EPF Industry Roundtable 2017

Summary Notes

Please note that these summary notes aim at giving an overview of the discussions held during the EPF Industry Roundtable 2017. The presentations made by the different speakers are not included in the summary notes but can be found as an annex.

1. Welcome

Marco Greco (EPF President) welcomed the participants and presented the **objectives for the day:**

- To give an overview of EPF's Strategy and Framework Partnership Agreement 2018-2021;
- To present EPF's achievements since our last meeting, some concrete plans for the coming year;
- To discuss "hot topics" during an open dialogue session;
- To present the report on the added-value of patient organisations to be published shortly.

EPF Board members in attendance: Radu Ganescu, EPF Treasurer (COPAC, Romania), Stanimir Hasurdjiev (NPO, Bulgaria), Juan Fuertes (PHA Europe, Spain).

Apologies: Brian West, EPF Vice President (EATG).

Tour de table

See annex for full attendance list

2. EPF Strategy & Framework Programme

Nicola Bedlington (EPF Secretary General) presented the long-term strategy of EPF, including the changes brought about during review of the strategic plan, and the main pillars of work in the coming years (see annexed slides).

Work plan 2018

Veronica Foote (Novartis) asked when EPF would be able to share its 2018 work plan with partners. Nicola Bedlington responded that this would be made available by mid-November, together with the slightly revised strategic plan, situational analysis and the report on the added value of patient organisations.

Online communities

Tresja Bolt (Biogen International) asked for more details on the work planned by EPF around online communities. Marco Greco explained that the idea of this work stream was to take into account emerging online patient communities, notably on social media. This phenomenon coincides with the fact that traditional patient groups are evolving - also using the potential of new technology to attract new audiences, whilst continuing to support traditional patient activities. Since online platforms "collect" the voice of patients, and are very lean and effective, our thought is to have a closer look at how we could engage with them in a more structural way.

Cooperation with WHO/OECD

Aoife Gallagher (Eli Lilly and co) expressed her interest in knowing more about the involvement of EPF in the cooperation between WHO/OECD. She wanted to understand how formalised this collaboration is.

Nicola Bedlington (EPF) responded that EPF's cooperation with both these institutions is quite intensive on a thematic basis. EPF works with the OECD on health systems performance and waste, and with the WHO on health systems strengthening and the wider Europe. EPF's board will reflect on how we develop these relationships and whether we acquire official NGO status.

Technology solutions

To the request for clarification from **Adrian van der Hoven (Medicines for Europe)** on the term "patient-driven technology solutions", Nicola Bedlington explained that this should be understood as an overarching term for technology under all its guises.

3. Looking back and ahead

Kaisa Immonen (EPF Director of Policy) and **Camille Bullot (EPF Director of Operations and Engagement)** presented EPF's work for 2017-2018 in further detail (see annexed slides).

Summer Training for Young Patient Advocates

There was a discussion around the 'pilot' of the Summer Training for Young Patient Advocates, organised by EPF in July 2017.

Camilla Krogh Lauritzen (Novo Nordisk) asked about the selection process for the participants of the Summer Training. Valentina Strammiello, EPF Programme Manager explained that the call for registrations was shared widely through social media, EPF's members, website, etc. EPF received 90 applications. The selection process was conducted by one member of the Youth Group and one external consultant. The final list of participants was put together by Valentina to ensure a good geographical, disease and gender balance of participants. The feedback from the trainers was that the selection of people was very good and that all participants were very enthusiastic.

Veronica Foote (Novartis) asked about future plans, and notably if there was an expectation that the advocates would go on to become patient leaders. She also asked whether there were plans to engage them with stakeholders. Finally, she asked whether it was planned to involve new participants in 2018 or to pursue with the same cohort. Marco Greco answered that the plan was to support these young patients and patient representatives to become patient leaders in the future and to bring them to key roles within their national organisations. With regards to involvement with external stakeholders, Marco explained that this would have to be decided by the Youth Group itself as they determine the focus of the training, but that learning how to work with stakeholders should obviously be part of becoming patient advocates, just as it is the case within EUPATI.

