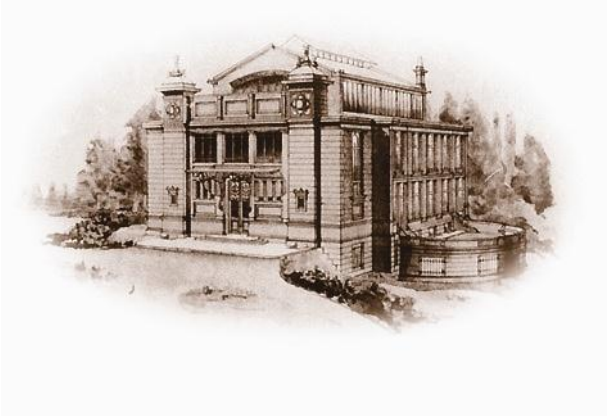
Report

High-level Roundtable “The Draft Directive on Patients’ Rights in Cross-Border Healthcare: Moving Forward on Health Inequalities, Patients’ Rights, Quality, and Safety”

1 December 2010, Solvay Library, Brussels



Introduction

Patients' rights in cross-border healthcare has been one of EPF's core policy dossiers since the Commission published its original legislative proposal in 2008.

EPF worked closely with the first rapporteur in the European Parliament, Mr John Bowis MEP, to ensure that the draft legislation adopted in the first reading in 2009 incorporated a patients' perspective. We continued this close co-operation with the new Rapporteur appointed for the second reading, Mrs Françoise Grossetête MEP. Her draft recommendation for the second reading, adopted by the ENVI Committee on 27 October 2010, reflected patients' concerns to a great extent, and was clearly based on the principles of universality, access to good quality care, equity and solidarity.

After unsuccessful attempts during the Czech and Swedish presidencies, the Council reached a political agreement in June 2010 under the Spanish Presidency, and formally adopted a common position in September 2010. The Council's common position reflects the concerns of various Member States, but is not very satisfactory from a patients' perspective – in our view, it took several steps backwards on many important issues, such as equity of access, and co-operation on safety and quality. The Belgian Presidency has played a valuable role in leading the efforts to reach agreement with the Parliament during the second half of 2010, though there is still disagreement between Parliament and Council on many issues.

Against this background, on the eve of the informal trilogues and the Council meeting on 6-7 December, EPF organised a High-Level Roundtable under the patronage of the Belgian EU Presidency on 1 December. It was attended by **Mr John Dalli**, Commissioner for Health and Consumers, members of the European Parliament, Commission officials, representatives of the Belgian Presidency and the Permanent Representations of Sweden, Denmark, Romania plus the Swiss negotiating team, as well as leaders of stakeholder organisations (nurses, doctors, community pharmacists, hospital, health managers, medical specialists, the pharmaceutical industry and medical devices industry). A full list of the organisations represented is included as an appendix.

The event explored various aspects of the draft Directive, focusing on the safety and quality of care and health inequalities. Participants also discussed its potential impact on the policy landscape in key areas such as e-Health and Health Technology Assessment, and the stakeholders' role at national and regional level.

This report gives an edited version of the presentations and contributions as well as the key issues addressed in the discussion.

First Session – Focusing on what is right for patients

Opening address

Giving the opening address, **Mr Jo De Cock,** Chief Executive Director of Belgium's National Institute for Health & Disability Insurance (NIHDI), stressed that the Belgian Presidency's approach to the Directive was not a simple application of the EU's internal market rules, but a sector-specific and integrated approach on the basis of high quality, affordability, equity and universality in healthcare.

While the principle of subsidiarity applies to the organisation and provision of healthcare services, more action should be taken to further encourage and support co-operation among Member States to share experiences and information (about good practices, available treatments, research outcomes, etc.) and thus contribute to improved quality and safety of healthcare throughout the EU. Once approved, the Directive will create a dynamic between the national health systems, by enhancing co-operation and knowledge-exchange on issues such as European Reference Networks for rare disease patients. "This draft directive concerns all patients in Europe, not just the one or two per cent of patients seeking healthcare abroad", he said.

Mr De Cock also emphasised that the debate is not just about general principles, but about practical issues that affect patients' lives and which therefore require solutions to be found. Patients must be able to rely on guaranteed reimbursement, and must be able to rely on full and clear information about their rights from national contact points.

Brokering the best possible deal for patients in the European Parliament

The Rapporteur on the draft Directive, **Mrs Françoise Grossetête MEP**, focused on the more political aspects of the legislative process so far. She said that MEPs want to reassure the Council that the purpose of the Directive is not to promote medical tourism or facilitate cross-border activity by healthcare providers. The vast majority of patients, given a choice, naturally prefer to use local care without adding to the situation extra complications related to travel, language, or currency. What is vitally important is that, when cross-border care becomes necessary, it is accessible, safe and good quality.

The current draft still contains areas of concern. There are practical issues that must be resolved, such as ensuring that health and social security systems are not overburdened, and that effective national contact points are established in order to inform patients reliably. The Directive will be a minimum solution that will need to be reviewed.

