

The European Patients' Forum Newsletter

// October Issue

A warm welcome to the October issue of the EPF Newsletter!

We are delighted to share with you important developments for the European patients' movement this month.

A key feature was, of course, the European Health Forum Gastein which was a very rewarding event. EPF led a session on patient empowerment while for the first time in the history of the event young representatives from patients' groups were involved as young 'Gasteiners' and the patients' perspective was included in many non 'patient-focused' sessions.



The last EPF Cross-Border Healthcare Regional Conference took place in Tallinn, Estonia. The feedback compiled at this and three other Regional meetings in the last year will inform our work in this area to contribute to the European Commission's first progress report due in 2015. Further meetings will be organised next year in other EU countries.

Other key achievements linked to our project portfolio are described in this issue. This includes the launch of the first Patient Expert Training Course of the European Patients' Academy on Therapeutic Innovation (EUPATI) and the adoption of patients' role as one of the key themes for further strategies on sustainability and cost effectiveness in healthcare under the WE Care project.

You will notice that the 'Read more' features of our newsletter direct you to a revamped version of our website. We are still updating content therefore we apologise for the occasional broken links or 'under construction' pages but the full content of this issue is also attached in PDF to ensure you do not miss anything. Feel free to email cynthia.bonsignore@eu-patient.eu if you encounter any problem with the website.

Warmest greetings for a pleasant and inspiring autumn – we look forward to continue working with you!

Anders Olauson, EPF President and Nicola Bedlington, EPF Secretary General



Health in the European Commission

Together with the wider health community, EPF **welcomed** President Juncker's decision on 22 October to keep the pharmaceutical portfolio in the **Directorate-General for Health and Consumers** (DG SANCO). His initial intention was to give back this responsibility to **DG for Enterprise and Industry** (DG ENTR). EPF expressed our worries regarding this move together with other health stakeholders in a **joint letter**. We remain concerned however that medical device will indeed be transferred to the Enterprise Directorate.



Health is one of the highest priorities of European citizens and we are delighted that Mr Juncker heard the civil society's call, at least for medicines (and de facto the European Medicines Agency – EMA) and pharmaceutical products. *“For patients, the overall priority is that these products are safe and of high quality in the EU. They provide a major contribution to life expectancy and quality of life of patients as well as the quality and sustainability of health systems,”* explained EPF President Anders Olauson.

Regarding medical devices' dossier to be transferred to DG ENTR, EPF highlights that no compromises can be made on patient safety and quality. *“The needs of patients should always come first. This is particularly vital at a time when European health systems are facing many challenges. Having a coherent EU public health policy is only possible if driven by the needs of patients,”* explained Anders Olauson.

We believe that medical devices' policies must have a firm grounding in public health, quality of care and patient safety. DG ENTR plays nonetheless a legitimate role in promoting **sound** European industrial policy and we hope that the two Directorate-Generals will work closely together on health-related issues. Cooperation is needed to take more effective action towards closing the gap on health inequalities so all patients across Europe have access to high-quality, affordable treatment.

A former doctor as Health Commissioner

Vytenis Andriukaitis, a former Lithuanian health minister and doctor, left MEPs happy to confirm him as the new EU commissioner for health and Food Safety at his confirmation hearing on 30 September. His priorities for the next five years, as he intimated at the European Health Forum Gastein will focus on the pooling of member states' efforts to invest in health, the promotion of cross-border healthcare, and the implementation of the tobacco legislation. He added that in times of austerity spending in health is not only expenditure but an investment in human capital. He finally summed up as his main concerns as being 'promotion, prevention, protection', with a focus on prevention to reduce costs and keep citizens in good health. (Full speech available [here](#), PDF).

Read [here](#) and [here](#) the joint statements made by the health civil society to President Juncker.

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Picture: © EHFG 2014, Flickr

Fourth Regional Conference on Cross-Border Healthcare

The last [EPF Cross-Border Healthcare Regional Conference](#) took place in Tallinn, Estonia, on 6-8 October. This final event in a series of four on this topic gathered patients' representatives from Denmark, Estonia, Finland, Latvia, Lithuania and Sweden. Further conferences will be organised in 2015 in other EU countries.



