questions:

Q.1 What are the challenges for re-purposing for new indications?

Q.2 How can we create opportunities to include new indications for authorised medicines?

Each group identified three issues which they considered to be the most important for each question. In a plenary session these ideas were shared.

The main issues identified as associated with **Q.1 - the challenges for repurposing for new indications** were:

Regulatory/administrative burden – There can be a lack of knowledge about the regulatory pathways and requirements for the authorisation of a new indication. There can also be a lack of knowledge about the availability of the evidence from dossiers supporting the original marketing authorisation. Even when the data in an original dossier is known, the administrative burden associated with obtaining and maintaining a marketing authorisation for a new indication was mentioned. It was considered that this burden was not offset by the possible incentives available to include a new indication within a marketing authorisation.

Evidence – It was noted that it is important to better understand the evidence requirements (efficacy and safety) to support an application for an extension of indication, and the means and sources to obtain the most reliable data possible. Overall, it was considered that it would be useful to understand the type of evidence that would be acceptable (randomised control trials, real world evidence). The evidence on the safety of a product when used in existing indications can support the evaluation of the evidence for a new indication and could allow simpler study designs. It was noted that researchers do not necessarily have the experience of preparing a dossier up to regulatory standards for marketing authorisation application purposes, which can mean that the design of the studies or the quality of the dossier is not in line with the expectations of the assessment and evaluation bodies. The question was raised about the feasibility of conducting a randomised controlled clinical trial once a medicine is authorised.

Off-label use of a medicine[1] – some considered that the incentives available to repurpose medicines for new indications are undermined by the off-label use of medicines. There are costs associated with the research and development necessary to include a new indication in a marketing authorisation, whilst there are for instance no current effective means to prevent off-label use of medicines. In particular, if there are generic medicines on the market, they will impact on the renegotiation of the price of the medicine. Off-label use can mean prescription and dispensing of the generic medicine in the new indication, undermining the incentives for innovators to invest and do the efforts associated with obtaining the new indication. Off-label use can also have an impact on the feasibility of data collection.

Financial aspects – there is the cost of the data collection, and the fees associated with the extension of indication variations or marketing authorisation applications and their maintenance. If prescription control mechanisms are used as a means to manage the use of a medicine, there can also be associated costs. Potential additional costs associated with the pharmacovigilance activities related to new indications were mentioned. There can be costs associated with the development of paediatric formulations needed to support paediatric indications. Issues around pricing and reimbursement of medicines with new indications was mentioned as a potential disincentive for both industry and payers. The re-negotiation of the pricing of an off-patent medicine when a new indication is introduced can mean that there is a call from the marketing authorisation holder (MAH) to have an increase in the price for the new indication whilst the pricing and reimbursement body are resistant to potential increase in price. For on-patent medicines, there can be pressure for a decrease in price as there could be an increase in the sales volume.

Responsibility for the marketing authorisation – the concept of a marketing authorisation is the right to market a medicine according to the approved product information. If a MAH wishes to extend the marketing authorisation they have to apply to amend it through a variation. The extension of indication for a marketing authorisation is under the control of the MAH. There is not a clear mechanism through which a regulator could have a new indication introduced for a marketing authorisation, even when there would be signs of evidence of supporting data and/or a public health reason to do so.

Regarding the challenges, it was noted that the challenges for the development and authorisation of new indications will vary depending on whether the medicine is a recent or older medicine, the nature of the available data, the market protection it might benefit from, or whether it is on- or off-patent. All these factors make it difficult to address the challenges identified with a single solution and a **case-by-case approach** would be needed.

The main issues identified as associated with **Q.2 – how to create opportunities to include new indications for authorised medicines** were:

Mechanisms to change the marketing authorisation – the possibility for a review of the evidence for a new indication being triggered by a body other than by the MAH and

[1] The terminology used in the meeting was "off-label" but the scope would cover both "off-label" and "cross-label" use of medicines.

for a recommendation or advice being given to the MAH regarding the suggested indication was mentioned by several groups. The possibility of a non-binding approach of recommendations or advice through Article 5(3) of Regulation (EC) No 726/2004 or inclusion in the European public assessment report (EPAR) on a medicine were mentioned. The option for an imposition of a new indication, possibly through Article 23 or Article 31 of Directive 2001/83/EC, were also mentioned. Regarding **non-industry organisations** – it was suggested that opening the possibility to amend or hold a marketing authorisation by body other than a pharmaceutical company could also provide a means for new indications to be authorised for an active substance. Another suggestion was the possibility for another organisation to directly apply for an extension of an existing marketing authorisation.

