## <u>Cross Border Healthcare – DG Santé 24/10/16 John</u> Bowis Former UK MP and MEP and Rapporteur on CBH

Health is not a European responsibility; it is a matter reserved to Member States – or so we are told.

In fact Health has always been on the European agenda, has been given greater emphasis in recent years and is going to go on growing in policy terms.

It is of course a curious fact that, under the Treaties, the European Union has the power – even the duty –to protect human health

but not to ensure that national health services are up to standard.

EU involvement in the health of its member states goes back to the 1950s, setting standards for Health & Safety at Work in the Treaty of Rome and its Coal and Steel and EURATOM origins.

Then steadily over the years Europe added competencies and standards from Public Health to Health Promotion;

with rules from tobacco to blood safety and guidelines from clinical trials to cancer screening;

pharmaceutical companies are regulated and medicines for people and animals licensed;

we have a range of activity in medical research, in the promotion of innovation and initiatives on healthy ageing;

and we have a compendium of directives and regulations on matters wholly germane to health, such as emissions, pollution, dangerous substances, waste disposal, water and air and soil quality, food safety and product liability.

But now it was not the Council, nor the Parliament, not the Commission that took the EU Health Competence forward. It was the fourth pillar of the EU's legislative process – and the one that is nearly always forgotten – the European Court of Justice.

In 1998, the European Court of Justice (ECJ) gave its judgement on two Luxembourg citizens in the Kohll and Dekker case. It was to prove a landmark case for patient mobility as for the next 10 years it was the European lawyers who decided policy on this issue as the continent's politicians had failed to do so.

The ECJ established that, under the Treaties, European citizens had the right to travel to another part of the European Union (EU) to receive medical treatment and, so long as the treatment was normally available in the home country and the reimbursable cost was no more than would have been paid in the home country, then the patient should not have to bear that cost.

Before this judgement, there was already a clearly established cross-border social security route — the E111, which has now transformed itself into the European Health Card. This covers citizens needing medical treatment while in another EU member state on holiday, studying or working. This means that if we have an unplanned health need, we can simply wave our card and receive treatment on the same basis as local residents. My own experience of a heart treble by-pass operation At Brussels' Jette University Hospital was a personally terrific example of this. I hope Belgium billed and was reimbursed by my country for this. The

important thing is that I as the patient did not have to pay.

We also had (and have) a bilateral block-grant system that transfers agreed amounts of money between member states to contribute to the healthcare needs of people retiring to live in another country, such as UK, Dutch and German retirees living in Spain, Cyprus or Malta.

Despite these options, there remained only the cumbersome and seldom authorised – apart from very small countries such as Luxembourg and very liberal ones such as Sweden – E112 system, which permitted people to go to another country specifically for treatment. This system required prior authorisation, which was rarely given and so rarely sought. It is from this restricted base that lawyers began to move patients' entitlement forward.

The 1998 rulings on Kohll (C-158/96 28/4/98) and Decker (C-120/95 28/4/98) confirmed that they could go to Germany and Belgium to receive orthodontic treatment and obtain spectacles respectively. This left open the question of whether such treatment and services could only be non-hospital services.

In 2001, two Dutch citizens, Geraets-Smits and Peerbooms (C-157/99 12/7/01) received respectively Parkinson's disease treatment in Germany and coma therapy in Austria. These cases confirmed that inhospital treatment was, indeed, covered by the Treaties. Further Dutch cases in 2003 – Mueller-Fauré and Van

Riet (C-385/99 13/5/03) – ruled that prior authorisation was not necessary for non-hospital treatment.

Then, in 2006, British NHS patient Yvonne Watts went to France for a hip replacement to avoid a long wait in England. Following a refusal by her Primary Care Trust to reimburse her costs, the case was referred to the ECJ, not by the patient but by the British courts. The ECJ judgement challenged the requirement for prior authorisation for in-patient hospital treatment and questioned whether a health authority could refuse authorisation by retrospectively reducing the waiting time for treatment.