Four conferences, one common concern: the lack of available information on the Directive for patients. Most of the Estonian participants did not know of it before receiving our invitation and the majority of them committed to disseminate what they have learned to their peers.

Baiba Ziemele, President of the Latvian Haemophilia Society (pictured, left), was one of the few aware of the legislative tool: *"I was waiting for it to solve many problems patients face in our national healthcare system. Unfortunately it doesn't help because of the high financial investment needed before actually getting the service abroad"* she complained.

Financial inequality appeared as a major barrier for healthcare access due to the requirement for patients to pay upfront for treatment before seeking reimbursement. An Estonian participant said: *"In the former Soviet bloc countries, cross-border healthcare is a dream as only few people have the resources to access it."*

Diversity of National Contact Points

The wide disparity in resources allocated by member states to the existing National Contact Points (NCP) was striking. The Estonian Contact Point for instance is alone whilst more than 70 representatives work across Sweden. A Danish participant pointed out that their *"NCPs are hardly visible in Denmark"* while Baiba already knew her Latvian contact person, having *"e-mailed each other on some questions"*.

The Tallinn session finally looked at what participants consider to be an ideal NCP. It emerged that they need a responsive, patient-friendly agency that does not only provide good information, but also offers solutions for the patient's journey. They specified that it should ensure patients who need care abroad actually access it without bankrupting themselves in the process.

Next steps

"These regional conferences have shown the important and valuable contribution that patients' organisations can make to ensure that this Directive reflects the realities of patients and has the maximum positive impact on the lives of European citizens. We will soon disseminate the Conference report, and we will also look at setting up a tool, such as an internet forum or a Facebook group, to enable all the participants to keep in touch with each other and share what they are doing at coming home. Next year will be important for patients. The European Commission will for the first time assess the implementation of the Directive in Member States and we will ensure that grassroots patients' experiences inform it" concluded EPF President Anders Olauson.

Please click [here](#) for more information and visit [EPF Facebook Page for pictures](#). Contact: Kaisa Immonen-Charalambous, EPF Senior Policy Advisor, kaisa.immonen.charalambous@eu-patient.eu

Strong Patient representation at European Health Forum Gastein

The [European Health Forum Gastein](#) (EHFG) was held on 1-3 October in Austria. Many patients' representatives were prominent at this important European health policy event, and not only in the 'patient-focused' sessions. The 17th EHFG was themed "Electing health – The Europe we want!" reflecting May's EP election.



A full and detailed report will be made available soon from the EHFG secretariat. The following gives a flavour of some of the debates. EPF organised a workshop on patient empowerment on the second day of the event. Presenting the conclusions, EPF Secretary General Nicola Bedlington reiterated the concept of 'co-production of health' as "patients want to be full partners in the management of their condition and need to be empowered to be able to do so."

Empowerment and access

Ilona Kickbusch of the Careum Foundation (pictured, right) in her keynote address to set the scene focused on the need to democratise health in relation to equity and access. She stated: *"We are at a turning point in health policy: the nature of 21st century health, changes in society and technology call for a radical change of mindset and a reorganisation of how we govern health. This changes the role of the health sector, health professionals, patients and citizens – as well as others including the private sector."*

Our Board Member Stanimir Hasurdjiev of the Bulgarian National Patients Organisation pointed out the strong link between access and empowerment two core pillars of the [EPF European election campaign](#). He presented the [Patient Access Partnership](#), a patient-led multi-stakeholder platform to address equity and access to health care across the EU that will formally kick-off in December 2014.

Empowerment and health literacy

The importance of [health literacy](#), one of the key tenets of patient empowerment, was also stressed in a session on "[Real World Patient Data](#)", alongside the patient health professional relationship and self-management. Pēteris Zīgalvis of DG Connect said the European Commission is currently involved in a project that tries to develop web-based skills in the workforce. The importance of this was highlighted in EPF's own project EPF [Chain of Trust](#) focused on patients' and health professionals' trust in and acceptance of ehealth services.