Regulatory pathways for extension of indications – suggestions included:

- having a scientific advice procedure tailored to academia and not-for-profit organisations so that they could be advised on study design, data collection and the regulatory procedures;
- a conditional marketing authorisation for a new indication;
- applying the adaptive pathways concept to the development of new indications;
- the well-established use pathway (although in this case it was also noted that the existing evidence on safety might not be sufficient when the new indication is for a therapeutic area which is very different to the original indication).

Education/training on the procedures – to overcome the knowledge gap regarding the regulatory requirements for the applications and maintenance of a marketing authorisation it was suggested that information should be available to organisations that are less familiar with the regulatory procedures for the authorisation of medicines.

Data collection – it was suggested to investigate means of data collection and exchange of information on the safety and efficacy of medicines used off-label, outside the authorised indications. For example guidance on off-label use of medicines or having structured data collection in compassionate use programmes. It was stressed that any changes to the marketing authorisation should be based on evidence of both safety and efficacy. An understanding of the data requirements and the mechanisms to collect the data necessary to provide the evidence are essential to support the introduction of new indications.

Incentives – it was considered that there were limited incentives for the introduction of new indications and that some were not effective. The US Food and Drug Administration paediatric voucher was suggested as a model that could be considered which would allow the voucher to be used against future applications or to be sold to another company for their use.

Joint research consortia – there was a suggestion to create research consortia through public calls for research which would be linked to a commitment of the participants to further develop and to seek an authorisation if the evidence generated is sufficient to support a marketing authorisation. It was mentioned that there are examples of already existing partnerships to that purpose under the Innovative Medicines Initiative (IMI).

Pricing – some suggested that new models for pricing of medicines should be investigated, for example indication-based pricing, although it was noted that the availability of generic medicines can affect the potential to use alternative pricing models.

Discussion

Following the sharing of the main issues coming from the brainstorming the invited experts were asked to share their perspective on some of the ideas which had been brought forward.

Regarding the **regulatory framework**, the idea of more flexibility, such as the possibility of having a conditional approval of a new indication, which had been previously discussed in the STAMP, was supported. It was recognised that a conditional authorisation of an indication would require a change in Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation which could be considered when the ongoing discussions of the co-legislators on the revision of Regulation (EC) No 726/2004 had concluded.

Advice to the researchers and academia on how to ensure that the evidence they have generated can be used to support extension of indications was considered important. It was suggested by one participant that early dialogue or engagement with, not only the regulatory authorities but also the health technology assessment bodies, pricing and reimbursement bodies and the MAH, could be useful. One participant noted that the priority of academic researchers is usually the publication of innovative results in high ranking peer review journals rather than obtaining or amending a marketing authorisation and there is a lack of knowledge of the regulatory approval procedures.

Some participants stressed the lack of effective **incentives and market access issues**, such as the pricing and reimbursement, meaning that industry has in many cases the probability of a lack of return of investment, with no incentive to invest into researching and amending marketing authorisations to include new indications. In addition, if products that do not have the indication included in their authorisation are used off-label, there is little incentive to have the indication authorised. Alternative incentives such as a voucher that could be used to prioritise or be used against the cost of future activities or tax incentives were mentioned as potential incentives.

The question was raised whether there are any barriers to a company making use of the evidence (e.g. published scientific literature) from a third party to amend their marketing authorisation. It was considered that the **quality of the data** could be a limiting factor. The possibility for a scientific assessment of the evidence and advice on the benefit/risk balance of the new indication could be further considered.

The idea of having **consortia** of academic researchers and industry was considered a potential mechanism to support innovation of indications. It was noted that there is already some experience, for example through the Innovative Medicines Initiative, in this area that could provide evidence on how it might work. The need to have clarity on the division of incentives across the partners in a consortium was mentioned.

The question of moving indications from **off-label use** to part of the marketing authorisation is challenging. One participant stressed the need for a holistic approach along the whole of the process of authorisation and marketing of a product.

