European Patients' Forum & Medicines for Europe Seminar Meeting Report

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On 31st May 2016, European Patients' Forum & Medicines for Europe organised their first 'Dialogue Seminar', including their membership.

The objective of this meeting was to gather the views of patients and of the generic, biosimilar and value added medicines sectors on how to optimise efforts for better access to high quality medicines.
This meeting was meant as an exploratory meeting: it aims at touching upon different areas to give participants an overview and identify potential areas where further dialogue could be beneficial.

The innovative step of this initiative is to roll-out similar dialogue settings at national level where both the EPF and Medicines for Europe have national coalitions/ associations. The exercise would be based on learnings from an EU-level while being tailored to country context, local requests and needs.

NOTE: this meeting was governed under the Chatham rules.

Welcome

Nicola Bedlington, EPF Secretary General and Adrian van den Hoven welcomed the participants.

Nicola Bedlington gave an overview of the cooperation between EPF and Medicines for Europe: PACT, Discussion Platform on Biologicals, including Biosimilars, Riga Roadmap…

Adrian van den Hoven presented the objectives set for the day:

Objective 1: to raise awareness

EPF and medicines for Europe's relations constructively evolved through various collaborations, especially in the EU advocacy scene. For this first time we convened this unique set-up (EU level) and with the ambition of "giving a flavor" of what is of interest to dig-in (either EU or national).

Objective 2: Sustainability

This first dialogue looked at the importance of jointly working on a greater understanding of the contribution of the generic, biosimilar and value added medicines sector with the ultimate goal of bringing access to medicines, ensuring patients have access to high quality treatments while preserving the healthcare system sustainability, striking the right balance between uptake of generic/ biosimilar product and access to innovative therapies.

Objective 3: National Impact

The goal foreseen is to replicating national setting through dialogue pilots tailored to national needs. First countries will most likely be France and Romania.

Session on access

Laurène Souchet, EPF Policy Adviser, presented the upcoming EPF Campaign on Access. The full presentation is accessible here.

The main theme of the EPF Campaign on access, to be launched in 2017, will be the road to universal access in the EU by 2030. The objectives of the campaign will be to define concrete steps that need to be taken by 2030 to be on the right track, and to change the focus of politicians from short-sighted cuts to a real commitment to a long-term vision where equity of access is a reality.

The five main themes for recommendation will be: (1) Providing access to quality care; (2) committing to sustainable investment in health; (3) encouraging affordability of healthcare products and services; (4) implementing access to a holistic range of health and social services; and (5) ending discrimination and stigma that patients are facing in healthcare.

At the end of the presentation, industry representatives were invited to explore how they could roll-out this campaign in their own environment.

Action points:

- Medicines for Europe to share data on improved access thanks to the entry of generic and biosimilar medicines after patent expiry
- Develop synergies to improve national roll-out of EPF campaign, reaching out to national governments, capitalizing on both organisations' experience. National dialogue should be encouraged to this purpose
- Discussion to be continued on development on a common definition of access with set of measurable criteria
- Closely follow SDGs and mini goals (short and long term vision) and see where both organisations can build on it.

Session 2: The value of generic medicines in healthcare system and patient empowerment

- **The Patient Empowerment Campaign, Camille Bullot, EPF**

Camille Bullot, EPF Membership & Stakeholder Relations' Manager, introduced the EPF Empowerment Campaign. The full presentation is accessible here.

She defined shortly the three key dimensions of patient of patient empowerment:

a. Health Literacy: patients must be given health information in an understandable and accessible format.

b. Self-Management: which is the extent to which the patient takes an active role for managing her/his health status and the condition. This is linked to the recognition that the patient is the expert of his own disease: s/he develops the coping skills to manage the impact of illness in his/her everyday life

c. Shared decision-making with Healthcare professionals: recognising that the patient has evolved from being a passive recipient of care to being an active and equal partner. This requires a fundamental shift in the medical culture.