A Eurobarometer survey on ehealth will likewise be launched soon. According to this review, 77% of EU citizens agree that the Internet is a good tool to improve their knowledge on related topics. Encouraged by these results, our Senior Policy Adviser Kaisa Immonen Charalambous nevertheless stressed the importance of *"distinguishing what is good and trustworthy information, and what is not, because we are bombarded with so much information, overall on the Internet."*

In the closing plenary session Nicola Bedlington emphasised that primary prevention, health promotion and patient-centred chronic disease management should be part of one continuum. Effective prevention can free up resources to provide healthcare for patients, while proper investment in high-quality chronic disease management can maximise patients' quality of life, reduce the disease burden and optimise the use of healthcare resources.

“My experience as a Young Gasteiner”

Our Policy Officer Laurène Souchet attended the European Health Forum Gastein 2014 as a Young Gasteiner. This was the first time that young representatives from patients’ organisations were involved in this programme. Laurène shares her experiences on our blog.



Just coming back from the European Health Forum Gastein 2014, I would like to share my experience as a Young Gasteiner. The programme was a great opportunity to come in contact with many young people who are active in public health all over Europe (healthcare professionals, researchers, representatives from NGOs). I learnt a lot from our discussions and I’m happy to be part of this vibrant network, overall as it is the first time that patients’ representatives are involved.

While the whole conference was interesting, what I found the most enlightening is the Cross-Border Healthcare workshop which was held with young gasteiners. We reflected together on many solutions to key issues in the implementation of the directive. My group focused on continuity of care between the home healthcare professional and the doctor visited abroad. We recommended electronic health records with some degree of harmonisation would be a key tool for exchange of information. And empowering patients is also key to ensure the information flows.

Another session that I particularly liked was on [Health System Performance](#), because it is such a prominent topic, and I now grasp the concept and its potential, which will be very helpful for my work. I think this is a key area where patients need to be engaged because the questions of access, patient centred healthcare, and quality of care are at stake.

I heard other interesting ideas at Gastein. Former MEP John Bowis in particular proposed to focus our efforts on the health literacy of decision-makers. And Ilona Kickbush presented the idea of health citizenship which means in a nutshell that citizens have rights in the context of healthcare, and should also have opportunity to take responsibilities.

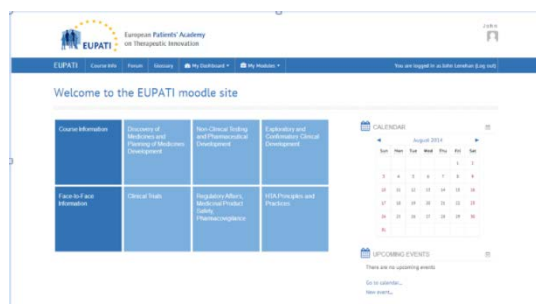
A part that resonated strongly with me is the speech of Dr Agis Tsouros from the World Health Organisation who explained that “health is a political choice”. He argued that if we have health inequalities in our society, this comes from decisions made by politicians who can chose to ignore a problem. Working on the question of access within EPF, I know that we will do our best to ensure that decision-makers work towards the right solutions.

I was glad to recognise some fellow patients’ representatives within the ranks of the Young Gasteiners, namely from our membership, Roberta Savli from of the [European Federation of Allergy and Airways Diseases Patients’ Associations](#) (EFA), Anne-Marie Borg from [Malta Health Network](#) and Elisabeth Kasilingam of the [European Multiple Sclerosis Platform](#). I believe the next step will be to involve young patients with chronic disease themselves, for instance from [EPF Youth Group](#). Patients are experts too, as was acknowledged several times during the conference.

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Launch of the first Patient Expert Training Course

On 6 October 2014, 53 trainees started the [first Patient Expert Training Course](#) of the [European Patients' Academy, EUPATI](#), which will continue until late 2015. This is one of the project's key educational programmes specifically designed for patient advocates who want to acquire expert-level knowledge in Research & Development. Two 'students' share their first impressions with EPF.



How did you find the course so far, what are your first impressions?

"Kick-off was great. The team showed us the technical side of the platform as the course uses a blended learning approach of online and face-to-face training. I love the materials; they are very understandable and useful for me. Some first questions are asked for the tutors on the participants' forum and they answer quickly. This is very helpful. I had a first look into the plans and the modules and the content I knew, this will be exciting" – Birgit Bauer from Germany.