The Chair thanked the participants for the sharing of ideas and the discussions. The participation of the external stakeholders had enriched the reflection of the STAMP. Some of the main points raised in the discussions were: lack of incentives to do research

into new indications; the knowledge of academics about the regulatory system; the quality of the evidence and the use of third party data to amend a marketing authorisation; off-label use of medicines being a disincentive to change the marketing authorisation. The ideas which had been shared would be considered and options for follow up should be discussed in the next meeting.

14 MARCH 2017

6TH MEETING OF STAMP

1. APPROVAL OF PREVIOUS MINUTES

The record of the 5th STAMP meeting (STAMP 5/27) was approved without changes:

http://ec.europa.eu/health/files/committee/stamp/stamp_stamp_record_draft_published_en.pdf

2. ADOPTION OF THE AGENDA

The draft agenda (STAMP 6/28) was adopted without changes.

3. OFF-LABEL USE OF MEDICINAL PRODUCTS

The Commission services presented the background paper on the off-label use of medicinal products (STAMP 6/30). It was explained that following concerns arising from Member States, stakeholders and the adoption of a European Parliament Resolution calling for specific action regarding the off-label use of medicines, the European Commission had decided to commission a study to understand the ramification of the issue of off-label use of medicines. The purpose of the study was to obtain a clear description of existing and foreseen practices of off-label use of medicines across Member States (drivers, prevalence, national frameworks) and a factual analysis of all parties' positions towards the existing measures and possible tools on the off-label use of medicines. The draft study report had been presented to the 5th STAMP meeting. Regarding the legal part of the draft report, the European Medicines Agencies Co-operation of Legal and Legislative Issues (EMACOLEX) was consulted in May and September 2016. The final study report was made publicly available on 28 February 2017[2]. It outlines policy options at regulatory, healthcare system and patient/healthcare professional level but does not provide recommendations.

Several STAMP members thanked the Commission for the final study report on off-label use, considered as being complete, detailed and useful. A first discussion took place on the basis of the report, but also of other sources of information from the members of STAMP.

[2] Study on off-label use of medicinal products in the European Union prepared by Netherlands Institute for Health Services Research (NIVEL), National Institute for Public Health and the Environment (RIVM), European Public Health Alliance (EPHA). Full report available at: http://ec.europa.eu/health/sites/health/files/files/documents/2017_02_28_final_study_report_on_off-label_use_.pdf

The members underlined the importance of identifying possible ways forward to move from "off" to "on" label and highlighted the need for STAMP to continue exploring with the relevant stakeholders the possibilities for repurposing. Related to this issue and the discussion held the previous day in the *ad hoc* session on repurposing, a member highlighted the importance to look at the incentives at the disposal of the industry to seek new indications.

Some members also identified the lack of understanding of the summary of product characteristics (SmPC) by physicians as a driver of off-label use that needs to be addressed in order to move from "off" to "on" label use. It was explained that the experience with healthcare professionals at national level sometimes shows that physicians consider the SmPC as an administrative document and do not fully understand how and why the SmPC is developed (especially the scientific data on safety and efficacy behind the SmPC and why some indications are in the SmPC and others are not). The usefulness of the European Public Assessment Reports (EPAR) as a tool to complement the information contained in the SmPC was also discussed.

The Chair noted the interest of the members to reflect on possible ways to improve the accessibility of the existing information. Following a proposal from a member of the group, STAMP members agreed that a reflection could be carried out within the existing Heads of Medicines Agency's Sub-group on timely access to medicines on the basis of the final study report, in collaboration with the EMA.

Members did not express the need for treatment guidelines to be developed at EU level. Several of them stressed the need for further reflection of possibilities for exchange of information and collaborative actions by Member States.

France made a presentation on the French system on RTUs (temporary recommendations for use) and the recent rulings from the French Council of State.

4. ACTIVITIES OF STAMP 2015 – 2016 AND BEYOND

The Commission services had circulated a draft report to the Pharmaceutical Committee on the activities of STAMP in 2015 – 2016 and proposed areas of activity for the STAMP in the coming months. The intention was to present the report to the next meeting of the Pharmaceutical Committee on 27 March 2017.