Unfortunately, rare disease patients are doubly vulnerable as things stand, which is not fair. Under the principle of subsidiarity, Member States are responsible for defining their own benefits basket. This penalises rare disease patients. The Belgian Presidency has done much to prepare the ground for possible agreement between the EP and Council positions, taking into account existing regulations.

Mrs Grossetête explained that the Belgian Presidency had suggested a specific article dedicated to rare diseases, whereby the Commission would encourage co-operation between Member States on the diagnosis of rare diseases, in particular by pointing out to health professionals the benefits brought by the "Orphanet" database and European Reference Networks. The Presidency also retains the EP's idea of encouraging a diagnosis based on clinical evaluation performed in the Member State of affiliation, and provisions are made for the Member States of affiliation which do not have sufficient expertise to draw on external expertise. This, she said, represents a considerable advance on the Council's original stance.

eHealth has proved to be a very difficult issue, causing a blockage in negotiations with Council that is not easily understood by the EP. Parliament wants the incorporation of strong provisions on eHealth, as it represents the future of healthcare.

Mrs Grossetête regretted the "lack of ambition" shown by some Member States, which seem willing to accept a continuation of the current system of patients seeking recourse to the courts in defence of their rights. However, she drew attention to the good work done by the Belgian Presidency towards resolving some of the draft Directive's more contentious aspects, and she was hopeful that these issues could be resolved in the "trilogue" meetings scheduled for 1 and 15 December.

She acknowledged that for patients, the issues of upfront payment, reimbursement and prior authorisation remain crucial. In order to ensure equity, and to prevent new inequalities from emerging, a workable system must be found to ensure that financial means will not become a form of discrimination. She mentioned the EP's proposal for a system of voluntary prior authorisation, whereby patients would receive written confirmation of the maximum reimbursed cost that would be directly transferred between institutions, thus avoiding upfront payment. The EP had also inserted amendments to encourage Member States to put in place systems for direct cross-border payments wherever possible.

Mrs Grossetête also recognised that waiting lists are a problem, especially for patients with restricted mobility or disability. For example, people needing hip replacement surgery can be obliged to wait for up to twelve months under their own systems, often in considerable pain. Based on the ECJ ruling in the 2006 Watts case[1] – that prior authorisation may not be refused on the grounds of national waiting lists, if this results in a medically unacceptable delay to the patient – she said the draft Directive offers a clear solution to patients, while at the same time helping to shorten national waiting lists.

What is at stake for patients?

Replacing Mrs Nathalie Chaze, **Ms Annika Nowak** from the Commission's DG SANCO Unit C5 (Health Strategy & Systems) addressed some specific issues in the draft Directive that directly relate to patients. As part of helping patients to access cross-border healthcare – which is one of the Commission's three core aims for the whole initiative – the draft Directive should offer clear rules on reimbursement, and procedural guarantees. Then, there is a need to ensure that patients can rely on a national contacts network for information on this and

[1] Summary judgement available online at http://curia.europa.eu/jcms/upload/docs/application/pdf/2009-02/cp060042en.pdf

other aspects of their healthcare. The second core aim – ensuring safer and better quality cross-border healthcare for patients – can best be achieved by clarifying responsibilities, and in particular those of the Member State of treatment.

The MS of treatment would be responsible for assuring: the standards for quality and safety of care; information and assistance to patients; the provision of mechanisms to seek redress and compensation for harm; protection of privacy and personal data; and equitable treatment of patients from the home country and from other Member States. It should be emphasised that all arrangements must be transparent, and monitoring systems must be put in place to ensure optimal performance.

Thirdly, the Commission set the objective of fostering co-operation between healthcare systems as a means of improving healthcare for all, with specific focus on eHealth, the European Reference Networks, Health technology Assessment, and the recognition of medical of prescriptions. This last element is new to the Directive, with special significance for chronic diseases patients.

Once the Directive is implemented, there will be a clear added value for EU patients, in that patients' existing rights will be clarified: the right of access to healthcare abroad on a non-discriminatory basis; the right to (relevant) information via National Contact Points; the right of choice of treatment and personalised treatment; the right to the observance of standards on patient safety and quality of care; and the right of access to medical records, which is an important aspect of eHealth, ensuring continuity of care.

As things stand, from the Commission's perspective there are four remaining issues for the trilogue meetings:

- Quality and safety: same standards or mutual recognition?
- Prior authorisation: will the patients know their rights in advance?
- Rare diseases: will rare disease patients have easier access to diagnosis?
- eHealth: will there be progress?

The discussion which concluded the first session focused on two points.

The **transparency of information regarding health professionals**: The availability of information varies from country to country, posing a problem for national regulators. In some recent examples, medical professionals were struck off in one country but were able to resume practice in another because the national authorities were not aware of their status. One of the grounds for refusing prior authorisation for cross-border healthcare is if there is doubt about the status of the healthcare provider or the medical practitioner providing the initial recommendation for treatment. The speakers acknowledged that such questions have yet to be tackled effectively, and this could possibly be resolved through co-ordination between Member States' National Contact Points.