"I started reading Module 1 right away. It's about the discovery of medicines and how the planning of medicines development. I have learned about molecules, receptors, about protein, etc. It makes you comprehend the very basics of medicine development. Besides being user-friendly, the online format allows me to study whenever I feel like it. For a lot of patients it is hard to follow regular classes, because unexpected hospital visits are part of our life. This course fits around my schedule, instead of the other way around" - Kate Sparkles from The Netherlands.

What do you expect from this programme?

"I hope to be a better patients' advocate and, as journalist in the healthcare area, I want to acquire more know-how to explain my readers content about the medicines development process" – Birgit Bauer from Germany.

"This course will give me the opportunity to understand researchers better about various aspects of their work e.g. their clinical trial. As a communication consultant, it is very exciting to bridge the gap between researchers and patients. To me, sharing information is the ultimate form of patient advocacy. My understanding of scientific articles has already improved, enabling me to write more of those often very complicated articles in lay man's words. And that's only the beginning!" - Kate Sparkles from The Netherlands.

More information: www.patientsacademy.eu and <http://walls.io/eupati>

Picture: © EUPATI 2014

Patients play a key role in sustainability and cost effectiveness strategies

Our Project Officer Valentina Strammiello and Board Member Robert Johnstone attended the fourth [WE CARE workshop on 9 October 2014](#). EPF is a partner in this project that works “Towards a sustainable and affordable healthcare” and we ensured that the patients’ role was taken into account as a major player for cost effectiveness strategies in future healthcare systems.



The October’s WE CARE workshop explored research topics that can help optimise the adoption of cost containment strategies. The previous meeting held in September already tackled this issue from an economic, institutional and political perspective and identified 30 aspects where evidence is crucial but currently insufficient (see [Workshop Green Paper](#), PDF)

The outcomes were distilled in eight major cross cutting themes:

- Incentives and payment methods
- Quality indicators
- Appropriate boundaries in the health system
- Governance and accountability
- Overcoming labour intensity in hospitals and LTC
- The political system and long-term vision for health
- Care coordination and integration
- **Patients’ role**

As EPF is involved as an associate partner in WE CARE, we played a core advisory role to ensure patients’ involvement is no longer considered as cost-driver but as the essential part of the solution for cost-effective planning. Promoting health literacy was therefore considered essential to equip patients with the knowledge and skills needed to take an active role in managing our health and healthcare.

The project consortium identified patients’ participation in the innovation process as another barrier to break down. Whether for low tech or high tech solutions, therapeutic or social innovation, we highlighted that it is important to ensure resources are well invested because of their added value and real potential for patients’ quality of life.

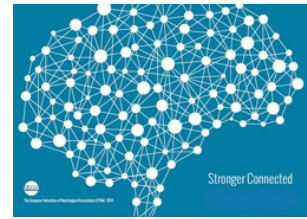
The last element for cost effectiveness is an enabling healthcare environment, whereby the principles of patient-centred healthcare are consistently embedded, applied and evaluated. Education of healthcare professionals should include education in self-care in general, and the key competences needed to support patients’ involvement in healthcare

The final conclusions of this FP7 project will be gathered at the [WE CARE final conference](#) taking place in Gothenburg on 14-15 April 2015.

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Stronger Connected: building national neurological alliances

The [European Federation of Neurological Associations](#) (EFNA) launched “*Stronger Connected*” – a guide to building national neurological alliances – at the [Advocate for Brain, Mind and Pain Workshop](#) on 24-25 September 2014 in Brussels. We took this opportunity to know more about our member’s efforts to create alliances at national level with an interview with its Executive Director, Donna Walsh.



What do you want to achieve with these alliances?

Neurological alliances bring together organisations working on a wide range of neurological issues, such as multiple sclerosis, epilepsy, stroke and many more. Groups with similar interests can be heard as a collective voice for greater impact. Being part of EPF is of huge importance to EFNA. As an organisation with just two staff persons, we do not have the resources to be active in every aspect of healthcare debate and decision-making. EFNA can then more easily contribute from our more specific angle to EPF patients’ perspective which is a real benefit to us in terms of being efficient in our work and not duplicating effort. Speaking with one voice also means that patients are more likely to be heard.