In the event, the ruling left a number of issues unclear but helpfully clarified not only that the judgements applied as much to taxpayer (Beveridge) models of health service funding as to compulsory insurance (Bismarck) ones, but also that a national waiting list policy was not sufficient to deny a patient cross-border rights, and that the British policy lacked clarity.

Step by legal step over the next five years the policy had moved on – without any involvement or authorisation by European politicians. As the French writer Jean Giraudoux said: "No poet ever interpreted nature as freely as a lawyer interprets the truth." This quotation – along with the words of another Frenchman Louis Pasteur: "Science recognises no borders, because knowledge belongs to humanity, and is the torch which illuminates the world" – encapsulated my own approach to the court judgements and the stark nature of the existing void in European political policy.

My belief was and is that politicians are elected to take decisions and make policy, not lawyers. The latter should interpret and enforce the laws agreed by legislatures – in this case the European Parliament and the Council of Ministers. I also believe that our European citizens should have the right to seek the benefits of medical science and knowledge from across our entire community. However, such access needs political management and guidelines. In short, we need legal certainty and procedural clarity.

It is that clarity and certainty that the European Parliament overwhelmingly demanded in its response not only to a Commission Communication on the ECJ judgements but also in the follow-up to the high-level reflection process on patient mobility (COM(2004)0301) and in the report on patient mobility (A6-0129/2005 for which I was rapporteur.

This led to the European Commission's long-awaited proposal, published in July 2008, ten years after Kohll and Dekker, on 'The Application of Patients' Rights in Cross Border Healthcare'. The proposal included imaginative provisions that went beyond the ECJ judgements in respect of e-health, e-prescriptions, Health Technology Assessment, and European 'Reference Networks' or centres of excellence for rarer diseases.

It did, however, leave some areas of uncertainty that my next report on the Commission's cross-border healthcare proposal (2008/0142(COD) sought to clarify and address. Firstly, I made it clear that this proposal

reflected the new opportunity for patients set out by the ECJ. It was about patients' rights and not – as some colleagues thought – about the mobility of health professionals or health services.

Secondly, I outlined the reasons why EU-level crossborder healthcare policy should be about patients with needs, not patients with means. I did not wish to see patients having to travel, clutching cash or credit cards to pay upfront for often expensive in-hospital treatment. I believed – and still believe – that we should establish a system of reimbursement, whereby the hospital where the treatment is performed receives payment direct from the patient's home country. This would be simplified if payment were made through a central clearing house, because of the complications arising from the fact that the home country and the hospital's country could be not only in different countries but with different currencies and different health funding systems. This has however not yet been put in place.

I recognised, of course, that it would be difficult to plan and manage services if the powers that be had no information as to how much might be payable for crossborder patients. My solution — to help both patients and health services — was the carrot of a 'voucher' in return for prior notification. In other words, if patients 'notified' the home authority, they would thereby provide the latter with information about likely cost and numbers, therefore satisfying budget planning needs.

If too many were 'notifying' for a particular treatment then the prior authorisation process could be triggered. The patient would take the 'voucher' to the hospital or clinic, which would guarantee them payment by the home member state or insurer. The patient would not have to pay direct and the hospital would be assured of payment. In short, I wanted the maximum freedom for the individual compatible with the overall health needs of all citizens in the home country. In the final compromise this 'voucher' concept is permitted but not required.

We are not talking about vast numbers of 'vouchers'. We do well to remember that most citizens prefer the comforts of our local community - most of us are not rushing to sample the delights of beds and bedpans in remote hospitals. Language may also be a deterrent. In short, as a society we prefer local, if local is available. It is only when we have to wait too long that we become interested in exploring other options. Some of us may have relations or friends in other parts of Europe and want to recuperate with them. Others may have heard of especially good or appropriate treatment in a particular hospital or clinic. But the truth is most of us are not packing our bags as a result of the ECJ judgements. Instead, we are hoping that domestic services may be improved, while keeping our eyes on whether our new rights are soon to be realised. If member states are worried about money flowing out of their treasuries their patients are dissatisfied with the standards of local care then that should be an incentive to improve those standards. Equally, if Member States have spare capacity and citizens of other Member States choose to come to use this spare capacity, then money will flow into the treasuries of those countries.