The **"basket of benefits"** available under each national health insurance system: Cross-border healthcare is based on the patient's need – i.e. when the treatment she or he needs is not available in the home country. However, to date reimbursement under the draft Directive is only for healthcare that is among the benefits available in the "healthcare basket" of the Member State of affiliation. Speakers stressed that the aim of the legislation was to minimise the need for court cases by providing clarity; also, the position of the Commission and the Parliament has been that patients should be entitled to reimbursement for "the same" or "equivalent" treatment.

Second Session – The wider context of health inequalities, patients' rights, quality and safety

The first contributor was **Ms Antonyia Parvanova MEP**, one of the shadow rapporteurs on the dossier, who addressed the wider topic of health inequalities, and set the Directive against the importance of addressing the existing health inequalities across the EU. Currently there are huge disparities between and also within Member States for many patients and citizens. The Commission and Parliament are currently working on a wider strategy for health inequalities, including the Commission's Communication of 20 October 2009, and the report currently being discussed in the ENVI Committee. She stressed that it is crucial to uphold the right of all patients – not only the minority who seek cross-border treatment – to access good quality healthcare in their own countries, particularly in the context of the current economic climate. She also warned against the possibility that the various grounds on which Member States will refuse authorisation might, over time, create new inequalities.

Regarding rare diseases, initially Ms Parvanova had been opposed to any exceptions, which she considered unfair on other patients – including those with major chronic diseases such as cancer, respiratory and heart disease, musculo-skeletal disorders and diabetes, which are very significant for the whole society and have a big economic impact. But the whole question of diagnosing rare diseases poses difficulties to patients and Members States alike. What are the chances of a patient from a remote village even being diagnosed as having a rare disease? Unless patients can access early diagnosis, there is little hope for them. There is a wider issue, too, about the training of doctors and about raising awareness of rare diseases. Mrs Parvanova thus supported amendments to the Directive which would allow for patients to be referred to another Member State on the basis of clinical evidence where a clear diagnosis is not available, and which will complement Member States' efforts to improve professional awareness and expertise in diagnosing rare diseases through the development of European Reference Networks.

On eHealth, Ms Parvanova expressed her surprise that the most advanced countries in terms of quality, safety standards and opportunities for patients appear so reluctant and inflexible. She pointed to the necessity of exchanging information on medical professionals in a coordinated way in order to ensure the professional status of practitioners who move across borders. This is also key for the implementation of the Council's amendment that provides for the possibility for Member States to refuse prior authorisation in case of uncertainty about the qualification of the healthcare provider.

She, too, stressed that the Directive should be seen as a first step, which on the basis of analysing the results of implementation should later serve to promote a wider approach on public health initiatives at EU level.

The second speaker, **Ms Katja Neubauer** who is Team Leader in DG SANCO Unit C5 (Health Strategy & Systems), focused on patient safety and quality of care, saying these had been controversial negotiation issues from the outset. Substantial work has been done at EU level on patient safety: the Commission's working group set up in 2004 first addressed only safety, but had quality of care added to its mandate in 2008. A Communication and proposal for a Recommendation on patient safety were adopted by the Commission at the end of

2008, and the Council Recommendation was adopted June 2009. In parallel there have been a series of projects, under both the Framework Programme for research and the Health Programme. One very successful project was EUNetPas[2], which established a network on patient safety between Member States. To implement the Council Recommendation, a Joint Action is now under preparation and is scheduled to start in early 2012. Quality of healthcare was integrated into the Joint Action, as it was the preferred policy option of Member States to initiate co-operation on quality.

Next year, Member States will have to report to the Commission on their implementation of the patient safety Recommendation, and the Commission in turn will produce its own report in 2012. This should give a real picture of patient safety in the EU.

How does all this fit in with the Directive? There are two major differences between the work done so far, which has been on a voluntary basis, and the Directive. The first is that the Directive primarily looks at patients seeking to cross borders for healthcare, whereas the work done so far on patient safety and quality has looked at the benefits for all patients, including those who stay in their own country.

The second difference is that the Directive will specify what must be done. The Commission hopes it will include a strong notion of Member States collaborating on standards of patient safety and quality of care. The work done until now, emphasising the sharing of experience and best practice, can give the answer on *how* that should be done.

Replacing Ms Maria Navarro, EPF Board Member from Spain, who was unable to attend because of the bad weather, **Ms Kaisa Immonen-Charalambous**, Project Officer at the European Patients Forum, highlighted some of the key concerns of patients, as summarised in the EPF Position Statement of 25 November 2010.

One key "deal-breaker" from the perspective of patients with chronic illness has been the issue of upfront payment. EPF believes firmly that access to healthcare, including cross-border healthcare, should be based on "needs, not means". In order to avoid exacerbating existing inequalities and creating new ones in terms of access to healthcare, EPF called for a mechanism to be put in place that will enable patients and their families to avoid having to bear the financial burden of cross-border healthcare themselves.