The Chair noted that the background to the establishment of the Group had been the discussions in the Council and the European Parliament about access to medicines in 2013/2014. The Pharmaceutical Committee had agreed to establish the Group to provide a forum to consider the optimisation, within the existing regulatory framework, of access to medicines for patients.

The interest in the issue of access to medicines continues and there have been Council Conclusions adopted in 2016[3] and a European Parliament Resolution in 2017[4]. Links

[3] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, 17 June 2016 (https://publications.europa.eu/en/publication-detail/-/publication/b49097b2-5096-11e6-89bd-01aa75ed71a1/language-en)

[4] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI))

with other groups had developed during the first 2 years of activity of the STAMP. The members were asked for their views on the future work of the Group.

The members considered that there was a need for continuing work on the issue of access to medicines and the STAMP was important as it had a horizontal aspect and could make links with other bodies, for example the health technology assessment, pricing and reimbursement bodies and the Heads of Medicines Agency. This is also reflected in the Council conclusions. It was considered that the means of making such links should continue to be explored and that small focused groups would be the most effective way to collaborate on issues. The *ad hoc* session on the repurposing of established medicines that had taken place on 13 March was considered a successful format and way to involve other stakeholders.

5. SYNERGIES WITH HEALTH TECHNOLOGY ASSESSMENT (HTA) NETWORK

The Commission services presented the outcome of the public consultation on strengthening EU cooperation on Health Technology Assessment[5] and proposed follow up to the reflection paper on *'Synergies between regulatory and HTA issues on pharmaceuticals'* which was adopted during the 7th HTA Network meeting on 10 November 2016[6].

The HTA Network proposed to follow up the reflection paper through the formation of an *ad hoc* Synergy Group. The proposal was to have a small group with equal representation from HTA and regulatory bodies that could be coordinated by the European Commission. The *ad hoc* group would prepare an overview of the activities in the respective groups and identify which group could take the lead on particular issues.

Members of STAMP were invited to volunteer to join the *ad hoc* Synergy Group. The nominations for the *ad hoc* Synergy Group would be considered by the Pharmaceutical Committee on the 27 March 2017 and the composition of the group would be finalised during the 8th meeting of the HTA Network on 29 March 2017.

6. REPURPOSING

The Chair presented a short overview of the STAMP brainstorming session on repurposing held the previous day (13 March 2017). The focus of the brainstorming had been how the inclusion of new therapeutic indications in the labelling of established medicines can be supported. The discussion was around the questions of the challenges and opportunities around the inclusion of new indications for medicines. The main challenges identified were: the regulatory framework; data quality; incentives; pricing; off-label use; and, cooperation between stakeholders.

The Chair noted that some research is done by academia but there can be a lack of knowledge about the regulatory framework for the authorisation of medicines/therapeutic indications which can be a barrier to including an indication for a medicine. It was

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http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2017-0061+0+DOC+PDF+V0//EN (provisional edition)

[5] https://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en

[6] https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co06_en.pdf

considered that support or advice on the regulatory framework and evidential requirement could be helpful.

It had also been noted that there can be reluctance for marketing authorisation holders to extend the indications for a marketing authorisation. It could be helpful to identify the underlying reasons to understand if there would be opportunities to promote the extension of marketing authorisation when supported by appropriate evidence.

There was a suggestion to bring stakeholders together within a platform which could potentially be established under existing mechanisms such as the Innovative Medicines Initiative (IMI).

The ideas which had been shared in the session would be further analysed and considered in the next meeting of the STAMP.

With regard to the point raised in the brainstorming session that researchers and academia might need to have advice on how to exploit their research in the area of pharmaceuticals, the Commission services informed the STAMP that consideration was being given to the possibility of a Coordination Support Action (CSA) funded by DG Research & Innovation. Members of the STAMP considered that design of clinical trials and the exploitation of the results of research was important. It was noted that there are existing mechanisms and structures for coordination/cooperation in the Member States and at EU level (e.g. EU Innovation Network). DG Research & Innovation confirmed that complementing and coordination of existing initiatives would be the purpose of this CSA, with the intention to strengthen regulatory knowledge by coordination and/or harmonisations of efforts among Member States and at European level.