Nicola Bedlington (EPF) added that new participants would be invited for the next Young Leadership Programme but that EPF would keep close contact with the former participants and look for ways to engage them in our work.

Cooperation with ICHOM

Paul van Hoof (GSK) asked whether EPF had considered working with ICHOM directly in the context of its work with the OECD. Kaisa Immonen replied that EPF had initiated an exchange with them and that as a first step they have asked us to facilitate the identification of patient representatives. EPF will advise them on patient involvement, particularly in areas that are very new to ICHOM such as multimorbidities.

Discrimination

Paul van Hoof (GSK) asked whether EPF was pursuing and would pursue its work on discrimination and vulnerable groups. Kaisa Immonen explained that EPF is still working on discrimination in the context of a piece of work we are currently doing on enhancing the

representativeness of patient organisations. In that context EPF has developed a Roadmap on how to involve and take into account the position of groups vulnerable to social exclusion (migrants, homeless people, LGBTI community…) with advocacy organisations representing these groups.

Vaccinations

Paul van Hoof (GSK) took the floor and asked about what aspect of vaccination EPF would be working on. Marco Greco replied that EPF's position on vaccination is that it is closely linked to the issue of health literacy, on which we have been working for years. Marco explained that EPF sees the huge developments of anti-vaccine rhetoric as the result of inefficient health literacy. EPF has been in touch with the European Medicines agency and Vaccines Europe about a potential campaign on raising awareness of the importance of vaccinations. More details will follow as we decide the planning for each year.

Capacity-Building Programme

Vincent Clay (Pfizer) asked about the next steps and timeline regarding the capacity-building programme in the Western Balkans.

Camille Bullot (EPF) explained that our plans regarding the Capacity-Building Programme for 2018 would be clearer by the end of the year. With regards to the implementation of a module in the region of the Western Balkans, an activity in this region would require some reflection and the development of a specific methodology as it is clear a copy-paste of our current approach would not work in the region. She added that any action in that region should be needs-driven.

Nicola Bedlington (EPF) explained that EPF was aware of the eagerness of patient organisations in the Western Balkans, but that there was also a resource issue. EPF will need to see if the relationship between the trade associations and patient groups is solid enough in the countries where we are currently implementing the programme, and whether we could transfer the management of the programme to our national coalitions in these countries. She added that further countries had been calling on EPF for capacity-building: Lithuania, Latvia…

Patient Empowerment, Roadmap on Access

Daphnee Pushparajah (UCB) asked about which resources EPF was using to develop the toolkit for patient empowerment and the roadmap on access. Kaisa and Nicola explained that EPF relies mostly on the feedback from our members, but that we also welcome feedback from external stakeholders. We consult with our Woking Groups or, in the case of the toolkit on Empowerment, set up a dedicated Task Force.

Digital Health

Gudula Petersen (Grünenthal GmbH) enquired about EPF's activities in the field of digital health. Nicola answered that EPF had already been engaged in this topic from different aspects, like our work on the GDPR, through our involvement in the project AdaptSmart, etc. Nevertheless, a more coherent approach is needed, she added, and EPF will therefore set up a separate Working Group on Digital Health to drive our work in that area to follow up effectively on the Commission Communication on digital health anticipated for the end of this year and our cooperation in the framework of Big Data for Better Outcomes, an IMI programme, the Institute for Health Innovation through Data, and the Microsoft Cloud Council on Health.

Cooperation with IAPO

Camilla Krogh Lauritzen (Novo Nordisk) asked about the status and modalities of the collaboration between EPF and IAPO. Nicola Bedlington explained that EPF has a long-standing relationship with IAPO, which is formalised in a Memorandum of Understanding. There is a clear definition of geographical remits and EPF and IAPO do work together on specific issues, such as biosimilars and patient safety, in order to ensure complementarity and avoid duplication.