EPF very much supports the proposal made by the European Parliament for a system of "voluntary prior notification", and it also supports the provisions which call on Member States to co-operate and collaborate in developing a future system which would help them to manage direct cross-border payments effectively.

The EP's perspective on prior authorisation and reimbursement is very welcome, as it introduced much-needed clarity into the draft Directive. The key issues for patients include knowing in advance what their rights are, what the available options are, what will and will not be reimbursed; and that the application system is easily understandable, transparent and fair, and includes options for appeal and getting a second opinion.

In terms of safety and quality of healthcare, which is hugely important, EPF welcomes the fact that the draft Directive acknowledges explicitly the principles of universality, access to good quality care, equity and solidarity. EPF supports very strongly the call for Member States to define clear quality standards for their national health systems – this is not a question of defining a "European standard", so much as hoping that collaboration and sharing information on national quality standards can support all Member States' efforts towards better safety and quality of care.

[2] http://www.eunetpas.eu/

By the same token, it is important that the same standards are applied to eHealth and telemedicine as to "traditional" healthcare. Clearly, eHealth is a crucial support element for patient safety, but it is also key for supporting those future innovations which will be so important to the long-term sustainability of health systems.

Another aspect, which has received substantial support from the EP and the Commission but not so much from the Council, is the issue of stakeholder involvement. EPF's position is that stakeholder organisations, particularly patient organisations, should be involved in providing information to patients, by collaborating with the National Contact Points. This is absolutely key for ensuring that the information is relevant and meets the needs of the patients, and also is disseminated effectively. Patient organisations should also be involved in the various aspects of Health Technology Assessment (HTA), both at national and European levels through the proposed network, and of course in the process of providing feedback to the Member States and the Commission on how the Directive works in practice, following its implementation.

Ms Birgit Beger, Secretary General of the Standing Committee Of European Doctors (CPME), noted that the position of CPME has very much in common with that of EPF. She congratulated the EP and the rapporteurs for their achievement, and said that overall CPME was supportive of the Grossetête Report on most aspects – including safety and quality of care, equity, eHealth, HTA, prior authorisation and rare diseases. She hoped that many of the amendments would be carried through the trilogue process.

She particularly highlighted eHealth as a great opportunity and an important tool for achieving good quality of care for patients all over Europe. Data confidentiality is an issue to consider, but a workable system can be put in place. She raised CPME's concern regarding the capability of National Contact Points to provide information fully accessible to all people with disabilities, and said an explicit connection between eHealth and the Contact Points was needed to facilitate the sharing and provision of information.

Like other speakers, Ms Beger also expressed puzzlement about the difficulty of reaching agreement on eHealth. She referred to the example of the area of Justice, where eJustice is very much driven by Member States, including the interoperability of judicial systems. She suggested that perhaps Justice Ministers should talk to the Health Ministers to convince them that synergies are possible within eHealth, and that national systems can safeguard their quality and at the same time talk to other national systems, thus offering solutions to citizens and patients.

Regarding HTA, CPME sees this as an opportunity to provide efficiency and cost-effectiveness, but also better quality of care. National priorities notwithstanding, there is a need for co-operation at European level to share best practice. CPME also welcomes the European Reference Networks for rare diseases, and believes that while the overall aim should be effective, good quality treatment for all, exceptional provision should be made for patients with rare diseases. Information and adequate assistance should be offered for vulnerable patients, people with disabilities and complex needs. There should also be information-sharing between national authorities on professional qualifications and licences of health professionals, in order to ensure patient safety.

Ms Elizabeth Jelfs, Deputy Director of the European Health Management Association (EHMA), focused on the real-life implications of the Directive, pointing out that health managers' experience of cross-border healthcare varies enormously across the EU: while some health managers deal with it every day, many have little to do with it in their normal daily business. At its best, health management enables healthcare organisations to deliver

high-quality care, so it is very close to the patient's concerns, but from the point of view of systems and organisation rather than the individual. But cross-border healthcare is dealt with in the context of many other pressures, especially the huge financial pressure facing health systems across Europe today.

The Directive therefore has potentially major implications for the balance of health systems, if the way it is implemented allows the influx of patients to cause financial instability, which does not serve the best interests of the patients.

Ms Jelfs said that the progress achieved in the negotiations should be recognised, adding that it may be unrealistic to expect very rapid political agreement on controversial issues such as eHealth or quality of care. However, the fact that a legal framework has been created is an achievement in itself, as it brings a significant degree of clarity.

The issue of eHealth is very complex, with interoperability being just one aspect. Initiatives like the eHealth Governance Initiative and the EPSOS Project, where summary care records are being shared across borders, show that there is not a lack of action on this issue; rather, it is a hugely complex area both at the political and practical level.

