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Briefing – EU at the crossroads

The EU term that is drawing to a close has seen a remarkable rise in its global role and influence. In 2014, when the new European Parliament was voted in by citizens and the European Commissioners were endorsed, very few imagined that next time around in 2019, all eyes would be on Brussels. Some of this growth in influence was by design, but much of it was driven by external events.

Global political turbulence since 2014 has brought the EU's raison d'être into sharp focus for many of its citizens and observers around the world alike. It would have been unimaginable in 2014 that a meeting between the European Commission President and the President of the United States would be front page news (above the fold) for three days in the New York Times. The spectre of trade war made it possible, and the New York Times was even on the side of the Luxembourg man. The EU's slow and steady modus operandi no longer appeared boring. It looked downright sensible in light of worrying political change around the globe.

The EU is of course not without problems within and close to its own borders. However, it does represent an attempt at political and trade stability with recent successes. That is recognised by many commentators as an important though flawed bulwark against darker forces. While the US antagonises China, the EU signs a trade deal with Japan. The UK has already discovered that such terms of trade will not be achievable alone.

The EU lead figures are recognisable; Tusk (handsome, stoic, pithy sense of humour), Verhofstadt (bold, looks like an American artist's caricature of a European politician), Barnier (winner of 2018's Most Zen Person Award) and Juncker (let's just say, a big character). In the age of social media EU politicians have managed to attain a similar international profile to national leaders for the first time. The new platform has largely been used effectively to demonstrate what the EU stands for.

"Strasbourg is like the EU's Mar-a-Lago, right?"

The course of the next few months will be a major turning point for the Union. We could have a hard Brexit, financial crash and the strongest ever Eurosceptic voice elected in the European Parliament amid concerns around the nefarious use of social media and political funding. Or we may see none of these things. Nigel Farage may still be an MEP, or he may not! Making predictions ahead of such a storm is unwise; all one can reasonably do is plan for different scenarios.

On health policy

The usual existential debates are starting up again ahead of a new European Parliament and Commission term; where in the European Commission should competency for health be? Should the EU even bother with public health policy at all?

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BRIDGES

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Polls consistently indicate that health is a top priority for voters, but the EU has never shown it much love. Part of this is down to Treaty competence of course. One gets a sense though that so much more could be done, while better publicising what is already being done.

What were the main developments in pharmaceuticals?

There has been a growth in exploratory projects at the technical level, and a whole lot of soul searching at political level, around access to medicines at a reasonable price.

The EU spent twenty years creating the system that exists today, which stimulates companies to develop breakthrough medicines and treatments for rare diseases and complex disorders that were previously not considered viable. However, many policy makers of today are now unsure if the system of predictable and fast Regulatory approval, strong patent protection, exclusivity and other incentives have swung the game too far in favour of industry.

The second health biotech stock boom has not been seen as entirely positive for Europe's patients. Certain cases have drawn attention to the high stakes challenge of making expensive but life-saving medicines available to patients, such as Hepatitis C and Cystic Fibrosis.

The debate around the potential adoption of a Regulation for an EU system of Health Technology Assessment demonstrated a rare political near-consensus among EU and national policy makers, patient and medical stakeholders alike, that "something needs to be done" about medicine prices and access. There was a strong sense that pressure could be applied to the problem by working together.

However, it was also clear that several important Member States do not see a role for anything mandatory from the EU on HTA when it comes to the crunch.

The EU system of medicines regulation appears stronger than ever, with another five years of experience on the clock, and the EMA's move to Amsterdam appears to have been handled as effectively as could be expected.

Were there any major developments in medical technology?

Changes in EU legislation and processes for medical device and in-vitro diagnostic (IVD) product approval rumble on. It is not straightforward. The new Regulations were proposed in the last term, adopted midway through the current one, and will fully enter into application during the next term. That's not to mention the many Delegated and Implementing Acts that are needed to complete the EU's safety system for medical devices and IVDs.

Stakeholders, including national competent authorities, notified bodies (who grant CE marks), industry and healthcare professionals, are all investing huge resources to implement the new Regulations. It is clear that the timeline, long as it has been, cannot be allowed to slip. If central planks of the system are not ready in time, decisive action must be taken to ensure the entire new system is not jeopardised. It is time, finally, to put this to bed and refine the system through real-time experience and learning.

This rolling approach to implementing legislation may possibly be the only way to do it, considering the vast number and diversity of products concerned. However, the long period of uncertainty on medtech legislation delivers a drag effect to the sector and patient access to new innovations.

The loss of the UK to the EU's medtech policy making system will be unfortunate.

