The third is the implementation of Brexit. Furthermore, the clock has started ticking for the medical devices industry, which must comply with new and stricter requirements within 34 months from now.

Brexit
As stated in this column, the UK people’s decision to leave the EU has serious repercussions on medicinal products and medical technology. The European Medicines Agency (EMA) has its seat in the UK and the UK competent authority MHRA is a very significant contributor to the European regulatory system. A new city to host the EMA must be found and the anticipated loss of MHRA’s contribution must be counterbalanced by the remaining authorities. This is not only true for marketing and manufacturing authorisations, but also for patients’ access to medicines. UK’s NICE has set the standard for Health Technology Assessment, which has been an issue mainly for the individual member states, but is increasingly raised to the level of the EU.

EMA and the European Commission have built a website dedicated to the consequences of Brexit. On 2 May 2017, EMA published the first version of a Q&A document dealing with such questions as:
• What if I am a marketing authorisation holder established in the UK?
• What if my Qualified Person for Pharmacovigilance resides and carries out his/her tasks in the UK?
• What if my batch release site is located in the UK?

As Brexit means that the UK will not remain a EU member state, the answer to these types of questions is obvious: all activities and responsibilities that require presence in a member state will have to be relocated to a country still in the EEA (EU or Iceland, Norway, or Liechtenstein).

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In regard to the future seat of the EMA, cities such as Amsterdam, Athens, Barcelona, Copenhagen, Dublin, Lisbon, Milan, and Stockholm have been nominated by their governments as preferred cities and there have been more. The decision will be made by the remaining member states and consensus is required. It is expected that this will not be an easy decision.

The latest news possibly affecting Brexit is the outcome of Prime Minister Theresa May’s decision to hold a snap election to strengthen her political backing for Brexit negotiations. This plan backfired: Mrs. May did not win extra seats in the parliament but rather lost her majority and has pursued a coalition government just as Brexit negotiations officially began on June 19, 2017.

Implementing New EU Medical Devices Legislation

Since the adoption and publication of the new legislation about medical devices (Regulation [EU] 2017/45 and Regulation [EU] 2017/46), the clock is ticking for medical technology companies. The new rules aim at:

- Stricter control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at the EU level
- Reinforcement of criteria for designation and processes for oversight of Notified Bodies
- Inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations
- Introduction of a new risk classification system for *in vitro* diagnostic medical devices in line with international guidance
- Improved transparency through establishing a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification
- Introduction of an “implant card” containing information about implanted medical devices for a patient
- Reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-center clinical investigations
- Strengthening post-market surveillance requirements for manufacturers
- Improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.

*For in vitro* diagnostics, a transitional period of five years applies; manufacturers of other medical devices should be compliant with all new rules within three years. To stay compliant, recertification will often be necessary: Any certificate expiring during the transitional period will have to be replaced with one under the new legislation. At the end of the transitional period, all medical devices not certified under the regulation must leave the EU market. Looking at changes of classification and the clinical information that will be required for recertification, as well as the actual recertification process to be conducted, the timeline to May 2020 is very short indeed.

Entry into Application of EU Clinical Trial Regulation Postponed to 2019

The EMA Management Board has decided that the applicability of the new legislation concerning clinical trials (Regulation [EU] 536/2014) must be postponed to 2019 due to technical difficulties with the development of IT systems. EMA is working closely with its IT service provider to ensure that corrective measures are implemented and will closely monitor progress. The EMA will provide an update at the next meeting of the Management Board (October 2017), where a new delivery time frame will be discussed once progress has been confirmed. Due to these delays, the EU Clinical Trial
Regulation will now come into effect in 2019 instead of October 2018, as previously scheduled. EMA says their priority is to ensure that a high quality, functional system is delivered to the EU regulatory network and its stakeholders. The EU clinical trial portal and database supports the ambitious modernization of the processes for authorisation and oversight of clinical trials in the EU laid down in the EU Clinical Trial Regulation. The system will provide a single portal for submission and maintenance of clinical trial applications and authorisations, and support coordinated assessment and supervision. The portal and database will also serve as the source of public information on the full life cycle of all clinical trials conducted in the EU, from their initial review up to the publication of their results.