She also raised the issue of measuring the impact of the Directive, pointing to the relative lack of data on why and how people move. In order to understand the implementation of the Directive there is a need for more data, particularly on the motivation to seek cross-border healthcare. The 2009 annual survey by a large German statutory health insurance company showed that fewer than 20 percent of its patients were aware of the Cross-Border Health Directive and its implications. Whatever the final form of the Directive, reliable information and patients' equitable access to it will be key.

During the discussion that followed the panel contributions, the **representatives of Member States** present were asked to comment on the issues raised. While they were unable to comment on specific details due to the ongoing negotiations, by and large they shared the optimism that an agreement could be reached between the Council, Parliament and Commission during the Belgian Presidency. Given the wide range of views on so many aspects, and the way the political process works, it is unlikely that the Directive in its final form will be 'perfect' and solve every problem at once, but it will be an important first step. The feeling was that the process is in this sense more significant than the exact content of each article, and that it is important to start the process of implementation and set up the necessary structures, which will show where the gaps are and where further improvement is possible.

In the words of one representative, several years ago, when the process started, Member States were very reluctant, "making it difficult to imagine having a Directive at all. Now we are so close to having an agreement, with both the Council and EP having shown willing to move from their positions, that it would be a pity if the current momentum is not used."

Another question was raised concerning **the role of patients' organisations**. Patients and citizens' organisations should be involved at national level to monitor the implementation of the Directive and ensure that its provisions are respected consistently for the benefit of patients. This is particularly so when it comes to the provision of information to patients on their options and entitlements. By sharing that information widely, patients' organisations can contribute towards raising the general awareness of patients' rights in their own countries.

An interesting comment came from **Switzerland**, which as part of its negotiations with the EU has initiated research into the legal and economic impact of eventually harmonising Swiss law with the Directive. The initial results of the study showed that in Switzerland, up to 10 percent of patients would go abroad for healthcare, most likely for economic reasons as healthcare in some neighbouring countries is significantly cheaper. However, there are more than simply economic criteria in play – people may choose to prioritise proximity to family or other support networks over simple costs.

Third Session – The real potential of the Directive for patients with rare diseases and their families

The afternoon session began with a presentation by **Ms Avril Daly**, Board Member of the European Organisation for Rare Diseases (EURORDIS) and of EPF, who spoke via an audio-link, having been unable to travel due to the bad weather. She outlined the main issues concerning rare diseases.

Between five and 8,000 conditions can be described as rare diseases. Although the number of patients with a particular condition may be small, when put together rare disease patients constitute a very large constituency of people. There are around 30 million patients with rare diseases in the EU. These figures point to the important problems faced by both patients and the medical practitioners dealing with them, in particular the lack of specialised expertise in smaller countries.

The very nature of rare diseases means that there is already a cross-border dynamic within the EU – between patient support groups, among medical practitioners and scientists, and in terms of the provision of treatment. Experience has shown that this is the best way to develop programmes and strategies in Europe for people with rare diseases.

While EURORDIS encourages the mobility of patients, it strongly promotes the provision of high-quality healthcare close to where patients live – whenever possible, the expertise should travel, not the patient. While a high standard of healthcare should be available to all citizens in their own country, in the context of rare diseases, this is not possible.

Diagnosis is a pivotal point in the journey of a person with a rare disease: due to the lack of medical expertise, people with rare diseases often have to wait for years to get an accurate diagnosis. This often means the window of opportunity for effective treatment is lost.

Sending a patient from one department to another within a hospital, then to different hospitals within a region, can prove more expensive than providing the opportunity for that

person to travel abroad for an accurate diagnosis – thus offering him/her an appropriate intervention and enabling the person to make a valuable contribution to his/her country.

Mrs Daly said EURORDIS had recently had constructive discussions with the Commission on the potential benefits and practical issues of the Directive for people with rare diseases, in order to identify what aspects would be most beneficial for the patients. The first key area is diagnosis: enabling cross-border diagnosis for rare diseases patients in the first instance would be an acceptable starting point.

The second area is prior authorization, which should be based on accurate clinical assessment by a specialist physician familiar with rare diseases and their complexities. A clear procedure should be established for such cases.

The third key area is the financial burden and importance of equity. In common with other chronic diseases, patients with rare diseases are already financially vulnerable. Upfront payment should be avoided, and reimbursement after treatment should be handled quickly.

In response to a question from the floor concerning **eHealth**, Ms Daly commented on its importance for rare diseases. The Irish government is already keen to develop eHealth within its national strategy for rare diseases. eHealth can have huge benefits in terms of access to healthcare in remote areas, and not just for people with rare diseases.

To another question concerning the provisions of **Regulation (EC) No.1408/71 and No.883/2004**, it was pointed out that the reason the Regulation does not work for rare disease patients is that under its conditions, Member States cannot be forced to reimburse treatment that is not among the benefits of the health insurance system. The Directive in its current form has the same problem – reimbursement is limited to what is in the benefits basket. The Directive does, however, contain provisions for the future European Reference Networks, and the proposed compromise on diagnosis will "open the door" to patients with rare diseases.

