

The European Patients' Forum Newsletter

// November Issue

A word from EPF President and Director

A warm welcome to the November issue of the EPF Newsletter.

We are looking forward to our forthcoming Cross-Border Healthcare Conference on 9-11 December in Brussels ([link](#)). It will be a key opportunity to take stock of how The Netherlands, Luxemburg, Germany, France and Belgium are implementing the EU Directive through the eyes of patients' representatives.

We really want to encourage national patients' organisations to work with the Directive. For instance, patient organisations can contribute to the effectiveness of the National Contact Points by ensuring dissemination of information to the grassroots level. We can also provide constructive critique and guidance to ensure that patients really benefit, at the end of the day.

Some of the other key highlights of the last month include the vote on 22 October of the European Parliament on Medical Devices, the organisation of our 6th Regional Advocacy Seminar in Zagreb, Croatia, our co-organisation of the Lithuanian EU Presidency Conference on the Sustainability of Health Systems, the launch of the second phase of our Capacity Building Programme in Romania and Hungary, and the launch of a video on the InterQuality project, etc.

We are also delighted to welcome Camille Bulot, our new Membership Officer, dedicated to working closely with our members both at European and National level.

Warmest greetings,

Anders Olauson, EPF President and Nicola Bedlington, EPF Director



The Vilnius Declaration to ensure future sustainable healthcare systems

The major Lithuanian EU Presidency Conference on “Sustainable Health Systems for Inclusive Growth in Europe” took place in Vilnius, on 18-19 November 2013. It leads to urgent call for immediate action to protect Europe’s healthcare systems.



EPF President Anders Olauson and EPF board members - Stanimir Hasurdjiev, Chairperson of the National Patients’ Organization (NPO); Vida Augustinienė, President of the Lithuanian Diabetes Association; and Tomasz Szlagowski, general director of the Federation of Polish Patients (FPP), represented EPF at the Vilnius Conference.

Mr Olauson moderated a specific session exploring the “Effects of health inequalities” and board member Stanimir Hasurdjiev shared with participants the real situation of patients in Bulgaria and also throughout Europe.

The NPO Chairperson highlighted that “There are many patients in EU who need access to quality healthcare urgently. Therefore, European policy makers, member states, healthcare experts, industry and patients organizations need to work in collaboration and partnerships to find solutions that save lives of patients most in need now.”

In the closing session, our President emphasized the important role of patients’ organisations and their involvement in all spheres of decision making in the health system, together with all stakeholders.

The Conference resulted in the Vilnius Declaration described by Commissioner Borg as “a crowning document” of all the work done by the Lithuanian Presidency to ensure healthcare systems are sustainable for the future.



Our President commented “the huge health inequalities faced by patients across the EU are evermore apparent, with unacceptable consequences. The Vilnius Declaration represents a collective commitment to rethink how health systems operate, where patients play a role, through patient empowerment, in delivering high quality sustainable, equitable healthcare.”

He concluded: “We look forward to working with our fellow stakeholders in transforming the Declaration into reality”.

For more information please visit the conference website: <http://vitaltransformation.com/sustainablehealth/>.

EPF urges the Council to prioritise discussions on the Medical Devices Regulation

EPF welcomes the vote on 22 October of the European Parliament on Medical Devices. The adopted text maintains commitment towards more transparency and safer medical devices. However EPF urge the European Parliament and the Council to address the remaining shortcomings in the legislation and adopt it before the 2014 European elections to ensure that EU patients gain access to safer medical devices without delay.



“We hope the EU institutions will send a strong signal to patients and citizens that the safety and quality of their care is still a priority on the EU agenda before the elections, with the Regulation on Medical Devices as a tangible result” said Nicola Bedlington, EPF Director.

Improved assessment process but weaker scrutiny

EPF is supportive of the improved conformity assessment process. Special notified bodies designated by the European Medicines Agency will carry out the assessment of high-risk devices. In addition, an independent expert committee, the Assessment Committee for Medical Devices, will be able to review some devices on a case-by-case basis.

However, we are disappointed that the scope for scrutiny has been considerably watered down compared to the ENVI report. We believe all class III devices and implantable devices in class IIb which are considered to be potentially high-risk for patients, need appropriate scrutiny by this committee composed of medical experts – not only implantable class III devices, which received particular political attention in the wake of the scandal over PIP breast implants.