Marco Greco (EPF) added that EPF and IAPO had been discussing their respective geographical remits and the question of enlarging EPF's membership beyond the EU Member States to EU neighbourhood countries. He explained that this should not be a problem given that IAPO's focus is mostly on other regions. The relationship between the two organisations is very good, he concluded. IAPO is interested in the second phase of EUPATI and we exchange experiences and know-how, which is very useful on both sides.

4. EU Hot topics

Participants were asked to present topics that were of interest to them so as to initiate a discussion on those topics.

Brexit

Vincent Clay (Pfizer) kicked off the discussion by asking EPF's position and current thinking on Brexit. Nicola explained that EPF does not have the resources to go into this extensively, but that we actively monitor and are taking part in briefing meetings with other stakeholders to have a bigger impact. EPF has one full member (National Voices) and two associate members in the UK and we are considering amending our Constitution to enable them to continue playing a role within EPF as part of a broader reflection of cooperating with countries

forming the Wider Europe. Furthermore, National Voices, and patient representative and EPF member Nick Meade (EGAN), and member of Genetic Alliance UK is part of the UK Brexit Health Alliance and is cooperating at EU level, as is EURORDIS. **Nicola Bedlington (EPF)** added that EPF had also sent out a letter earlier this year regarding criteria for the relocation of the EMA, focussing on the importance of patient safety, efficacy, minimal disruption and the need to safeguard public health. There have been attempts to lobby EPF by a number of member states in their bid to host EMA however EPF feels it is highly inappropriate to engage.

Adrian van der Hoven (Medicines for Europe) shared that EFPIA and EuropaBio were working together on this topic. He explained that one of the major challenges for industry was that they had received indications that all products would need to be registered in both the UK and an EU country by the cut-off date in March 2019 if they were to still be marketed. The implications of this are quite far-reaching and with many legal aspects at stake, which would have an influence on supply. Adrian added that Medicines for Europe was asking for a transition period (no hard cut-off date), and a new framework that would include a deep cooperation in relation to the MHRA.

Timea Rezi-Kato (Medtech Europe) took the floor and said that MedTech Europe was very concerned with Brexit given that a lot of MedTech companies obtain their authorisation from bodies in the UK. Regulatory collaboration will be key. She announced that MedTech Europe would soon be publishing a position statement and case-studies of how the medical technology industry will be affected by Brexit. The organisation is also part of the (for the moment) informal alliance on Brexit.

Vincent Clay (Pfizer) urged patient organisations to take a more active role as it not only industry that should be speaking about potential lack of supply of medicines.

Veronica Foote (Novartis) reminded that it is not only UK patients that are at risk, but also European patients.

Nicola Bedlington (EPF) highlighted that this issue will be discussed at the EFPIA Patient Think Tank in October and also suggested that this issue to be added to the Cross-Industry Patient Dialogue meeting on 5 December.

Intellectual Property

Veronica Foote (Novartis) asked about EPF's stance on the Intellectual Property debate.

Marco Greco (EPF) explained that EPF was not vocal in what is a very delicate debate at the moment. He said that EPF would need to inform and consult its members before publishing an official position. He added that EPF would not have a radical view on this topic: up to now, when it comes to pricing, EPF has always argued that innovation should be recognised and

rewarded, otherwise the system would collapse. He reiterated that in EPF's view, innovation should nevertheless be accessible, and made available for the patients and there needs to be a fair framework to move forward.

Paul van Hoof (GSK) said the report by Copenhagen Economics will be open to consultation and asked whether EPF had been asked to contribute actively to the process. Nicola said that EPF had not been asked to contribute to the process and that our perspective at this juncture was to wait until the report had come out and to comment on it. She said she expected it to be a very technical document and that EPF would look at it from the patient perspective. She added that EPF was also revising their document on pricing since the environment has changed. This would go out for consultation with our membership.

Nicola Bedlington (EPF) asked whether despite the visible reluctance of industry on the incentives review, there was a way that this report could lead to something positive for the industry.

Paul van Hoof (GSK) commented that in his opinion, the debates on IP and pricing and accessibility should be separated, a statement that Veronica Foote (Novartis) supported. Paul added that in his view the dossier was quite political rather than technical.