7. ADAPTIVE PATHWAYS

a. Innovative Medicines Initiative ADAPT SMART platform

The Innovative Medicines Initiative platform ADAPT SMART[7] had been launched in September 2015. The aim of the platform is coordination of activities on Medicines Adaptive Pathways to Patients (MAPPs) with investigation of tools and methodologies, and engagement of relevant stakeholders. Representatives of ADAPT SMART (Coordinator - André Broekmans – Lygature, Solange Rohou - AstraZeneca, Valentina Strammiello - European Patients' Forum) had been invited to present some of the outputs of the platform so far.

During the presentation it was explained that that the approach being investigated through ADAPT SMART is suited only for life threatening or severely debilitating diseases or conditions where there is a high promise to meet the unmet therapeutic need. It was stressed that there is no intention to lower the evidential standards for the authorisation of medicines. The work has been undertaken in the context of the existing legislative framework and standards of scientific assessment and evaluation.

It was noted that randomised control trials are the gold standard. There has been investment in new approaches to real world data collection of evidence of the medicine in clinical practice. The presenters considered that in cases where a medicine underperforms that should be an exit strategy. It was explained that the novelty of the

[7] ADAPT SMART - Accelerated Development of Appropriate Patient Therapies a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes (http://adaptsmart.eu/)

approach is the early involvement of the HTA and pricing and reimbursement bodies in the discussion regarding medicines in the development pipeline.

STAMP members sought clarifications on certain aspects of the activities of ADAPT SMART, in particular, how it compared to the EMA adaptive pathways concept. It was explained that the MAPPs approach was broader and tried to accommodate new methodologies as a way to get efficient and speedy access to the right patients. The real world evidence would supplement the clinical trials and help to provide the information sought by HTA and pricing and reimbursement bodies on the effectiveness of a medicine. Some STAMP members considered that there is a need to involve a broad range of stakeholders from all Member States. Some noted that it can be difficult to manage the authorisation of a medicine and the patient expectations when a product does not perform as expected. Some considered an alternative approach would be access to the medicine prior to authorisation, for example through compassionate use schemes, rather than having mechanisms for early authorisation. On the other hand another member noted that for some therapies, for example where there are small population groups or the nature of the therapy itself, it can be difficult to complete randomised clinical trials. But there could be concerns related to the safety of a product if there is no long term clinical data.

The ADAPT SMART representatives stressed that the benefit/risk balance would need to be positive. The platform has looked at managed entry agreements with the bodies responsible for payment or reimbursement and a document is being prepared as one of its deliverables. The work will be completed around the end of 2017 and recommendations on the scientific, clinical development, HTA and patient perspective are expected to be developed.

The Chair thanked the ADAPT SMART representatives for the presentation and interesting discussion.

b. Adaptive Pathways Pilot and Workshop

The EMA adaptive pathways pilot started in 2014. Since the 5th meeting of the STAMP the EMA published its report on the adaptive pathways pilot[8] and a workshop with stakeholders, which had been organised at the request of the European Commission, took place on 8 December 2016[9]. The workshop involved representatives of patient, consumer and industry organisations, HTA pricing and reimbursement bodies, academia and regulators.

The EMA gave a presentation on the workshop. It was noted that following the completion of the pilot, in future the support and advice will be provided through the mechanisms of scientific advice and parallel HTA advice. It was anticipated that the earliest that products which had been part of the pilot could receive a marketing authorisation was 2019. It was explained that authorisation of the products which had been considered within the adaptive pathways pilot would be within the existing

[8] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/08/WC500211526.pdf

[9] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/09/event_detail_001324.jsp&mid=WC0b01ac058004d5c3

legislative framework and the most likely authorisation route would be as a conditional marketing authorisation.

A member of STAMP who had participated in the workshop, considered that it had been very useful to bring the different stakeholders together. Explaining that it had highlighted that stakeholders understanding of adaptive pathways concept varies which contributes to the difference in the perception of the concept.

The Chair thanked the EMA for organising the workshop which had allowed a good exchange of ideas between the different stakeholders.

8. CONDITIONAL MARKETING AUTHORISATION

Report on ten years of experience at the European Medicines Agency

The conditional marketing authorisation (CMA) was introduced in 2006 as a tool for early access to medicinal products. Discussions in the STAMP and the public consultation on the EMA Committee for Medicinal Products for Human Use scientific guideline on the scientific application regarding the conditional marketing authorisation had highlighted the interest in having an overview of the experience of the CMA. The EMA had prepared a report on the 10 years' experience of the Agency of the conditional marketing authorisation which had been published on the 23 January 201[10]7.