Progress on patient involvement

The European Parliament listened to our call for more patient involvement. Patient representatives will be involved in the Assessment Committee for Medical Devices and in another advisory committee with relevant stakeholders. Patient organisations will also be involved in ensuring information to the public is user-friendly.

It is vital that patients are involved in medical devices regulation in a similar way as they are involved in medicines regulation through the Patients and Consumers' Working Party of the European Medicines Agency. Patient involvement is a legitimate right, and beneficial for safety and quality of devices: patients can contribute their expertise at various stages of the process from clinical investigation to vigilance.

EPF believes that patient involvement will foster better quality information to the public and more transparency in the system. There is a strong commitment in the report to improve this, notably through opening parts of the Eudamed database to the public, and through giving better information on implants to patients. In addition, a summary of the safety and performance report for Class III high-risk devices will be accessible to the public.

Better clinical investigations but need for more clarity and transparency

The report also improves the rules to conduct clinical investigations; an area previously pointed out as a weakness of the system. All investigations would be subject to an ethics review, and patients' views would be taken into account in assessing applications for clinical investigations on medical devices. Sponsors would have to plan for post-trial treatment of patients participating in investigations. The results of investigations, including a layperson summary, would have to be provided to member states within clear deadlines.

However, EPF would welcome more transparency towards the patients and the public on investigations, with clarity that the layperson summary of results will be available to the public on Eudamed.

A real achievement: the vigilance and post-market surveillance

We call on the Council to maintain the text adopted by the European Parliament as regards vigilance and post-market surveillance. The report ensures patients have the possibility to report suspected safety incidents; the availability of key safety information in the EU database; awareness campaigns for patients and health professionals to encourage reporting; the obligation for manufacturers to report all incidents; and the collection of information about users' errors. We welcome these as major step forwards toward putting in place a real patient safety culture in medical devices. Unclear provisions on re-use of devices

We consider that the rules for reprocessing of single-use devices still need to be improved by legislators. This practice is currently unevenly regulated across the EU, and this is potentially dangerous for patients as reprocessing may lead to device malfunction or healthcare-associated infection if not carried out properly.

We agree with the setting-up of clear definitions for single-use and re-usable devices, and that standards to ensure safe reprocessing will be established. However, the text does not currently require reprocessors and manufacturers to prove the safety of re-use before they are allowed to label a device as re-usable. We consider this an important gap in patient safety.

EPF is committed to continue engaging in this debate with decision-makers to ensure patients have access to safe, high quality medical devices in the EU.

For further information see EPF's position paper on medical devices, available on our website in the [policy section](#). You can also contact Laurène Souchet, Policy Officer, at laurene.souchet@eu-patient.eu for more information.

EPF President appointed expert in the Horizon 2020 advisory groups

The European Commission has appointed 15 groups of independent experts to advise on priorities for Horizon 2020, the next EU research and innovation programme. Our President Anders Olauson will represent the patients' perspective in the "Health, demographic change and wellbeing" group.



In 2014 the European Union will launch a new, seven year research and innovation funding programme called Horizon 2020. EPF had contributed in 2012 to establish the framework of this programme through the European Health Policy Forum's (EUHPF) position paper on the Commission proposals.

"At EPF, we want to include a comprehensive approach to Horizon 2020 to achieve a healthier Europe. When designing research programmes and setting priorities, it is crucial to look not only at innovative solutions but also at public needs, including those of patients", said EPF President.

Among the different groups, the health-focused one is tasked with the assessment of the overall health, demographic change and wellbeing challenge concept and approach. The experts will analyse what has been achieved and where the problems are, assessing any amendments needed to improve the functioning of the current systems and also identifying the conditions for launching further work programmes.

The mandate of the selected experts is for a period of 2 years with the possibility of renewal for a further maximum 2 years. The call for expressions of interest will stay open for the lifetime of the Horizon 2020 programme in order to accommodate the renewal of groups at the end of each mandate.

Most of the groups can already be found on the European Commission's online register for expert groups, along with some additional information and the original call text: http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=h2020-experts.

In addition to the advisory groups, the Commission will soon launch a further call to establish a database of experts to advise and assist on activities like evaluation of proposals and the preparation of future programmes.

