November Issue // The European Patients' Forum Newsletter

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

The new Commission started its five-year term on 1 November. We feel it is really important that we now move forward swiftly and resolutely on the formidable challenges ahead, in a spirit of urgency and commitment to real change for the benefit of patients and citizens in all parts of the EU. Nothing demonstrates this more clearly than the recent debacle over hepatitis C treatments.

As you remember (link) EPF welcomed, together with the wider health community, President Juncker's decision to keep the pharmaceutical portfolio in the Directorate-General for Health and Consumers (DG SANCO). Our overall priority is that these products are safe, of high quality and accessible to all patients in the EU.

Regarding the transfer of the medical technologies' dossier to DG ENTR, EPF's stance is that the needs and rights of patients on safety, access and quality should always come first. Our input and position on current medical devices legislation reflects this (link).

Much has been made of the 'one Commission' approach and philosophy in the last few weeks. We are keen to see how it will play out in real terms, enhancing policy coherence and transparency regarding specific 'health dossiers' and indeed 'health in all policies'. This is more crucial than ever before.
In Commissioner Andriukaitis' mission letter (PDF), a strong focus is placed on 'health system performance assessment'. We hope to contribute on this dossier with our activities on quality of care, patient empowerment and advancing access from the patients' perspective.

We are currently moving forward with the Patient Access Partnership on Equity of Access to Quality Healthcare that will hold its first Assembly on 9 December – more details will be shared in the next issue of this newsletter.

Involvement and contribution of DG SANCO to the European Semester process from a health stand-point is another area where we believe the public health community including patients, can play a key role , based on our direct experience of barriers, hurdles and opportunities on the ground.

President Juncker's core message regarding the 29th State of unemployed people, many of whom are young, strongly resonates with EPF.

We see through our membership the challenges faced by communities of young & older patients with chronic diseases- who with the right support and opportunities would also be able to participate in the labour market- and indeed the wider long-term physical and mental health implications of exclusion from working life. This is a key area we are exploring with our youth group and with sister organisations in the field of discrimination.

Warmest greetings,

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

EPF liaises with the Council on In Vitro Diagnostics Regulation

The Regulation on in vitro diagnostics, a specific type of medical device, is currently being discussed in the Council. We have updated our previous position after consultation with our members and sent it to the Council with the hope that the revised law will increase transparency on the safety of the devices and provide better access to quality information about these devices.

In Vitro Diagnostic (IVD) medical devices comprise all tests performed on patients to provide a diagnosis, either through a test tube or through devices for self-testing. They are important to the patient community as they provide information on medical conditions that may assist doctors with providing a correct diagnosis, monitoring the progression of an illness, or, in some cases, determining predisposition toward a disease.

We call on the Council to retain the following key positive points in the European Parliament's position:

- Measures to ensure better information and transparency to patients on in vitro diagnostics devices,
    - in particular new information requirements for self-testing and near patient testing devices (devices that are used by healthcare professionals, not in a laboratory environment),
    - transparency through summary of safety and performance report for In vitro diagnostics devices that are in the higher risks categories.
- Measures on clinical performance studies that aim at ensuring better patient involvement in the assessment of the study, and particularly in ethics committees.
- More transparency on clinical performance studies' outcomes through a layperson summary of the results.

Key EP proposals that we would like to see changed:

- The European Parliament included provisions for mandatory genetic counselling after a genetic condition has been diagnosed. We do not support this provision, as there are different risks brackets within genetic conditions, and there will be instances when genetic counselling is not necessary. We would welcome instead guidelines on genetic counselling, drafted with involvement of healthcare professionals societies.
- The European Parliament asks for patients to give written consent before a genetic test. EPF believes informed consent is essential however written consent is not the only valid form of informed consent across Europe.

For more information, please contact Laurène Souchet, EPF Policy Officer (laurene.souchet@eu-patient.eu).

EUPATI National Platform launched in Spain

On 4 November, in Madrid, over 60 patient, academic and industry representatives celebrated the launch of the Spanish Platform of EUPATI, the European Patients' Academy led by EPF. Such a platform will accelerate the implementation of the project in this country and is the third of its kind, following two other successful launches earlier this year in the UK and in Ireland.

EUPATI project seeks to enhance patients' involvement across the medicines research and development process. It provides patient advocates and the health-interest public with access to educational and training materials in 12 European countries, including Spain.

The project establishes National Liaison Teams in each country to facilitate the implementation. These teams in turns support the creation of EUPATI National Platforms.

Mercedes Maderuelo, of the Federation of Spanish Diabetics (FEDE) and Spanish National Liaison Team Chair, confirmed "the absolute need for a platform allowing patients, academic and industry to interact, not only with each other, but also with other national actors including government and regulatory bodies, healthcare professionals and the media to strengthen patient engagement in medicines R&D".