Adrian van der Hoven (Medicines for Europe) replied that there is a clear link between IP incentives and pricing (example: generic and biosimilars). He added that for him it was clear that incentives were needed. He agreed that this was a delicate dossier for EPF given its ongoing collaboration with both the Commission and the industry. Nevertheless, a good framework encouraging R&D and innovation is needed, he added. Adrian suggested a dedicated seminar to make a series of presentations for EPF to gain knowledge on the topic and access to objective information.

Marco Greco (EPF) welcomed the idea put forward by Adrian and said this would be discussed at the EPF Board meeting the next day.

Stanimir Hasurdjiev (EPF) shared his concerns about patient access to innovation: patients want and need innovation, he said, but patients also want access to the treatment. He deplored the fact that certain medicines were not launched in whole regions and stressed the need to work on that. Even if this is a systems flaw, he said, we need to find a way to solve this. He added that there was also a need to work on the transparency of pricing.

Future of EU Health Collaboration

Nicola Bedlington (EPF) raised the issue of future of health collaboration: she explained that EPF had been quite vocal about the threat on the future of DG SANTE and of the Health

Programme (letter to Juncker, collaboration with PACT). Nicola invited trade associations to lend their support to our actions and to reaffirm the need for future health collaboration.

Adrian van der Hoven (Medicines for Europe) explained that in his view it would be quite difficult for trade associations to get involved in that debate following the consequences of their involvement in the debate on whether the pharmaceuticals 'portfolio should move from DG SANTE to DG GROW (2014), which shed a very bad light on the trade associations involved in the discussion.

Stanimir Hasurdjiev (EPF) expressed his disagreement with Adrian. To him, the support and positioning we need from industry is not about how the Commission should be structured, but about how much health collaboration we need in Europe. This contribution relates to the debate on the future of Europe and not to internal matters, he said.

Paul van Hoof (GSK) said that he had personally not heard much about the possible discontinuation of the Health Programme. In his opinion the Commission recognises the importance of health collaboration, but the question is to what extent its role should differ from the one it has now.

5. The Added-Value of Patients' organisations

Camille Bullot (EPF) presented the upcoming EPF report on the added-value of patient organisations (see annexed presentation).

Daphnee Pushparajah (UCB) asked when the report would be released. Commenting on one of the report's finding stating that patient organisations had to demonstrate their added value and impact more than other stakeholders, she said, commented that industries funding such organisations need to know about their impact. Camille said that the report was being finalised and would come out in a month's time. Regarding measurable deliverables, she said the criticism made by the report was that scrutiny put on patient organisations was not limited to how these performed, but extended to their very nature and governance.

Stanimir Hasurdjiev (EPF) added that deliverables are indeed important but that patient organisations do many things that cannot be measured like policy and advocacy.

Daniel De Schryver (Janssen) asked about potential actions that patient groups can take to tackle the reputation issue described by the report. Camille replied that EPF's feeling was that patient organisations and EPF are doing quite a lot to tackle this: from developing transparency guidelines, to encouraging the professionalisation through capacity-building activities, through training of leadership. Drawing on a parallel with the reputation of

environmental NGOs, she concluded that the main question remained on how to gather wider support from the general public.

Responding to a comment from **Stanimir Hasurdjiev (EPF)** that application and procedures to receive funding from companies still varied too much across Europe, **Veronica Foote (Novartis)** said that it would be great if there was one EFPIA framework that all companies could use. **Nicola Bedlington (EPF)** suggested that this issue could be tackled at the Cross-Industry Patient Dialogue meeting on 5 December).

In the concluding session, **Nicola Bedlington (EPF)** highlighted that she would be in touch will all sponsors on a bilateral basis to follow up on support for 2018. She highlighted that processes generally had been much smoother in 2017 and she thanked both companies and our Finance Manager Stefano Tironi for their great efforts in this regard.

Marco Greco (EPF) closed the meeting with warm thanks to all for the good and lively exchange and invited all participants to join the EPF office official opening cocktail.