For more information about the EU Programme, please visit this website: http://ec.europa.eu/research/horizon2020/index_en.cfm.

Patients' representatives sharing learning and good practice

The 6th EPF Regional Advocacy Seminar took place in Zagreb, Croatia, on 28-29 October 2013. EPF organised this event in cooperation with the Coalition of Associations in Healthcare (KUZ) to develop tools together with the participants to advocate effectively at European and National level.

More than 40 participants attended the EPF two-day event including patients' representatives from Croatia, The Former Yugoslav Republic of Macedonia, Serbia, Montenegro and Turkey as well as speakers such as Bernard Merkel from DG SANCO.

The participants learned how the legislative process works as well as where EPF takes part in this process. They also got a flavour of opportunities for collaboration with other stakeholders and of possibilities for fundraising.

The different workshops looked at different areas to reinforce the capacities of their organisations, as follows:

- How to build a credible representative patient organisation?
- How to liaise with donors and build a fundraising strategy?
- How to successfully partner with stakeholders?
- How to develop and implement an advocacy strategy?
- How to develop and implement a communication strategy?

"The seminar was very useful for me to expand my knowledge about the actions of the patient's NGO in the society. I hope that we will meet and cooperate again" concluded one of the participants.

For more information about the seminar or our capacity building activities, please contact Liuska Sanna, EPF Project Manager, at [liuska.sanna\[at\]eu-patient.eu](mailto:liuska.sanna@eu-patient.eu).

Tools to use the EPF Campaign for the 2014 EU Elections

We are now at the stage when we take the next step of our campaign entitled “Patients + Participation = Our Vote For a Healthier Europe” ahead of the 2014 European elections. We just released our [guidance](#) to help patients’ organisation to cascade our messages and [background papers](#) for policy-makers to hopefully galvanise a high level of support among them.



Our Campaign guide aims to offer a framework with advice and core material to our members and patients’ organisations to prepare the period ahead of the elections. We kept our campaign deliberately very general to ensure patient groups can adapt it to their unique needs to make the most of the 2014 EU Elections.

The background papers provide further details to our Manifesto. They enrich the content with more information about our position, the figures and concrete cases we have, as well as an explanation of our key asks. These are living documents that will be regularly enriched with concrete facts.

Patient advocacy at EU level is crucial to drive positive change for patients. The elections next year will provide an opportunity for candidates to hear and listen to the patients’ voice and include this when they set the priorities for the new parliamentary session.

We represent a high proportion of voters for the next EU elections as we are supported by our 61 members, themselves representing an estimated 150 million people with chronic disease. We hope our voice will be heard by decision-makers and that they will add a patients’ perspective in their work.

When we will cast our ballot, we will therefore be confident and feel good about voting for a healthier Europe where patients are seen as a part of the solution for high-quality, sustainable and cost-effective healthcare.

For more information, please contact our Communication Officer, Cynthia Bonsignore, at [cynthia.bonsignore\[at\]eu-patient.eu](mailto:cynthia.bonsignore@eu-patient.eu).

Second phase of the Capacity Building Programme in Romania and Hungary

EPF will launch the second phase of our Capacity Building Programme in Romania and Hungary. While the first phase was about strategic planning and organisational capacity assessment, the second phase is much more implementation-oriented. For their part, patient organisations from Slovakia and Bulgaria are starting with the first phase.



Ten patients' organisations in Romania and Hungary will benefit of the second phase of our Programme. It consists in providing training related to operational planning to the patient organisations involved in the programme. We will also assist them in developing the first annual plan implementing the Strategic Plan developed and agreed for each organisation in the previous phase of the Programme.

“Operational Planning emerged as a major need in both countries. Organisations requested support to be able to implement the strategic plans with clear operational objectives aligned with the strategic goals” said Liuska Sanna, EPF Capacity Building Programme Manager.

Local experts will train the organisations with a two-day face-to-face course followed by a three/four month coaching period.

The ten patients' organisations highlighted the importance of developing and implementing consistent annual plans with clear operational objectives, activities, and resources correlated with the strategic goals and the missions defined in the Strategic Plan. They will also develop the necessary skills to produce such a plan for 2014, but also on how to assess it and plan resources.