Oscar Prieto, President of the Asociación de Afectados por Tumores Cerebrales en España and NLT patient member, called for "greater awareness raising around the patient's right to participate in this process and around the educational and training tools needed by patients to access this right – now and in the future!"

Improving the quality of patient involvement and the number of patient leaders who can engage, is not a task left only to patients. Academia, Regulators and industry are key partners in enhancing patient involvement across medicines research and development processes.

Sara Perez, a researcher with the Complutense University of Madrid, spoke about a 'paradigm' shift in the collective approach towards patient involvement. Daniel Gil of Farmaindustria further echoed the need for companies to urgently and continuously adapt and respond to the needs and demands of patients.

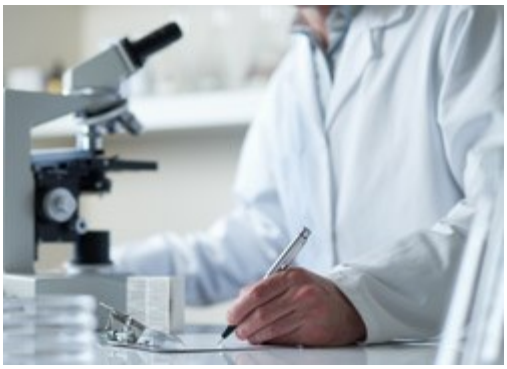
National Platforms Coordinator Laura Kavanagh welcomed "the clear take-home message around the importance of patient-centricity and the call to action under the banner '¡Por, Para y Con el Paciente!'(*everything for and with the patient)".

You can join the EUPATI National Platform in Spain on twitter: @EUPATI_Esp and on Facebook.

Contact: es-nltteam@eupati.eu or the EUPATI National Platform Coordinator on eupati@ipposi.ie.

More information about EUPATI: www.patientsacademy.eu/.

Increased transparency 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 has just released a statement to welcome it as a step forward towards greater transparency of the regulatory process on clinical trials (link).

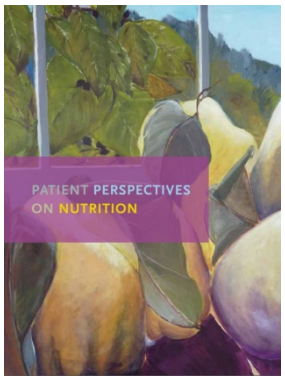
"B*oth clinicians and patients need to have access to all the relevant information to makemeaningful therapeutic decisions in partnership. We trust the EMA policy will significantly contribute towards that goal*", commented EPF Senior Policy Advisor Kaisa Immonen-Charalambous.

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 detail those concern in our statement available in the 'related information' box.

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.

Contact: Kaisa Immonen-Charalambous, EPF Senior Policy Advisor,kaisa.immonen.charalambous@eu-patient.eu.

Unmet needs of patients regarding nutrition



EPF Secretary General Nicola Bedlington attended the "Optimal Nutritional Care for All" conference on 4-5 November in Brussels. The event was organised by the European Nutrition for Health Alliance (ENHA) with whom we held an event in 2013 to launch the booklet on nutrition published on the initiative of our member, the European Genetic Alliances Network (EGAN).

Patients have unmet needs as regards nutritional care throughout Europe. EPF believes that the EU has a role to play in this area to support a better approach to nutritional care throughout Europe alongside Member States, for example through facilitating exchange of good practices between countries and raising awareness about these.

Appropriate screening to identify patients at risk is essential. Chronic diseases patients and older patients are indeed more vulnerable to risks of malnutrition and under nutrition. This may lead in turns to increased risk of infections and complications, increased hospitalization, longer hospital stays and increased risk of death.

For patients, receiving optimal nutritional care is key but it encompasses more than treating under - nutrition. It means integrating nutrition in the care continuum, in prevention, treatment and management of their disease. As Olle Ljungqvist of EHNA noticed, "we have to look at care not in silos but along the patients' journey, which is usually quite complex".

Cees Smit of EGAN illustrated the lack of information on nutrition for patients with the example of the book 'Ongezouten' which means 'Unsalted' (pictured). Written by a Dutch actress Olga Zuiderhoek whose partner developed liver problems, it describes their journey to find out how to prepare meals without using salt.

In her conclusion, Ms Bedlington reiterated that patients should be part of a multi-stakeholder approach to improve nutritional care across Europe. M. Smit further suggested the idea of a partnership between EPF, EGAN, EHNA and patient groups willing to be more involved in nutritional issues.