Why have you decided to create national alliances?

EFNA is launching a Member of the European Parliament (MEP)’s Interest Group on Brain, Mind and Pain in 2015. For this group to be optimally effective we need to build an efficient channel of communication to the national level through which we can see the real impact of EU decision-making on neurology patients. We also wish to empower these groups to help us in reaching out to their national MEPs, tabling issues for our agenda and disseminating the results. Only a handful of alliances exist today in Ireland, the Netherlands, Poland, Scotland, Spain and the UK.

How does it work concretely to create an alliance?

EFNA will not set rules on how an alliance should operate. Stronger Connected is a collection of experiences from existing alliances which should inspire and encourage national patient groups to work together on issues of common concern. A formal channel would involve a registered National Neurological Alliance in an EU Member States which becomes an Associate Member of EFNA. As the process will take time, we will link in with active patients’ advocates or clusters of national patients’ organisations who may be cooperating nationally without registering as a non-profit organisation.

What are the challenges EFNA is facing to create those alliances?

The main challenge is the lack of resources, in terms of time, personnel and – of course – funding. Even existing alliances struggle in this regard. However, lots of solutions were put forward to overcome these obstacles and with committed organisations involved, we are confident that we will see new alliances in future even if we know it will take time.

If you are a representative of a national neurology patient organisation in your country and would be interested in working with EFNA to build an Alliance, contact: executivedirector@efna.net.

Caring for carers of those living with schizophrenia

World Mental Health Day, celebrated annually on 10 October, shined a light this year on those living with schizophrenia. Our Member, the [European Federation of Associations of Families of People with Mental Illness \(EUFAMI\)](#), shared the initial results of their major family carer survey¹ “Caring for Carers” [C4C] on this occasion.



“The stigma and taboo surrounding mental illness do not only affect the patient. Great is the ignorance and incomprehension of the outside world and even of the close family. I want to infringe the taboo and give a voice to those who can’t or don’t dare to stand up for themselves. As a mother, I feel valued and empowered by the fact that I try to do something positive with a negative life experience”, testified a mother of a person living with schizophrenia to show the social determinants that lie behind the disease.

In line with this year's theme, the first EUFAMI research's outcomes focus on family carers of relatives directly affected by schizophrenia. They perform their caregiver role as a part time job which places a huge emotional and physical burden on them, due to the undetermined and long-term nature of schizophrenia.

Approximately 10 million family carers in the EU support their child or sibling with a serious mental health condition on a daily basis. This is a massive and valuable contribution, not just to individuals, but to society as whole and to the financially strained healthcare systems across Europe.

“This hidden workforce of family carers is a lifeline for society and we must take steps to ensure they are fully recognised for their contributions and they are supported in order to allow them to continue caring effectively and safely for their loved ones, without putting their own physical and emotional well-being at risk,” said Kevin Jones, Secretary General of EUFAMI.

With this constant level of pressure, a third of carers are reported to be reaching ‘breaking point’ and feeling they cannot carry on with things the way they are. The findings emphasise the urgent need for action from both governments and society to recognise the role of carers, their contribution and the need to provide support and hope for their future.

You can follow the conversation around the C4C Survey and World Mental Health Day on EUFAMI'S [Facebook page](#) and on Twitter using the hashtags #WMHD14 and #LivingWithSchizophrenia.

Picture: © EUFAMI

¹ EUFAMI's research is at its first phase and covers now five countries in Europe (France, Germany, Italy, Spain and the UK) as well as Australia and Canada. It will extend over 25 countries with full results planned for publication in spring 2015.

EPF welcomes the new policy for the release of clinical trial data

The [European Medicines Agency \(EMA\)](#) formally adopted on 2 October 2014 its new [policy for the release of clinical trial data](#). EPF welcomes it as a step forward towards greater transparency of the regulatory process on clinical trials.

“Greater transparency on clinical trial data will contribute to empower patients. In order to make meaningful therapeutic decisions in partnership, both clinicians and patients need to have access to all the relevant information needed to make those decisions”, commented EPF Senior Policy Advisor Kaisa Immonen-Charalambous.