The first phase officially kicked off on 25 November in Slovakia with seven patient organisations, including EPF's local member, the Association for the Protection of Patients' Rights. Ten Bulgarian patient organisations, including the two EPF's members the Confederation Health Protections (KZZ) and the National Patient Organisation (NPO), are also ready to start with the kick-off meeting taking place on 17 December.

Likewise Romanian and Hungarian organisations that joined the programme last year, in this initial phase they will learn how to develop a strategic plan and benefit from a comprehensive organisational capacity assessment process that will inform the shaping of the next phases of the programme.

To get a glimpse of the EPF Capacity Building Programme in three minutes, please watch this [short video](#).

A video to understand the InterQuality project

How do we know whether a healthcare system is good? The [InterQuality Project](#) looks at to what extent it can deliver efficient, effective and equitable care. Watch the project on video to understand more how resources are spent in healthcare.



“In several countries of the European Union, resources are wasted because of poor management and governments are unable to reimburse innovative pharmaceuticals, buy new equipment, or shorten waiting lists. Spending more on healthcare often doesn’t result in improving quality and access to services. Therefore the key is to spend better!”, says Tomasz Hermanowski the project leader from the Medical University of Warsaw.

The knowledge gained from the project will provide models for Member States to choose the right financing mechanisms in the different areas of the health care system, according to their needs and possibilities. Ultimately it will try to demonstrate that, to get better quality, we don’t need to pay more: we need to pay smarter!

Link to the video: <http://www.youtube.com/watch?v=-yYTLS4iTaE>

For more information about the project, please visit this website: <http://www.interqualityproject.eu/>.

Upcoming Consensus Meeting on Access and Equity

We support our member organisation, the Federation of Polish Patients (FPP), with the organisation of the “[Consensus Meeting on Access and Equity for Patients](#)” that will be held on 3 December 2013 in Warsaw, Poland. The meeting aims to continue the dialogue on access to healthcare initiated in 2012.



The [first conference on health inequalities](#) held in Sofia, Bulgaria, concluded with the adoption of a Resolution by the participants. The document recalls the importance of health inequalities as a main political priority and reflects also the will to look at the discrepancies among the EU Members States with regards to access to healthcare and the quality of care.

The [second meeting](#) laid the foundations of a European partnership for equity of access to quality healthcare. It will consist in a platform to combine the efforts of authorities, stakeholders and industry to identify possible new mechanisms for ensuring that patients have access to affordable and quality healthcare. A MEP Interest Group was also set up at that moment.

The [forthcoming Consensus Meeting](#) will build on the outcomes of these two conferences. The participants will undertake a mapping exercise to outline the commonalities and differences in access to healthcare in Poland and in other Member States, in an effort to reduce the gap. The event will highlight the positive role of collaboration between countries and within and between patients and stakeholder groups, as well as best practices regarding the active role of patients.

The Consensus event will also explore our [Campaign for the next EU Elections](#) as one of the key asks concerns access barriers. In this campaign, we reiterate the fact that access to quality healthcare is a basic EU citizens’ right and that it is still not a reality for many of us. We highlight that if we do not get the care we need at the right time, we may develop more severe illness, reducing our capacity to live a full and productive life and increasing health, social and economic costs. All of us deserve a chance to contribute to society.

“As there are several aspects of reducing health inequalities, all of them will be raised during this meeting. There is an urgent need to build mutual understanding about equity in access to high quality healthcare. The implementation of the Cross Border Healthcare Directive Another will also play a key role in reducing health inequalities”, said Tomasz Szelagowski, the FPP President and Treasurer of EPF.

For more information, please visit the FPP website: <http://www.federacijapp.pl/consensus-meeting.html>.

6th Patient-MedTech Dialogue

Patient leaders from EPF membership and representatives from the medical technology industry met for their 6th MedTech Dialogue Meeting on 6 November in Brussels. This event provides a constructive platform of exchange between EPF and EUCOMED, and patients' organisations and the MedTech industry. This time the event focused on discussing the achievements of the Dialogue in 2013.