The EMA presented the report, noting that the CMA can be seen as a regulatory tool for early access to medicines for patients, allowing authorisation before comprehensive data is available, whilst making the provision of the comprehensive data a specific obligation for the authorisation.

The provision of the comprehensive data took on average 4 years to be completed and assessed. In terms of compliance with specific obligations, only 5 out of 83 conditional marketing authorisations had major changes to their scope and for 11 out of 83 the due date for the completion of the specific obligation(s) was extended beyond 1 year. Over time, a trend has been observed for submission of results from specific obligations earlier with 33% being submitted more than a month earlier in relation to due date.

The EMA considered that further improvements in terms of prospective planning and early dialogue with other stakeholders within the context of the CMA would be possible.

The Chair thanked the EMA for preparing and presenting the report which gave a comprehensive overview of their experience of the CMA.

9. UPDATE ON EUROPEAN MEDICINES AGENCY ACTIVITIES

The EMA gave a short update on the following issues:

PRIME (PRIority MEdicines) scheme – 19 products have been accepted into the scheme since its launch in March 2016 until February 2017. A workshop on the experience of the PRIME scheme is planned by the EMA in May 2017.

[10] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000925.jsp

Advanced Therapy Medicinal Products (ATMPs) – in May 2016 the EMA held a workshop on ATMPs and has recently published a document of the ongoing and planned activities of the EMA in the area of ATMPs.

Biosimilars – the EMA is working with the Commission (DG Internal Market, Industry, Entrepreneurship and SMEs) on a guidance to healthcare professionals on biosimilars. The next stakeholder workshop organised by the Commission on the uptake of biosimilar medicines in the EU is on 5 May 2017. In addition, the EMA is doing a study on biosimilars and adverse event reporting.

10. UPDATE ON OTHER EU INITIATIVES RELEVANT FOR TIMELY PATIENT ACCESS TO INNOVATIVE MEDICINES

The Commission services gave a presentation on pharmaceutical policies for effective, accessible and resilient health systems and a perspective on international aspects of the healthcare systems. In the presentation it was noted that on average pharmaceuticals is 15% of the total healthcare expenditure. Although there is a wide variation across Member States in terms of volume, structure of consumption and prices. It is considered that there are opportunities for efficiency gains in pharmaceuticals and health technologies. The Commission is promoting cooperation and the presentation gave some examples in this area covering the EURIPID[11] project, the Organisation for Economic Co-operation and Development (OECD) study on Sustainable Access to Innovative Therapies[12] and the Expert Panel on Effective Ways Investing in Health[13]. In addition the activities under the EU economic governance, including the European Semester and the Structural Reform Support Services (SRSS) was presented. These activities are intended to support the Member States in particular in building resilience in their health care systems.

ACTION POINTS AND POINTS TO CONSIDER FOR THE NEXT MEETINGS:

- Members States to send:
- Comments on the draft report on the activities of the STAMP during 2015 – 2016
- Nominations for the *ad hoc* Synergy Group
- Ideas for support of researchers and academia through the proposed Coordination Support Action and further complementing activities and project(s)

The next meeting of the STAMP Expert Group is planned for **27 June 2017 (tbc).**

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[11] EURopean Integrated Price Information Database

[12] http://www.oecd.org/els/health-systems/pharmaceuticals.htm

[13] http://ec.europa.eu/health/expert_panel/home_en

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LIST OF EXTERNAL PARTICIPANTS

Name	Affiliation
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Francesca Cattarin	BEUC – European Consumer Organisation
Ilaria Passarani	BEUC – European Consumer Organisation
Sini Eskola	EFPIA - European Federation of Pharmaceutical Industries and Associations
Elise Melon	EFPIA - European Federation of Pharmaceutical Industries and Associations
Kevin Rieger	EUCOPE - European Confederation of Pharmaceutical Entrepreneurs
Michelle Mujoomdar	EUnetHTA Joint Action 3
Virginie Hivert	EURORDIS – Rare Diseases Europe
Diego Ardigó	IRDIRC – International Rare Diseases Research Consortium
Pieter Dylst	Medicines for Europe
Laura Mancino	Medicines for Europe
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