He concluded: "*We had two meetings on this topic in the Netherlands and we hope to formalise it in the beginning of next year and Europe could be a next step.*"

Picture: © Cover of the book "Patient Perspectives on Nutrition" (link, PDF)

Conference on Quality, Safety and Cost-Effectiveness

EPF Senior Policy Adviser Kaisa Immonen-Charalambous attended a conference on quality, safety and cost-effectiveness at the Italian Ministry of Health on 3 – 4 November. This intensive two-day event included four main sessions – quality in the health sector, patient safety, the economic perspective, and Improvement actions including the role of stakeholders.

What is the point of information to patients on quality and safety? Ms. Immonen-Charalambous explained it is a vital tool for patient empowerment and involvement. Individually it enables informed patients to become "co-managers" of their condition with their health professional and at organisation level it contributes to improve services for all patients. At policy level, involvement of patients can help shaping the healthcare system.

Kaisa recalled the Council recommendation of 2009 that tasked member states to involve patients' organisations in developing patient safety initiatives and policies, as well as disseminating information to patients. Similarly, the cross-border healthcare directive 2011 requires that patients receive information on safety and quality of healthcare.

However, currently patients still do not have easy access to the information they need (link). Information on quality and safety, including standards and guidelines, needs to be improved so that the information is useful and understandable to patients.

"*To achieve this we need to map the currently available information, identify good and bad examples, and put together recommendations on how to provide information to patients on these topics*" she said.

"Patients need guidance on how to interpret quality and safety information – explaining key concepts, such as accreditation, in simple terms. Safety and quality legislation should be provided as "lay summaries. Finally, the information needs to be comparable – across institutions in the member states, but also across borders" she concluded.

Next year, EPF will initiate an information campaign on patient safety for patients' organisations. We will also develop a survey for our members to explore what the key aspects of "quality" mean from the patients' perspective.

More information on the event is available here.

Contact: Kaisa Immonen-Charalambous, EPF Senior Policy Advisor, kaisa.immonen.charalambous@eu-patient.eu

Patients' engagement in the production health innovation

The European Group on Ethics in Science and New Technologies (EGE) invited EPF to give a keynote speech on 22 October in Brussels. This open roundtable addressed the topic of citizen involvement in health, including in the development of new health technologies.

The EGE is an independent advisory body appointed by the European Commission to examine ethical questions arising from science and new technologies. The European Group on Ethics is currently looking at citizens' involvement in health in a view to issue an Opinion at the request of the European Commission.

This paper will examine the societal and ethical implications of public engagement in the production of knowledge and innovation, particularly with regard to health policy, technology and practice. Our Senior Policy Adviser Kaisa Immonen-Charalambous informed the audience about the importance of patients' involvement.

Innovation can transform lives of patients with serious lifelong conditions. It is however important to identify 'valuable innovation' that contributes to patients' quality of life in these times of health budget cuts. "*New does not always mean better. It is not only about new or better therapies but also better systems, and social change*" our Senior Policy Adviser said.

Patient involvement is recognised as a common operating principle of European health systems, but it is not yet a reality. Some of the barriers to meaningful patient involvement include the lack of recognition of patients' expertise or unequal power relations relating to who is allowed to 'do science' and even patients' lack of confidence and the resources to get involved.

"*It is now recognised, at least in the areas of research and regulatory affairs, that patient's representatives provide added value with our unique expertise of being patients. However taking these principles into practice is still a challenge*" explained Ms Immonen-Charalambous.

There is a need for greater clarity about the roles and expectations of different actors, which can be supported by codes of conduct. Advocacy and awareness is also needed to increase understanding of the patient's contribution. Capacity building for patient representatives is finally crucial to address the inherent imbalances of power.

The video of this event in its entirety is available online in English with interpretation in French and German.

Contact: Kaisa Immonen-Charalambous, EPF Senior Policy Advisor, kaisa.immonen.charalambous@eu-patient.eu

An employment pact for patients with multiple sclerosis

The European Multiple Sclerosis Platform represents 700,000 people affected by multiple sclerosis (MS). This month Emma Rogan talks about *Paving the Path to Participation*, a project focused on access to employment for people with MS and the Employment Pact, a commitment and checklist to best practice in the workplace.

Work is means much more than just money in your pocket. Having a job creates a sense of purpose, social engagement, boosts self-confidence and gives people a chance to fulfil their ambitions. MS, like other chronic conditions, impacts people's lives irreversibly, confronting people with difficult situations and changing circumstances.

The EMSP Employment Pact is a map and a checklist to assist everyone who is impacted- employers, policy makers and people with MS and other chronic conditions – in the workplace. Suggestions include flexible working hours, accessible building and toilet facilities, diversity and inclusion training for staff and evaluation of practice, policy and supports for planned 'return to work' and designated rest area for staff.