EPF actively involved from the outset

EPF has [consistently called](#) for the publication of all clinical trial results, regardless of the outcome of the trial. We reiterated this position in our response to the EMA’s public consultation in 2013 that contributed to build today’s policy (see [previous article](#)). We also stated that the Clinical Study Report (CSR) is not a commercially confidential document and should be made publicly available after the assessment is concluded.

Whilst applauding the Agency’s commitment to transparency, EPF nevertheless remains concerned about some details of the new policy, in particular the restrictive interface and the terms of use, as well as the process for redacting “commercially confidential information”. We are currently consulting our members regarding the revised policy.

In the consultation phase, we criticised the proposed restrictive terms of use and the lack of user-friendliness of the electronic interface. The final policy now contains two different levels of access. For all users, CSRs will be available in a searchable format but only in a view-on-screen mode. To be able to download, save and print CSRs, users will have to register and prove their identity. All users have to sign up to the terms of use.

The next step in the process will be for the EMA to further consult with stakeholders regarding publication of individual patient data. We are committed to continuing our collaboration with EMA to find a solution that benefits transparency and is acceptable to patients. We will ensure that the patient perspective is heard in future discussions, including the next review of the policy that is due by June 2016.

Agency’s report on interactions with patients

EMA also released in October an annual report outlining its *“interaction with patients, consumers, healthcare professionals and their organisations”* ([link](#), [PDF](#)). Information is given about the creation of a new [department dedicated to the interaction with patients and healthcare professionals](#) which we commend as a strong signal of their continued commitment to work with us.

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Picture: ©Shutterstock

A Pact For Patient Safety

On 15 October, Cristina Padeanu attended the [Irish Patients Association's](#) event to launch the [Pact for Patient Safety](#), an initiative by patients and for patients. The pledge establishes ten key commitments for health authorities and policy-makers to better protect patients from preventable harm.



“The Pact is a resource for patients and citizens throughout Europe and beyond as it generates awareness of safety in healthcare institutions. It will also support patients and their representatives to drive accountability for the 10 commitments of policy-makers” said Member of the European Parliament Séan Kelly (EPP, Ireland) who hosted the event.

The initiative adds to a number of actions taken by the European Commission and different stakeholders to raise the awareness on patient safety and the need for a high quality patient-centred care at the European level. EPF played an important role in bringing the input from its members into the work of the European Commission, and making it accessible to patients (see [link](#)).

Martin Seychell, the representative of the European Commission's DG SANCO, emphasised the openness of Commission to public involvement which represents the opportunity for a continuous contact between the public and the institution. EPF sees it positively in the discussion around patient safety and quality of care. *“Given that 1 in 10 patients are currently harmed while receiving care, it is time that patients' demand for safer care is heard”*, added Stephen MacMahon, Director of the Irish Patients Association and leader of the initiative.

The different players involved in these actions hope that the European Council will now turn its attention towards these issues. They believe that the [European Council meeting](#) in December 2014 could place an emphasis on the importance of patient safety and calls members states for further action to reduce the adverse events and tailor quality patient-centred healthcare systems.

More information about EPF work in Patient Safety is [available here](#).

Picture: ©EPF

Patient MedTech Dialogue meeting

On 15 October in Brussels, EPF and the MedTech Industry held their 8th Dialogue meeting. An important item on the agenda was the release of a patient-centred checklist for companies to better involve patients in the medical devices sector.

“Bringing value to your business through patient partnerships” was the theme of one of the sessions of the [MedTech Forum](#) the largest yearly meeting of the medical technology industry. The Patient-MedTech Dialogue was held the day before the MedTech Forum to ensure patients’ representation at both events.



This was the opportunity to launch the ‘checklist’ developed by patients and industry representatives in a task force. This tool was produced as an outcome of the Dialogue and showcases the importance and relevance of an industry that is patient –centred not only in words but in deeds.