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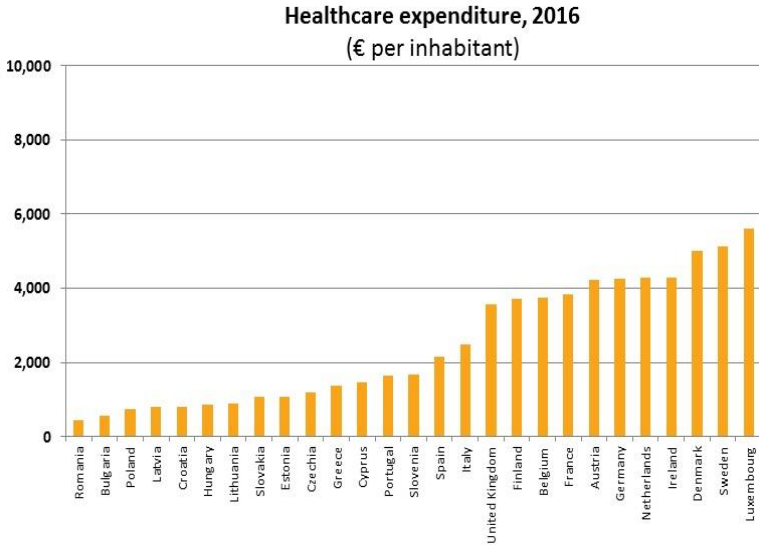
The national regulator MHRA has been fundamental in shaping the EU's approach and is appreciated by all EU and national stakeholders for its pragmatic and rigorous approach. The huge proportion of CE marks delivered by UK notified bodies and the country's thriving sector are further testament to smart collaboration by the UK government.

What progress on digital health?

In terms of digital health and apps some steps have been taken to protect patient safety and privacy, with many products included under EU legislation for the first time in the medical devices Regulation. The General Data Protection Regulation has entered into application with specific measures covering health data. There has also been the adoption of an EU privacy code of conduct between stakeholders and the European Commission. The debate around social media, data and advertising driven business models demonstrates that the EU finds itself in the position of the world's watchdog on such issues. Consequently, much more will need to be done next term to encourage innovation in digital health while protecting the rights of citizens and earning trust.

How did the Commissioner for Health perform?

The Commissioner for Health, Vytenis Andriukaitis, has been a resounding success with his open, knowledgeable and caring approach. For once having a Commissioner who has the luxury of prior personal and political experience in the field of health, and the effective way he led, exposed a clear weakness in how Commissioners are appointed portfolios according to other considerations than their prior history and knowledge. He will shortly stand down to stand for President in Lithuania. However that election turns out, his talents probably deserve a bigger role than Health Commissioner.



With such marked differences in resources, developing health policy relevant to all citizens is difficult (Figure – Eurostat, 2018)

How well did the Commission do on its own stated priorities?

The Jobs & growth agenda can probably be considered a failure in the field of health. Put crudely, life was made more difficult for healthcare companies under this mandate, which is likely to negatively impact investment.

DG GROW (internal market & industry) has not been a compelling voice or partner for the healthcare industry, probably due to its ridiculously large portfolio as a DG, and the greater powerbase for health accumulated by DG Santé (health and food safety). The term has passed by without an Industry Strategy either for the health sector level or indeed in general. Healthcare workers and informal carers, increasingly pressurised by demographic change, were barely mentioned in dispatches.

The "political Commission" spirit has reached health policy making without doubt. The proposal for a HTA Regulation was a nakedly political effort barely hidden behind technical assessments. There was a political and stakeholder demand for it and the Commission quickly responded with a bold proposition.

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For reasons that have been well discussed elsewhere the attempt appears to have stalled. A mis-reading of Member State desire to hand over responsibility for a sensitive facet of healthcare delivery, and a crude separation of clinical and non-clinical aspects of HTA have hamstrung the Regulation.

The European Reference Network (ERN) initiative has been a highlight of the term. DG Santé has, hanging onto a single line in a Directive, and with a whole lot of hard-earned goodwill, driven an initiative of real promise for European citizens with rare diseases. The EU continues to be a genuine world leader on fighting for those patients. The buy-in of top doctors, hospitals and patients around Europe demonstrates their belief that DG Santé has built a potentially winning project where the best expertise could be accessed more equitably in future. The next term must build on it; the ERNs budget is far too small to change the rare disease treatment paradigm, and the level of commitment by Member State must be higher.

Better regulation agenda

The quantity of propositions for new legislation did decrease compared to previous terms. On the other hand, the HTA Regulation proposal was one of the most controversial propositions in EU healthcare to date and was not received well in Council. Its proposed scope extended the EU's reach into national matters without an established legal competence to do so. At the same time, genuinely outdated legislation on blood and tissues & cells only moved forward at a snail's pace through early consultations or was largely ignored like the Advanced Therapies Regulation, despite a revival in technological developments in that area like CAR-T.
The application of the better regulation agenda seemed to be erratic, an excuse to be used to block proposals when it suited. It was largely abandoned across sectors late in the term due to a search for legacy policies and the need to legislate for Brexit.

What can the EU do with its new global status to improve public health?

One thing the world can agree on; Europe does health pretty well. The EU can look to build on its healthy reputation and new top-table position in world politics to take a lead on health issues of global importance. Examples might include healthy ageing, dementia, climate change impacts on health or (barely believably) tackling mistrust in the public about vaccines.

Good work has been done on Antimicrobial Resistance, both in the EU and through WHO collaboration. Common sense policies have been combined with co-ordinated actions in fields of greater competence than public health (agriculture, research) and on antimicrobials at EU and Member State level. More like this please!

Future challenges for stakeholders

Taking all of the above into account, for stakeholders there is cause for both concern and optimism. Reliable, up to date, information on policy developments and informed insights will be vital to support effective strategic planning that enables stakeholders to negotiate difficult challenges and capitalise on developing opportunities.

Whatever challenges and opportunities you may face, I can be your informed, honest and solutions-oriented partner.

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