Fourth Session – What are the "deal-breakers" and why do they matter?

The fourth session invited brief viewpoints from a number of stakeholder groups.

The first speaker, **Mr Paul de Raeve**, Secretary General of the European Federation of Nurses (EFN), said that EFN is particularly concerned with Directive 2005/36/EC on the recognition of professional qualifications, in view of its implications for cross-border healthcare. Health professionals move across borders too, and there are implications in both Directives on the safety and quality of care. Mr de Raeve expressed his strong support for patients' rights and EPF's work concerning the Cross-Border Directive, saying that while achieving final agreement on EU legislation can take many years, it is important to focus on areas where real progress can be achieved.

Mr John Chave, Secretary General of the Pharmaceutical Group of the EU (PGEU), representing community pharmacists, said the PGEU strongly supports the Directive overall. There are no deal-breakers, just a "headache" regarding the recognition of prescriptions. While the principle of recognition is welcome, this should not interfere with national rules for dispensing or the pharmacist's professional and ethical duty of care. The EP and, to an extent, the Council's position reflect this. So where does the headache occur? According to the Council's draft, the Commission has 18 months after the Directive's implementation to put in place a system for verifying the authenticity of prescriptions – an extraordinarily difficult task to do across borders, and something that will need a huge technical infrastructure. Currently there are not even online registers of health professionals or prescribers in every European country that are accessible, despite the fact that this would be very easy to do technically.

On eHealth and the interoperability of e-prescriptions, he remarked that the EPSOS project[3] on e-prescriptions has a budget of €23 million, but even at national level, e-prescription is extraordinarily difficult and costly. PGEU carried out a survey of prescriptions in all 27 Member States and found that no two prescription systems are exactly alike, either in the format, the information included, or how long a prescription is valid. He explained that the best solution would be simply to "leave it to the pharmacist's common sense". The challenge is to translate that notion into legal language!

Mr Pascal Garel, Secretary-General of the European Hospital and Healthcare Federation (Hope) also said that there were no deal-breakers for his organisation, so he focused on possible scenarios emerging from the Directive. Hospitals in border regions have for many years sought to exchange information, professional practices and even patients. But there are various factors involved in why hospitals accept overseas patients; sometimes technical, but also financial. The term "economies of scale" is heard increasingly in the health sector, for example when defining catchment areas for procuring a specific treatment such as cardio-surgery. So, in the case of rare diseases, for example, there is added value in seeking overseas patients.

Capacity and resources are also an issue. But there are a number of success stories in addressing this, for example in Belgium where three times the average number of cataract operations are carried out, because the system has been made more efficient. These examples can be shared.

It is clear that whichever solution is found, Member States will have to define their standards and guidelines for quality and safety, with or without the Commission. Quality and safety is the core of hospital work, so it must be tackled in each country. There is already an issue about monitoring the quality and safety of overseas hospitals, as people travel for example for cosmetic procedures.

Insurance cover is a big element, and patients need clarity about what kind of authorisation there is. Hospitals are under a lot of pressure from insurance companies, and the premiums are increasing rapidly. Mr Garel foresaw that the rate of increase would improve if hospitals take foreign patients – this is already seen in French hospitals that are expanding because of telemedicine.

He expressed concern over exacerbating the already existing inequalities in health, and the emergence of intermediaries who provide information on a profit basis on cross-border healthcare options. The National Contact Points must be good enough to counterbalance this.

Finally, he emphasised the importance of continuity of care. Many hospitals are working at the national level to try to avoid the "silo culture" between specialties, and between hospital

[3] http://www.epsos.eu/

and non-hospital care, and the social support services. This is more important than ever in the context of chronic diseases, so it is important to avoid such competition at EU level.

Mr Bernard Maillet of the European Union of Medical Specialists (UEMS) did not put forward any deal-breakers, instead highlighting some key words on which he offered comments.

It is important to provide *information*, not only to patients but also to healthcare professionals. This is linked to *transparency*: which healthcare services are included, the rules for prior authorisation, what has to be done for reimbursement – all such information needs to be provided in clear, understandable, non-administrative language. UEMS is working on improving the *quality* of training for specialists and lifelong learning by harmonising and working on CME/CPD, and aims to have the *competence* issue and lifelong learning included in the Directive on Professional Qualifications. *Mobility* is another basic European principle, both for patients and healthcare professionals; European Reference Centres could perhaps capture this combined notion. *Diagnosis* is not just important in rare diseases – any delay in diagnosis creates problems and lowers the quality of life. We should look at the social aspects of *technology*; for instance, when we speak about minimal data sets, we should also look at data protection. *Accessibility* is tied to the notion of *equity*: we must ensure that all patients have equal access to the highest level of quality. The issue of *liability* includes consideration of the burden on national health systems of complications after a patient has returned following treatment in another country.