Speakers included Audrey Craven, President of the European Federation of Neurological Associations, who explained why companies should work towards fulfilling patients’ unmet needs, and listen to patients: *“All medical device and In Vitro Diagnosis device companies should take into account the needs of the patient. Companies are increasingly positioning themselves on the full patient pathway and disease management. Therefore, further interaction with and empowerment of the patient, in addition to the healthcare professional, will become the new paradigm.”*

“Open and transparent dialogue between patients and the MedTech industry is key to ensuring that medical devices companies really do put patients at the centre of their work, and draw on patients’ unique experience and expertise as a partner for innovation and safety”, concluded our secretary General Nicola Bedlington.

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Picture: © MedTech Forum 2014

EFPIA/PhRMA Collaboration Summit

The EFPIA/PhRMA Healthcare Summit took place on 16-17 October 2014 in Brussels. The event gathered around 150 representatives from patients' organisations and the pharmaceutical industry. Attendees explored themes of empowering patients and citizens to becoming more involved in EU health policy decisions.



EPF President Anders Olauson led a session on “Data transparency: advancing science to the benefit of patients.” The discussion was around expectations from patients and industry, as well as from regulator’s view. There is a huge possibility in all data and the challenge is how to make it work together at the same time to keep patients’ integrity intact. *“To make data transparency work, we need to maintain trust, and for that we need to meet and work together, which today’s conference is an example of”* Anders said.

EPF Secretary General Nicola Bedlington moderated a session on Health Technology Assessment (HTA) and set it in the context of cross-border healthcare. The Directive established a voluntary network for cooperation between the bodies and authorities in member states responsible for HTA.

She outlined that EPF’s research project in this area clearly showed the need for patients’ organisations to be supported to be meaningfully involved in HTA processes. “There is much good will to involve patients in HTA but there is a lack of clear methodology and capacity.” During the session, the issue of appropriate financing of capacity building was raised.

Participants debated on what constitutes ‘meaningful’ patient involvement as defined by EPF’s flagship [project Value+](#) .

Kaisa Immonen-Charalambous, EPF Senior Policy Advisor, moderated a session on priority medicines. She highlighted the importance of innovation and that prioritisation must be based on patients' unmet needs. “In order to guarantee this it is vital that patients are involved throughout the innovation chain” she added. Participants suggested among other that patients’ representatives could build the capacities for industry and ‘teach’ companies how to engage with patients in a meaningful way.

The EFPIA Patient Think Tank will be reflecting on how to utilise effectively the outcomes of the Summit.

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Picture: EPF President Anders Olauson, © EFPIA/PhRMA Summit 2014

A patient-centred approach to regulatory affairs

EPF secretary General Nicola Bedlington and our Board Member Marco Greco attended the 11th [TOPRA Annual Symposium](#) on 13-15 October 2014 in Brussels, Belgium. They discussed the theme 'Matching modern regulation with modern medicine – a patient-centred approach to regulatory affairs?'



The Symposium brings every year together regulatory professionals to discuss and understand today's regulatory issues and debate future plans for regulation. In her

keynote address, Nicola Bedlington challenged attendees to consider if the current regulatory system was delivering patient-centred approaches to get products on the market (patient involvement in ethics committees, medical devices, transparency of trial results, patient safety, etc.)

“Patients are engaged and committed to working with partners in regulatory affairs to ensure equitable access to high quality patient-centred care – this is the name of the game” she said. “We are learning to work with regulatory environment but do you know how to work with us? How can we achieve maximum synergy whatever our entry points might be?”

Openness and transparency were also part of the discussions. Our Board Member Marco Greco explained how data disclosure supports patients: *“The smooth processing of health data is fundamental for the good functioning of healthcare services, patients’ safety, and to advance research and improve public health.”*

He also intervened into the pharmacovigilance session as he was appointed in 2013 as the alternate representative of patients to the [Pharmacovigilance Risk Assessment Committee](#) (PRAC) of the European Medicines Agency (EMA). Through this role he is ensuring that the deliberations of the Committee take into account patients’ needs and he acts as an important liaison role with the patient community.

“It is not only important to represent patients in such committee, it is symbolic. It means that patients’ advocacy has now entered a new dimension. This is the recognition of many years of work of many persons, many volunteers. Our voice is not only listened, but listened in the right place”, he concluded.

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Picture: ©TOPRA 2014