



## European Patients' Forum & Medicines for Europe Dialogue – Report (Confidential)

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**Date and time:** Wednesday 26 April 2017, 12:30 -17:00

**Venue:** Renaissance Hotel, 1 Rue du Parnasse, 1000 Brussels

**Meeting objective:** To gather the views of patient representatives and advocates, and of the generic, biosimilar and value added medicines sectors on how to optimise efforts for better patient access to high quality medicines. NOTE: this meeting was governed under Chatham rules.

**Joint welcome – Nicola Bedlington, EPF Secretary General and Adrian van den Hoven, Medicines for Europe Director General**

**Summary of discussion:** Participants were welcomed to the second annual EPF-Medicines for Europe joint dialogue. This partnership aims to prioritise patient empowerment and access to medicines, and is a project that both EPF and Medicines for Europe are committed to. The dialogue is particularly pertinent in the current climate of restrictive national healthcare budgets, an ageing population across Europe, and serious concerns being raised over the sustainability of national healthcare systems. This discussion also takes place in a time where activities on healthcare at the EU level are at risk of compromise, as EU high-level leaders discuss the future of Europe, with a possible view to reduce EU cooperation in health.

### Session 1 - Access to health

**The EPF Campaign on access to health care and how Medicines for Europe can contribute**

**Summary of discussion:** EPF presented the main aspects of their 'Access to Healthcare' campaign. The campaign is an opportunity to raise awareness about the barriers patients face in accessing healthcare, and to build on current political momentum – including the UN Sustainable Development Goals for health – to foster more EU cooperation on access to healthcare.

**Next steps:** The Access to Healthcare campaign will run until December 2017 and will culminate in the presentation of a Roadmap with concrete political recommendations at the end of the year. Medicines for Europe will review the campaign activities with EPF to identify concrete areas of support for the campaign.

### Generic medicines and shortages

**Summary of discussion:** The generic medicines sector provides high quality, safe medicines and creates value for patients in the management of their condition. The introduction of generic medicines



to the market has doubled the number of patients who receive the medication they need in key therapeutic areas such as cardiovascular conditions and diabetes. However, shortages in the off-patent sector can and do occur, creating a barrier for patient access to medicines. There is overwhelming evidence to confirm that the root cause of shortages of off-patent medicines are economic, stemming from government-led measures such as drastic price cuts or tendering and increasing regulatory costs. During the discussion, participants raised several issues, including that of parallel trade as an obstacle to access to medicines, and the danger of counterfeit medicines, increasingly available through online pharmacies. The relative failure of the cross-border healthcare directive as a tool to increase healthcare access was also mentioned.

**Next steps:** Open dialogue with all stakeholders is critical to find solutions for the main causes of shortages of medicine. Healthy competition policies can prevent medicines shortages; advocacy support from all stakeholders is needed to educate policy-makers about the economic and regulatory root causes of shortage. The patient perspective should be included in discussions on shortages, as patients should never have to face shortages of their medicine.

## Session 2 – Biosimilar medicines and variability - How to deliver on patient information needs?

**Summary of discussion:** The key question that shaped this debate was whether information to patients is satisfactory regarding biosimilars and variability between biological medicines. Participants agreed that much of the information regarding biosimilar medicines is product-specific, and it is important to have patient-suitable information on the basic principles of biosimilar medicines, including a definition, information on affordability and on substitution. Patient-tailored language and accessibility of information (including translations) are crucial for patients to fully understand biosimilar medicine. Patient empowerment and literacy is key in this area, as people are mostly 'afraid of the unknown'. Key information providers include patient representatives and advocates, nurses and pharmacists. Patient awareness of the EMA as a resource for information on biosimilars is low.

**Next steps:** The participants agreed that a common platform to discuss communication issues surrounding biosimilar medicines would be of value. This would be hosted by Medicines for Europe.