Invited to comment on the question of **health inequalities**, he said that we should differentiate between the social, economic and healthcare aspects of inequalities. UEMS focuses on the healthcare aspects, in that it is trying to help colleagues from all EU countries to have the same high-level quality of training and the same CME/CPD for their career.

Mr Garel also commented, referring to two inequalities in particular. First, spending on healthcare varies enormously between countries, but so does spending on social protection. So to begin with, we are not having the same social model applied in each country. He pleaded for countries to spend more on health. The second element of inequality is that people with higher income levels and socio-economic status get better care and better outcomes. The richer you are, the more you go to specialists and avoid emergencies, and so on. He asked whether the Directive will provide mechanisms for counterbalancing such inequalities.

Ms Meni Styliadou, representing the European Federation of Pharmaceutical Industries and Associations (EFPIA), said the Directive is a milestone, as we are seeing for the first time a legislative text that sets down the rights of patients at the European level. Even if it needs to be improved in due course, it is a very good start.

The second historic aspect is that the Directive signals a major new trend in the healthcare sector. The tripartite relationship between patient, doctor and payer, under which the doctor was trusted to make choices for the patient as his “trusted agent”, has been put into question. We are increasingly seeing the emergence of a fourth player: health technology assessment (HTA) agencies, whose role is to advise the doctor whether treatment A is better than treatment B or C. This has been already happening for a number of years, but

the Directive actually sets it down “in black and white”. The pharmaceutical industry welcomes the inclusion of HTA, because the financial pressures that have resulted from the economic crisis make it even more necessary to have evidence-based decisions. She said the concern is what will be the governance model for HTA agencies going forward. The role of these agencies will henceforward be to act as a new “proxy for society”: to say, on behalf of society, what kind of treatment society would like to be developed. But in order to be a good proxy for society, they should involve society (in the form of the relevant stakeholders: healthcare professionals, the payers, the patients, and industry) in their decision-making process.

She explained that while we cannot expect stakeholders to be part of the scientific decision-making process for each product; their role should be to assess the general work of the organisation at the governance level, ensuring that the HTA body takes the interest of every stakeholder into consideration, but remains independent of everybody.

Mr John Wilkinson, Chief Executive of Eucomed, representing the medical technology industry, continued on the theme of HTA. His organisation is, naturally, very focused on the HTA element of the Directive, as this has a direct impact on access of patients to technology. The Directive is a catalytic mechanism, which can help bring some consistency and some common sense to a process that is really in its embryonic stages. Although HTA has been around for some years, most of the work has been focused on pharmaceuticals, for obvious reasons. Increasingly, it has been applied to medical technologies, but this is not a question of a simple transfer of methodology and approaches, since medical technologies cover a huge range of products, from cardiac stents to walking-sticks.

HTA is emerging in parallel in a number of Member States. The Directive offers an opportunity for Member States to come together and learn from each other about consistency of approach. Mr Wilkinson said good HTA should be lauded, as it acts as a catalyst for the adoption of really good interventions and new ways of treating patients. Unfortunately, often we get bad HTA, which acts as a barrier to discourage the adoption of a technology – usually not through conscious ill-will, but rather due to lack of process, lack of understanding, etc.

Anything that can be done to bring consistency to the process and a better understanding and application of the process is going to be good for the patient and the community as a whole. For these reasons, Eucomed wishes HTA to move ahead as quickly as possible, and Mr Wilkinson supported the EP’s position which emphasises the need for good governance, transparency, the participation of the relevant stakeholders, etc.

Finally, he expressed some scepticism about eHealth, largely because of the many mechanisms which would need to be put in place and which would need some pragmatic collaboration that is not in place at the moment. He felt those things are not best dealt with by “heavy, broad legislation” of this sort, but actually by hard work among the Member States themselves working together to make things happen.

Statement by Mr John Dalli, Commissioner for Health and Consumers

The final key speaker of the day was the European Commissioner for Health and Consumers, Mr John Dalli, who delivered a statement and answered questions from the floor.

Mr Dalli began his contribution[4] by reiterating his guiding principle: "patients first". He thanked the EP for championing patients' rights, and the Belgian Presidency for negotiating common ground during the draft Directive's evolution. He indicated that, while the Commission supports the Presidency and EP in finding compromise solutions, we should not lose sight of the proposed Directive's original purpose: to clarify patients' rights to access safe and good quality treatment across borders, and be reimbursed for it.

He said that time is of the essence, since negotiations between the Council, the EP and the Commission were ongoing, with trilogue meetings scheduled for 1 and 15 December.

Mr Dalli then went on to highlight three outstanding issues.

