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# State of the Union in Health

## Introduction

With the election of a new Parliament and a new European Commission, 2014 has been an important year in European policy. Public health policy is moving faster at European Union level than at any time since the establishment of European Union marketing authorisations for pharmaceuticals and the EMA in 1995. The European Commission, European Parliament and even the Council of the European Union along with the European Medicines Agency are openly advocating for and working towards some form of significant European Union collective action on access to healthcare and pricing. High prices and price differences between EU Member States are currently in the spotlight and the intention of Member States appears to be to apply collective pressure on the healthcare industry to reduce prices.

Almost all of the larger Member States have adopted national measures and processes during the financial crisis designed to cut costs and separate responsibility for treatment decisions from politics. It is not expected that they want to reverse those measures now that the economy looks brighter; rather to further them in the coming years. This comes down to the fact that the biggest public health challenge remains as demographic change and adapting social security models that were designed for people to live only ten years beyond retirement. Expenditure on health products is seen as an important part of that picture.

Given the speed of new developments and important legislation currently on the table or due to be revised this term, it is worth taking stock of the environment that will shape the next five years of policy making.

## Responsibility for pharmaceutical products and medical devices in the European Commission

This time five years ago the announcement by Commission President Barroso that the responsibility for pharmaceuticals, medical devices and the EMA would move to DG SANCO from DG Enterprise was a major point of discussion. It had already been debated for some years whether the responsibility for legislation on the single market for health products should be joined with public health policy. At the time industry feared that the de-coupling of industry innovation policy from the product would be a negative development. It is also fair to state that DG Enterprise did not prioritise healthcare industries in the last term so the impact of the shift was widely felt. The reaction of the stakeholder and industry community to the potential move back to DG Enterprise suggests that most commentators had assessed DG SANCO to be more patient focused in the last five years.

A couple of factors are often under-considered in this debate. Firstly, both the pharmaceuticals and medical devices industries underwent public crises that struck confidence in the legislative framework in the last five years; especially regarding pharmacovigilance and the notified body system of approving medical devices. Such scandals would have required a strong response from whichever Directorate General was responsible. In the case of pharmaceuticals, DG

SANCO and the EMA have pushed strongly for changes and increased industry fees, whereas for medical devices the proposal for Regulation on Medical Devices was considered to be reasonable and proportionate. Secondly, the trend globally and in European Union member states has been for more patient focused legislation and policy and developments in Brussels may simply have reflected that fact. The healthcare industries must probably consider that DG Enterprise should be more proactively engaged in policies to boost the sector in order to make the most of the potential of two Directorate Generals working to boost the healthcare industry to be maximised.

Although public pressure from a range of stakeholders and key MEPs in the European Parliament caused President Juncker to reverse his decision to move responsibility for medicinal products from DG SANCO (due to be called DG Sante from 2015), to DG Enterprise, the fact that medical devices will still move to DG Enterprise seems to have gone largely unnoticed.

## Increasingly confident voice of EU institutions on pharmaceutical access and pricing

Severe austerity across the EU has led to a great deal of introspection by Member States on healthcare budgets. EU Member States have been forced to contract healthcare spending due to the need for belt tightening. The process of the Troika for countries being "bailed out" allowed the EU to have a direct say over how Member States managed their finances with respect to healthcare for the first time.

Until around two years ago, it was the case that Member States interpreted the EU treaty to mean that healthcare practice, treatment, spending and infrastructure was solely a national competence, and roundly rejected any attempts by the European Commission or the Parliament to infringe. Although the Lisbon Treaty has significantly expanded EU competence in several sectors, healthcare could not truly be said to be one of them.

Article 168 (formerly Article 152) holds that:

"*Community action shall be directed towards improving public health, preventing, human illness and diseases, and obviating sources of danger to human health" by "encouraging cooperation between the member States" and "lending support to their action*".

It is clear that this wording is very much open to interpretation and Council has used it in its favour both defensively and, more recently, increasingly proactively. What has happened to enact a change of direction is that EU Member States have seen the potential to pool resources and collaborate on new areas that directly affect or are intended to directly affect positively the cost of healthcare. The Decision on Cross Border Health Threats has further mandated joint procurement for treatments and vaccines on communicable diseases. It is also worth noting that in early exchanges in ENVI (Environment, Public Health and Food Safety) committee there is support being expressed from MEPs of all parties to directly take on the issue of sustainable access to medicines.