### The structure could resemble the following:

- **Objective:** to develop comprehensive, clear, balanced, short information about biosimilars and review dissemination channels
- **Who should take part:** Members of EPF and Members of Medicines for Europe
- **Modalities:** teleconferences, email, potential for face to face meeting before next EPF-Medicines for Europe dialogue (2018) and presentation of material during next joint dialogue
- **Output:** a brief on biosimilars for patients
- Two meetings (90 minutes each) between now and year end



- First meeting: define objectives for the group, discuss key messages/areas of focus (e.g., basic biosimilar concept, approval pathway, switching) (target timeline: July 2017)
  - Second meeting: review of draft deliverables and discussion of dissemination plan for 2018 (target timeline: October 2017)
  - Volunteers from patient orgs to 1) co-lead the task force and 2) act as members/reviewers
- Patient representatives and advocates who would be interested in participating in such a taskforce should contact the EPF/Medicines for Europe Secretariat by 23 June 2017.**

### Session 3 – Value added medicines – the role of patients in off-patent research

**Summary of discussion:** Patient involvement in the development of innovation is a key challenge for patients. Furthermore, the importance of patient input and preference in the regulatory, pricing and patient access process is fundamental to ensure the finished product best meets patient needs. The value-added medicines sector needs to focus on answering patients' unmet needs and improving their quality of life and enhancing social inclusion, by improving existing medicines based on known molecules. Both parties agreed that the current market access processes like Health Technology Assessment (HTA) do not assess sufficiently patient-reported outcomes nor involve sufficiently the voice of patients in the approval process.

**Next steps:** Medicines for Europe and EPF members agreed to cooperate/collaborate to address the above-mentioned situation. This collaboration will focus on identifying patients' needs and how the voice of patients should be better included in the development and HTA processes. Medicines for Europe will include patient representatives in their activities on value-added medicines to ensure the patient voice is represented throughout.

**Medicines for Europe would like to collaborate with patient organisations on the following advocacy projects:**

- A European Parliament lunch on the importance of value added medicines for patients → June 28<sup>th</sup> 2017
- A European Parliament exhibition, showcasing the patient experience → 22-24<sup>th</sup> November 2017
- Explore ways to exchange ideas to better identify patient unmet needs, assess current processes/pathways to report patient outcomes, and elaborate joint recommendations and define joint advocacy activities
- Patient representatives that are interested in being involved in these projects should contact the EPF/Medicines for Europe Secretariat by the 15<sup>th</sup> of June 2017.



## Main Conclusions

### General

- Based on feedback from members, the EPF-Medicines for Europe dialogue could roll out on national level. This could focus initially on central and eastern European countries, and should be based on an assessment of national opportunities and challenges.
- Medicines for Europe and EPF representatives should share information on common opportunities and challenges at European and national level to identify areas for further collaboration, e.g. patient involvement in health technology assessment.
- The national members of both associations are key stakeholders in implementing the outcomes of our joint dialogues.
- Information developed for patients should be accessible and appropriately written (not heavy/scientific/available in different languages) and respond directly to core questions.
- The annual dialogue between Medicines for Europe and EPF will continue in 2018, to discuss progress and further next steps. All parties look forward to continued collaboration for better patient access!
- Other stakeholders may be invited for part of the meeting at future dialogues, e.g. HTA authorities, payers, etc.

### Generic Medicines

- Maintain an open dialogue on the key causes of medicines shortages and work to prevent these

### Biosimilar Medicines

- Develop joint platform for patient-targeted information drafting and disseminating

### Value added medicines

- Gather case studies where value-added medicines have brought value to the patient community and set up patient representative group to provide patient perspective to the Medicines for Europe lunch debate and exhibition.

## Document gateway

EPF-Medicines for Europe 2nd annual meeting presentation [HERE](#)

EPF Access to Healthcare campaign [HERE](#)

EMA Q&A on Biosimilars for patients [HERE](#)



For follow up, please feel free to contact

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