- Striking the right balance in determining the system of prior authorisation for hospital-specialised and cost-intensive healthcare, while at the same time ensuring that patients can exercise their right to cross-border treatment, and that they know in advance the rules which apply. The aim is not to promote medical tourism, but to provide care to patients who need it. For rare diseases, for example, the expertise to diagnose and treat patients may not be available, so going abroad may mean a difference between a life of suffering and a better life with the appropriate treatment.
- The Commission's proposal on the quality and safety of healthcare proved to be ambitious. Member States were called upon to define clear standards of quality and safety, and to ensure that there are mechanisms in place so that healthcare providers meet those standards. Mr Dalli said that while discussions with the Council have shown that Member States are not prepared to go that far at this stage, progress can be made "one step at a time". This Directive would mark the first step towards sustainable European co-operation in the area of healthcare, and as such would increase the level of both safety and quality since it would require Member States to make their standards publicly available. He said, "I am confident that once adopted, this Directive will pave the way towards a convergence of standards in this area."
- eHealth has the potential to greatly improve healthcare and to improve and even save patients' lives. These advantages are the reason why several MS are already investing in eHealth; however, the main obstacles to progress are the lack of interoperability of applications, and the lack of trust, confidence and acceptance of new technologies by healthcare professionals and patients. The Directive offers a good opportunity to formalise eHealth in legislation for the first time, to ensure compatibility of systems across the EU.

[4] Full speech available online at http://ec.europa.eu/commission_2010-2014/dalli/docs/speech_patients_rights_01122010_en.pdf

Mr Dalli concluded: “I have been working on this proposal on patients’ rights and cross-border healthcare for the past three years. During this time, many voices have been heard; the time has come to find a solution, so that patients’ rights are properly enshrined in EU legislation and become a reality across the European Union. The time has come for compromises and flexibility. The stakes are high for patients and their families. We cannot afford to miss this valuable opportunity.”

Mr Dalli then took some questions from the audience. To a question on **how to ensure it is the patients, not the medical insurance companies, who ultimately decide where a patient can go to receive treatment**, he replied that there are various provisions in the Directive to make sure that patients get the treatment that they need, at institutions that are safe and institutions that are professionally adequate. The value aspect is controlled by the proviso that the reimbursement is kept to level of the cost of the home country. But it is also very important to keep working to find the correct position on prior authorisation – “if we encapsulate prior authorisation in a way that makes it transparent, then the situation will be much clearer for the patients themselves.”

To another question on **the role of citizens and patient associations** in the application of the Directive at the national level, he responded that patient organisations have a role to play, as a “watchful eye” to ensure that the provisions of the Directive are adequately implemented and that there are no abuses, for example in refusal of prior authorisation; but also to give feedback, to ensure that the Commission enforces compliance.

A final question concerned **medical tourism**. Mr Dalli reiterated that the purpose is not to promote medical tourism, but care. There are many provisions in the Directive that militate against the misuse of those facilities, including the pre-authorisation mechanisms which will make sure that people who are moving are people who need to. Reimbursements are limited to the cost in the patient’s own country. All this works as checks and balances against misuse. He also said he could see the Directive as contributing to a reduction of health inequalities, by pushing governments to invest in health in order to ensure that their citizens get the best possible treatment in their own country. That, he said, is the ultimate objective of the Directive.

Closing

Closing the proceedings, EPF President **Mr Anders Olauson** thanked the speakers and summarised the key messages that emerged during the day’s discussion.

He emphasised that once the Directive comes into force, there will be much work involved in its implementation, and its eventual review. The real-life impact of the Directive on patients and all the other parties will only become clear as it is implemented across the EU. The involvement of all relevant stakeholders, including patients’ organisations, in this process will be key to its success.

He stressed the importance of keeping the principles of equity and solidarity at the centre of the draft Directive: “At heart, the Directive is, after all, about people – the patients, who need equitable access to good quality healthcare. We as EPF, and through our member organisations and allies all over Europe, are committed to playing the part of a proactive and constructive partner in this ongoing process, and we look forward to working together with the Institutions, and with all stakeholders to make the Directive the best it can be.”

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APPENDIX: List of organisations represented

Active Citizenship Network
Association Internationale de la Mutualité (AIM)
Association of the European Self-Medication Industry (AESGP)
European Cancer Patient Coalition
Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)
Council of Representatives of Patients' Organisations of Lithuania
EUCOMED
European Commission DG SANCO
European Committee for Standardisation (CEN)
European Consumers' Organisation (BEUC)
European Diagnostic Manufacturers Association (EDMA)
European Federation of Allergy and Airways Diseases Patients Associations (EFA)
European Federation of Nurses' Associations (EFN)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
European Health Management Association (EHMA)
European Heart Network (EHN)
European Hospital and Healthcare Federation (HOPE)
European Kidney Patients' Federation (CEAPIR)
European Organisation for Rare Diseases (EURORDIS)
European Parliament
European Social Insurance Platform (ESIP)
European Union of Medical Specialists (UEMS)
Federation of Polish Patients (FPP)
German Medical Association
Johnson & Johnson
Malta Health Network
National Institute for Health & Disability Insurance of Belgium (NIHDI)
NHS European Office
Permanent representation of Denmark to the European Union
Permanent representation of France to the European Union
Permanent representation of Sweden to the European Union
Pharmaceutical Group of the European Union (PGEU)
Standing Committee of European Doctors (CPME)
Swiss Federal Office of Public Health