The main focus so far has been on expanding EU role in assessing pharmaceutical products for cost-benefit of innovations collectively, in addition to assessment of the risk-benefit by the EMA. Risk-benefit is of course a crucial factor in national pricing and reimbursement negotiations, so the greater influence at EU level is to be considered very carefully given its direct impact on commercialisation of those innovations. Increasing role of European Union in HTA (pharmaceutical and medtech) driven by European Commission and Member States

With the advent of the economic crisis, and in the now clear legal frame of Article 15 of the Cross-Border Healthcare Directive, progress on cooperation at EU level on Health Technology Assessment (HTA) has become reality. EU Member States, particularly small and medium-sized, have realized that pooling their resources is an effective way of dealing with medicines and medical devices' assessment for reimbursement. The EUNetHTA network, which includes EU and Member States' relevant authorities, has created a rapid Relative Effectiveness Assessment (REA) process which has now reached the pilot project phase focused on specific products and product classes. From 2020 onwards these efforts will become part of a permanent structure at EU level. The 2014-2019 policy cycle will therefore be essential in shaping both the scope, and the depth of these developments.

## Potential impact of TTIP on the sector

The Transatlantic Trade and Investment Partnership talks, known as TTIP, are currently being negotiated between the European Union and the United States. Tariffs and regulatory barriers are already relatively low between the US and the EU.

There has been some debate in 2014 about whether healthcare should be included or excluded. This has been most notable in the United Kingdom where stakeholders, including the British Medical Association (BMA, of which all practicing healthcare professionals are members) have raised concerns that it's free at the point of delivery NHS would be jeopardised by TTIP further opening the door to privatisation. The UK government has asserted in response that healthcare must be a part of TTIP. The United States has a thriving private healthcare sector and indeed this could be understood as a potential threat to the NHS. However, the privatisation of certain aspects of the NHS is not to be driven by TTIP, rather the government of the time and this has been pursued by successive governments in attempt to make the NHS more efficient. The BMA has clearly made its voice heard that they feel this privatisation has not improved standards or efficiency.

In countries with insurance based systems the concern has been rather, as with several other highly political sectors; that further powers might be granted to industry vis-a-vis national governments and as such it will be more difficult to regulate markets for pubic benefit.

It is generally considered that TTIP would allow for significant economic benefit for the EU and the US, but due to the nature of negotiations very little information is available about the content of exchanged terms or negotiation talks. This has even been a concern raised within the larger individual country governments of EU Member States. It has been accepted in the last months that greater transparency is needed towards both national governments and the public as this secrecy has given rise to speculation about what the worst potential outcomes could be. This is especially important in policy fields where standards are considered to be widely different between the two, such as environment legislation.

Little specific is known about healthcare negotiations in TTIP, however it is clear that regulatory convergence could prove difficult considering that different healthcare systems and legislation exist and are already differing between each US state and each EU Member State. Despite both the White House and the European Commission pointing to significant potential economic benefit of TTIP, it may be that protectionism is a stumbling block to adoption. The US and EU are no strangers to trade disputes moderated by the WTO, which suggests a long road ahead.

## Upcoming and ongoing legislative changes

**Medical Devices Regulation/In Vitro Diagnostic Devices Regulation:**

After the European Parliament elections this year, many key figures involved in the Medical Devices and In Vitro Diagnostic Medical Devices Regulation were not re-elected or did not run, leaving a gap that needed to be filled by new MEPs.

The key position of Rapporteur for the MDR was given to Ms. Glenis Willmott (S&D, UK), a very experienced and respected MEP active on health who is a believer in patient focused policy and legislation.

The European Council still must adopt a position on these dossiers and little progress seems to be being made under the Italian Presidency. The Latvian EU Council Presidency, to begin in January 2015, should see the Council reach a Common Position.

**Transparency Directive**

DG Enterprise originally published its proposal for a new Directive to repeal Council Directive 89/105/EEC in 2012. It contained ambitious proposals to bind Member States to timelines on medicinal products tightly, with financial penalties for non-compliance. The European Parliament Resolution largely backed this plan (although allowing more flexibility of Member States who have a HTA process lasting longer and established in national law) but the proposed measures have been coldly received by EU Member States and as such remains locked in Council. The overlap with Health Technology Assessment which has risen on the EU agenda significantly since 2012 when the proposal for Directive was launched, has probably served to cause further complication on this dossier.

**Blood Directive**

The Blood Directive is the oldest of the three European Union Directives on substances of human origin, having being adopted in 2002. Although it is widely considered to have been a generally successful legislation, DG SANCO are currently considering to propose a revision of the Directive to take account of technical and medical developments in the intervening years. The Directive sets minimum standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

**Council Conclusions on Chronic Disease**

Expected for 2014, but it is likely they will be published in early 2015. A key focus of these conclusions, due to Parliament pressure over the last 5 years will be on the costs (in terms of economics and health) of diabetes.

Chronic diseases are likely to be a topic that will dominate health policy over the next few years. The challenge of an ageing population, a reduction in the number of effective drugs for previously treatable diseases and a significant deterioration of healthy lifestyles are of major concern to policy makers.

**New work programme for Horizon 2020**

With a budget of almost 80 billion and a broad range of healthcare objectives, Horizon 2020 has attacked renewed interest from researchers and first time interest for many industries. A new work programme for 2016 is likely to be published in July 2015 rather than the end of December 2014 which was originally expected.