One particular highlight was the successful session designed by Dialogue participants and the Steering group for the [latest MedTech Forum](#), a yearly large conference of the health and medical technology industry throughout Europe. The session was dedicated to patient-centred care entitled “How patients perceive the medtech industry and their thoughts on patient centricity”. During this session two representatives from EPF members had the opportunity to present their view on patient centricity and share what it means with representatives from industry coming from across Europe.

The dialogue was also the occasion to exchange on the respective views of patients and of the industry on the outcome of the vote in the European Parliament on the proposal for a Regulation on Medical devices and next steps (see [related article](#)).

Participants also discussed the way forward and future activities of the dialogue for 2014. A key focus of the dialogue will be to finalise by mid-2014 a check list, based on brainstorming by participants at previous meeting, to define further what a patient centred culture is. A task force was nominated to take this deliverable forward. This will be a key tool to raise awareness of the industry on the potential of patient centred innovation and how to achieve it.

Strengthening health Systems through the Tallinn Charter

Our President Anders Olauson attended the second conference on “Health Systems Strengthening” in Tallinn, Estonia on 17-18 October 2013. Marking the five year anniversary of the signature of the Tallinn Charter, the conference organised by Who Europe was entitled “Health Systems for Health and Wealth in the Context of Health 2020”.



Our President chaired and moderated the session on “Coordinated/integrated health services delivery: towards people-centred health systems”. He explained that for citizens with actual or potential health problems, the maintenance of optimal health depends not just on healthcare services, but on support for social care (nutrition, hygiene, mobility, etc.) and other aspects of daily living.

This event provided a platform to understand new frontiers to improve population health, exchange inspiring examples of health system strengthening, and agree on future directions weaving together the commitments in the Tallinn Charter and the Health 2020 policy framework.

The WHO European Ministerial Conference on Health Systems, held in Tallinn in 2008, was a milestone signalling the importance that Member States placed on improving the performance of their health systems. Their political commitment was marked by the signing of the Tallinn Charter: Health Systems for Health and Wealth, and its later endorsement in a Regional Committee resolution. (EUR/RC58/R4).

The outcomes of the meeting will feed into the final report of the Tallinn Charter implementation and a Resolution on the main health systems strategic directions 2015-2020 within the context of Health 2020 to be presented at the regional Committee in 2015.

More information: <http://www.euro.who.int/en/about-us/regional-director/speeches-and-presentations-by-year/2013/presentation-health-2020-taking-the-tallinn-charter-to-the-next-level>

New version of EudraCT Database: A step forward for greater transparency

EPF strongly welcomes the new version of the European Clinical Trials Database (EudraCT) hosted by the European Medicines Agency (EMA). This new version, EudraCT V9, marks the initial step of a process through which summary clinical trial results will be made publicly available which allows for greater transparency.



As of now, clinical-trial sponsors are encouraged to register on the EudraCT website to start uploading summary results. Until now they only provided protocol-related information on clinical trials conducted in European Economic Area countries and/or in third countries, if they are included in a Paediatric Investigation Plan (PIP).

These results will be available towards the end of the year.

The publication of the clinical trials summary increases transparency and represents a positive step for patients wishing to access information about clinical trials in Europe. We have for several years called for the publication of the results of all clinical trials in a timely manner, regardless of the outcomes. Ensuring that after a research project finishes, the results are promptly published, can, arguably, be said to be as important as the approval of the trial in the first place.

Even results of trials that “failed” or produced unexpected or inconclusive outcomes add to the totality of our evidence base and can help target future research better. Moreover, in order to implement patient-centred care and empower patients to make fully informed decisions concerning treatment options in partnership with their health professionals, it is vital that both clinicians and patients have access to all the relevant information needed to make those decisions.

For further information see our policy page on clinical trials on our website or contact Kaisa Immonen-Charalambous, EPF Senior Policy Adviser, at kaisa.immonen.charalambous@eu-patient.eu.

Welcome Camille, our new Membership Officer!

Camille Bulot has just been appointed as our new Membership Officer. Her role will be to provide targeted ongoing support and information to members on their requests and to develop a membership strategy to ensure that EPF serves the needs of its members to the optimum.



Camille holds a Master degree in European Affairs from the Institute of Political Studies in Paris. Before joining EPF, Camille worked as a Policy Coordinator at the Assembly of European Regions (AER) where she was managing the Social Policy and Public Health Committee.