On the health care products front, 2017 presents issues of concern, along with some positive developments:
• Brexit
• Elections in Germany, France, and the Netherlands
• Political attention for equal access to medicines
• Interaction of patient representatives with regulators
• Adoption of new medical devices legislation
• Implementation of Clinical Trial Regulation and new clinical trial transparency.

BREXIT
At the time of this writing, the UK’s approach to implementing Brexit is still unclear. This is even truer for the positions of the EU institutions and remaining EU member states. One thing is clear: The UK will not be allowed “cherry-picking” (allowed to trade unhindered in the European free trade zone) without accepting the EU legislation – the EU Acquis - and without accepting the free movement of people. Whatever choices are made, the results will be painful for the UK and the EU.

Unfortunately, one of the most affected sectors will probably be the Life Sciences industry, including the European Medicines Agency staff and the London offices of pharmaceutical and biotech companies.

EUROPEAN ELECTIONS
Euro scepticism is of importance not only in the UK. The “populist” political parties – like Front National, Alternative für Deutschland, and the Dutch PVV – all favor the end of European integration, and, because of the electoral success of these parties on this issue, more mainstream political movements will move in the same anti-EU direction. The EU is at the core of the campaigning in the coming months, and election outcomes might lead to France, Germany and the Netherlands coming closer to countries like Hungary and Poland, which already want to cut the remit of the EU and get back more autonomy.

WHY IS THE EU SO IMPORTANT FOR THE LIFE SCIENCES INDUSTRY?
The life sciences industry is a global industry. It is impossible to develop a new medicinal product for just one country, as the necessary investments are just too large. This also applies to medical technology and biotechnology. Therefore, a common European market – especially in this sector – is of utmost importance. If authorization and intellectual property protection moves from the scale of the EU down to the national level, operational costs will rise and profits will sink. Furthermore, a consistent and predictable regulatory system – like current EU practice – is key for this industry.

HOW DOES THE INCOMING US ADMINISTRATION FIT IN?
One of the new Administration’s stated intents is to abandon situations where the US pays not only for themselves but also for their friends. Examples include the development of medicinal products, where investments are financed to a large extent by US shareholders and companies and have an impact on Europe. It will be both a challenge and an opportunity to balance the investment climate for the development of new cures and treatments.

EQUAL ACCESS TO MEDICINES
In the past decade, focus in the EU (as in other regions of the world) has been on equal access to treatments. Legislation has been developed to create incentives for orphan and pediatric medicinal products; as the European population grows older, a new focus will be on diseases of the elderly. A tendency towards national solidarity for the benefit of patients can be discerned in both the EU and the US. One of the encouraging signals is the evaluation of legislation creating incentives that is currently taking place in the EU.

FAIR PRICING
Reasonable prices for important new medicines is a policy goal both in the US and the EU. Discussions about the added value of new medical products are taking place all over the world. The outcomes of these discussions may contribute to the goal of treating more and more patients with the best possible medicinal products without having to refuse treatments for patients who cannot afford premium prices. In his first press conference, the US president-elect addressed this issue already, together with his wish to get pharmaceutical activity back in the US.

PATIENT INVOLVEMENT
On both sides of the Atlantic, regulators clearly understand that they must “climb down from their ivory tower” and talk with their most important clients – not the life sciences industry, but the patients who require better treatments. Health care professionals have also become more representative of patients than of industry.

BETTER MEDICAL DEVICE LEGISLATION
The outcome of far-reaching discussions in the EU institutions about the regulation of medical devices will soon surface. This new legal system will look at improving the interests of our life sciences industry and protecting public health. (We will further discuss this specific matter in the next issue of Global Forum.)

CLINICAL TRIAL LEGISLATION
The clinical trials regulation, replacing the existing clinical trials directive, comes into full force in 2018, and we are only a year away. The new regulation has been announced as a trigger for boosting innovation. However, there are also fears that the new centralized system will create new barriers for the life sciences industry. Important issues are the obligation to publish trial outcomes within a year of the end of a trial and a clinical summary report within 30 days after the granting of a marketing authorisation. Furthermore, the effective implementation of the regulation depends on the functionality of the newly developed platform, including an extensive database.

MORE TRANSPARENCY
Most people favor the development of more transparency, especially for clinical research outcomes. This should be in the best interest of patients, health care professionals, and also the life sciences industry; for the latter, transparency means opportunity to illustrate their commitment to improve health for all.

IN CONCLUSION
2017 is an exciting year. Certainly, things are going to change without us knowing if such change will be good or bad. On the other hand, it is important to realize that changes are necessary for us to reach higher. The classic Greek philosopher Heraclites supposedly adhered to the motto Panta Rhei: Everything Flows. It is only through change that improvement is found. Let us all work together to turn the challenges of 2017 into changes that benefit all stakeholders.