- **The value of generic medicines in the healthcare system sustainability, Maarten van Baelen (Medicines for Europe)**

The full presentation is accessible here.

- **Interactive session led by Camille Bullot, EPF**

This brainstorming fostered an exchange on generic medicines can contribute to the different dimensions of patient empowerment, including health literacy, self-management and dialogue with health professionals. Here are the outcomes of the discussion:

Health Literacy

- Importance of the knowledge factor and time factor: patients feel imposed with a medication
- Patients not confident enough to ask questions
- Emergence of the 'Google patient'
- Psychological effect prevent patients from engaging in the discussion, for fear that what they say will not be "valued"
- Generic medicines are not always explained, general information on generic medicines are needed (public issue)

- Doctors should endorse websites providing good information
- Need for increased support to public health programmes, the industry to engage

Self-Management

- Self-management starts with the availability of information
- The healthcare professional should be connected with patient groups
- Need to reinforce Stakeholders' information and education through trainings and workshops
- Involvement of nurses that play a key role in patient's treatment course
- Good practices should be disseminated and rewarded

Shared decision-making with Healthcare professionals

- Healthcare professionals need to understand the disease
- Conditions for shared decision making: ability/time, willingness and culture
- Can be encouraged by: multi-disciplinary teams, HCP seeing the benefits of shared decision making and patients being prepared with questions and expectations

Session 3: What has been the patient experience with biosimilar medicines?

- **Presentation, Julie Maréchal-Jamil (Medicines for Europe)**

Please note that the full presentation is accessible here.

In her presentation, Julie Maréchal-Jamil, Medicines for Europe, demonstrated how biosimilar medicines have the potential to increase patient access to modern therapies. Some surveys show that there is still room for improvement to better understand biosimilar medicines.

- **Interactive session led by Clara Zachmann (Medicines for Europe)**

This discussion aimed to identify these gaps by focusing on the patient experience with biosimilar medicines to date. The main outcomes of the discussion were as follows:

- Remaining mantra fear expressed 'similar but not identical';
- The name 'biosimilar medicines" seems to be confusing for patient groups as it is implies "differences";
- Multi-morbidity issue: most of the time, patients have to deal with several (heavy) conditions so need further discussion is needed before switching;
- Literature should be targeted to stakeholders' needs. It should also be addressing language barriers;
- Critical point to jointly address the information gap on biologicals, including biosimilar medicines;
- Clear willingness express to pursue dialogue on this topic.

Session 4: Value-added medicines

- **Research and development in the off-patent sector, Pieter Dylst (Medicines for Europe)**

In his presentation, Pieter Dylst provided an overview of how to push the frontier of innovation though the whole product life-cycle and how off-patent pharmaceutical actors build on molecule knowledge and patient experience to tailor them to specific patient community needs.

The full presentation is accessible here.

On the request of the participants, Peter Dylst gave a number of examples of what "value-added" medicines could be:

1. A value added medicine can be a fixed-dose combination of 2 products already available on the market and used as free dose combination in arterial hypertension to reduce pill burden and avoid intake errors in a highly medicated patient population

2. A value added medicine can be a self-injected subcutaneous formulation of a product already available on the market as intravenous formulation administered only at hospital under medical monitoring in a severe inflammatory disease.
3. A value added medicine can be a new formulation of a well-known chemotherapy product helping to reduce serious side effects of the original product used in many chemotherapy regimens.
4. A value added medicine can be a re-positioning a well-known product in a rare pediatric indication as an alternative to reference treatments not specifically approved in this indication.
5. A value added medicine can be a new inhaled device to administer genericised products in COPD indication with evidence of reducing inhaler errors versus current device used with these active substances.
6. A value added medicine can be an extended-release formulation of a product already available on the market reducing administration regimen from once-weekly injection to 3-monthly injection in a neurocognitive disease indication.
7. A value added medicine can be a therapeutic drug monitoring device in association with a known cancer therapy exhibiting a narrow therapeutic window to potentialise drug efficacy while minimizing toxicity.