Businesses can incorporate this tool as part of responsible business practices and as a signal to current and potential staff of commitment to support people with chronic illness to stay or return to work. Policy makers can use it to gain a better understanding on what needs to be implemented in daily best practice in the workplace. People with MS can finally use it in their discussions with their employers on how to best manage the effects of the condition in a way that is beneficial for all.

MS is often diagnosed during the prime working years of life (20-40 years of age), a time when people are building their careers and making plans for their future. Unfortunately, up to 80% of people with multiple sclerosis stop working within 15 years of diagnosis, losing on average 18 years from their working life. This is a massive loss of human potential as well as having economic implications for society. But it does not need to be this way.

What if the situation was different? What if people understood it is possible for people with MS and chronic conditions to stay in the workplace given the right support? People would have flexibility to manage their workday and employers would benefit by retaining staff, demonstrating responsible business practices and proactively dealing with challenges of a changing workforce. Implementation of good practice if good for business.

On 2-3 December there will be an EU Commission Conference about access to employment for people with disabilities to mark the European Day of Persons with Disabilities. Emma Rogan will be speaking about the importance of flexibility by all parties and how people with chronic illness who are well enough, can maintain their ambition and stay in work.

EMSP would like your feedback on the Pact and how it may be of use to you, your business or your organisation. Please send your comments and suggestions to Emma Rogan emma.rogan@emsp.org.

Health Interest Groups in the new European Parliament

A number of health specific and disease specific interest groups of particular interest to patients, are being currently being established, or re-established in the European Parliament. On the menu this month: access to healthcare, mental health and innovation in health and social care.

We are supporting the launch of the Interest Group on Access to healthcare in the European Parliament on 27 January 2015. This is in line with our strategic goal and with the implementation of the Patient Access Partnership that we are setting up with our Bulgarian member, the National Patient organisation. More on this will be shared in the next issue of our Newsletter.

Relaunch of the Interest Group on Mental Health

Our member, the Global alliance of mental illness advocacy networks-Europe (GAMIAN Europe) relaunched the interest group on mental health, wellbeing and brain disorders on 19 November 2014 at the European Parliament. Launched five years ago, this group composed of Members of the European Parliament and civil society's representatives was among the most active in the previous parliament.

Mental health problems remain highly prevalent in Europe and constitute a major burden for our economies and societies as a whole. Two recent studies (a patient survey carried out by GAMIAN Europe on mental health and employment and the mental health integration index) show examples of excellence in mental health care provision as well as areas of deficiency which need to be addressed.

Ms Childers reminded that "there is no health without mental health. This is the reason why we need policies that strengthen the links between mental health, public health and other policy areas. Our interest group provides the right platform to exchange views and initiate policy action in this regard.

Launch of an Interest Group on Access to Innovation in healthcare

On 12 November, Health First Europe (HFE) celebrated its 10 year Anniversary by launching a new European Parliamentary Interest Group on Innovation in Health and Social Care. Co-Chair MEP Marian Harkin (ALDE, IE) hosted the reception that celebrated the achievements of the Alliance and outlined the priorities for the Group. The primary aim of the Interest Group on Innovation in Health and Social Care is to improve patient access to innovation in health and social care by influencing EU policy.

Health First Europe's President John Bowis further insisted on the importance of working in partnership to bring forward policy solutions to issues of organisation of care, access to health and social care, patient involvement and researching the value of innovation in health. The organisation will use the new Interest Group as a vehicle to bring forward such solutions.

EPF will create a special section with the EPF website to keep track readers informed of these, and report on major developments in the newsletter.

Picture: ©European Parliament, Paul Artel of GAMIAN (left) and MEP Nessa Childers (right)

A day to promote responsible use of antibiotics

European Antibiotic Awareness Day was marked on 18 November. This year the European Centre for Disease Prevention and Control (ECDC) coordinated national campaigns in more than 40 countries on the prudent use of antibiotics, focusing on self-medication.

Many Europeans still wrongly believe that antibiotics are effective against colds or flu. However they are only effective against bacterial infections, not viruses. The campaign was an opportunity to remind us all that only medical doctors can make correct diagnosis and decide whether antibiotics are necessary.

The day also raised the issue of antibiotic resistance. Bacteria can become resistant to antibiotics when patients do not follow the instructions correctly, for example shortening the length of time of treatment, taking a lower dose or not taking the antibiotics at the correct time interval prescribed by the doctor.

This resistance has increased in the past years to the point of being a major threat to the future effectiveness of antibiotics. Combined with a lack of new antibiotic treatments, the intensification in antibiotic-resistant bacteria now constitutes a serious risk to public health.

More information on antibiotic resistance is available on ECDC website. You can also download a brochure for patients.