Most people will probably prefer to travel under a scheme organised by their health service or insurer and we already have experience of bilateral and multilateral agreements between health services and governments, such as the UK's contracts for batches of patients in Bruges in Belgium and Thessaloniki in Greece. We also have regions — Maastricht/Aachen/Liege and Veneto/Slovenia — that cross international borders, and we have 'Interreg' hospital building alliances, such as Strasbourg, Luxembourg and Liege. So there is already considerable experience of running cross border health schemes successfully.

The European Parliament supported the report in Committee and then in Plenary before the end of the Parliament in the summer of 2009, both by very large majorities. At the same time, the Council of Ministers was taking a rather more restrictive line and insisting on the home countries' prior authorisation for planned cross-border healthcare services.

In the new Parliament, my colleague Francoise Grossetete took over from me as Rapporteur and took the report to the Environment and Health Committee. She succeeded in reinstating most of the European Parliament's amendments from the first reading, which the Council had rejected. She then led the 'Trialogue' process, and reached a compromise agreement. On 28 February 2011, following overwhelming support at the Parliament's January Plenary, the European Council gave its support for the proposal (7056/11). While Austria, Poland, Portugal and Romania voted against (and Slovakia abstained), the other 22 countries voted in

favour. Member states were given 30 months from that date to transpose the Directive into national law.

As the final statement made clear, the Directive provides clarity about the rights of patients who seek healthcare in another member state and supplements the rights they have at EU level through legislation on the coordination of social security schemes.

Patients are now allowed to receive healthcare in another member state and be reimbursed up to the level of costs that would have been paid by their home country if it had been provided there. In addition, instead of reimbursing the patient, member states <u>may</u> also pay the overseas healthcare provider directly, which means the patient should not have to pay up front.

Furthermore, prior authorisation to manage the possible outflow of patients is now limited to healthcare that requires overnight in-patient hospital care or treatment that involves highly specialised and costly medical equipment or where a treatment presents a particularly high risk for the patient or the population.

It will not be permissible to discriminate in treatment or cost between domestic patients and incoming EU ones. However, there is no requirement on a country to accept a patient, and they are allowed to manage outflows by requiring notification and authorisation if there is an overriding reason of national interest in order to ensure sufficient access to healthcare for its own citizens. Clearly crucial will be

accurate and accessible information for patients and their medical advisers.

We had long debates on the issue of Standards of quality and safety and which were the responsibility of the EU and which of Member States. We agreed in the end that the safety of patients was an EU competence and Member States would each take responsibility for their own quality standards. But it was up to each Member State to publish the quality standards they were adopting.

In turn, member states will have to establish national contact points to provide patients with information about their entitlements and practical aspects of receiving cross-border healthcare, including information about healthcare providers, quality, safety, complaints procedures and accessibility of hospitals for people with disabilities so that patients and their GPs and specialists can make informed choices.

The Directive strengthens co-operation between member states in e-health and e-prescriptions and through the development of a European health technology network. It will also, in time, foster cooperation on rare diseases.

So we have made a very significant stride forward on behalf of patients. We have established in legislation their right to go to another member state for treatment and have it paid for in the same way as it would have been paid, had they been treated locally. We have provided the legal certainty and procedural clarity that were missing following the ECJ judgements and the Commission's initial proposal. Is it perfect? No; but it is a great deal better than the previous situation and opens the way for good cooperative policy making on health in a number of areas in the future. We really are taking healthy steps in Europe.

My main and continuing bone of contention concerns the reinsertion into the text of the concept of 'undue delay', which was included in the early ECJ judgements around a decade ago but was deleted by the European Commission and European Parliament. Such wording, we agreed was impossible to define. As a result member states will be able to refuse people their cross-border health rights if the healthcare could be provided in their own country 'within a medically justifiable time limit'. In effect, this means very complex formulae will be necessary to determine acceptable waiting times - not only for every medical condition and the relative severity in each case, but also for every patient. This, in my view, can only lead to more ECJ referrals to test the acceptability of such formulae - referrals we were trying to avoid in the first place through legal certainty.