The presentation was followed by a guided discussion led by Natalia Hawken (Creativ-Ceutical) which aimed at capturing patients' perception and better understand their needs and expectations on medicines after patent expiry.

- The concept of "value-added medicines" was overall welcomed by patient groups;
- Participants recommended to further explore concepts such as social acceptability, ease of application, quality of sleep, at home setting treatment administration as these are essentially the issues that matter for patients;
- Participants required further explanation needed on the reason behind the term "value added medicines" and suggested renaming these to avoid misinterpretation;
- There was a discussion on pricing and economic sustainability of this new sector;
- Patients asked for further explanations on the regulatory pathway;
- Participants recommended to ensure that patient voice is taken on board at a very early stage (e.g. at the design process)

Wrap-up and next steps

Nicola Bedlington & Adrian van den Hoven closed the meeting and invited participants to express their opinion on the following points:

- How to best structure the initiative for forthcoming meetings
- How to replicate this dialogue at national level where both EPF and Medicines for Europe have a national coalitions/ associations.

- Any interest in setting working group that would be established for this purpose and work on TOR

Feedback from the participants

Many participants expressed their satisfaction with the discussion that took place that afternoon and their wish to pursue this dialogue between the members of the European Patients' Forum and Medicines for Europe on a regular basis.

Industry representatives welcomed the opportunity to receive feedback from patient organisations on topics such as biosimilars and the trust generated by early patient involvement in drug development.

They regretted to not have had more time to discuss each topic more in depth and recommended that the next meeting allows more time for discussion.

One participant suggested to increase the level of information available for patient leaders through small workshops and through social networks.

Further recommendations made by the participants included:

- To insure regularity of these gatherings (e.g twice a year)
- To insure increased representation from the industry
- To focus on joint solution development rather than joint position adoption
- To have some public report of such joint gathering to increase transparency of this approach and showing best practice of collaboration
- To identify 'topic ambassadors' both from the patient and the industry sides, who could then take the lead on session shaping (supported by both secretariat dedicated team)

CZ, CB July 2016

List of Participants

1. Adrian van den Hoven, Medicines for Europe
2. Andrea Zanaglio, Teva
3. Annette Dumas, ASDM Consulting
4. Camille Bullot, European Patients' Forum
5. Cécile Rémuzat, Créativ-Ceutical
6. Christoph Stoller, Teva
7. Clara Zachmann, Medicines for Europe
8. Elke Grooten, Sandoz
9. Erick Tyssier, Teva
10. Erika Satterwhite, Mylan
11. Fiona Cohen, Teva
12. Heather Clarke, EFNA
13. Jana Moravcova, IFsbH
14. Juan Fuertes, PHA Europe
15. Julie Maréchal Jamil, Medicines for Europe
16. Kathleen M. Sprangers, Sandoz
17. Klara Zalatnai, Hungarian Osteoporosis Patient Association
18. Laurène Souchet, European Patients' Forum
19. Louiza Poly, Pancyprian Federation of Patients' Associations and Friends
20. Luisa Avedano, EFCCA
21. Maarten van Baelen, Medicines for Europe
22. Mary-Lynne van Poelgeest, World Federation of Incontinent Patients
23. Mondher Toumi, Université Aix-Marseilles
24. Nathalia Hawken, Creativ-Ceutical
25. Nicola Bedlington, European Patients' Forum
26. Orosz Andras, Gedeon Richter
27. Peter Turek, Gedeon Richter
28. Pieter Dylst, Medicines for Europe
29. Robert Johnstone, National Voices
30. Robert Russel-Pavier, BGMA
31. Ruth Wilson, Teva
32. Souzi Makri, ENFA
33. Stanimir Hasurdjiev, NPO Bulgaria
34. Susanna Palkonen, EFA
35. Victor Lino Mendonça, Mylan
36. Yves Brand, European Multiple Sclerosis Platform