NORTH AMERICA

GMED LNE GROUP

Implementation of the New Medical Device European Regulation (EU) 2017/745 in Non-European Union Member States

Since its publication, many articles have been published regarding the potential implications of the new European Medical Device Regulation (MDR) on the CE-marked medical devices within the European Union. However this change of regulation goes further than only the European Union (EU) and affects also other European countries (Not European Union Member-State).

Today, all 28 countries who are Member States are affected by the European Directives on Medical Devices and In Vitro Diagnostics Devices regarding the CE-marking. Iceland, Norway, Lichtenstein (members of the European Economic Area: EEA, also covering the European Union countries), Switzerland and Turkey could also access the European market for medical devices through the CE-marking. Although those countries could play on an operational and technical role regarding Medical Devices Directive, the differences with the Member states per say, is that they have no official role (no votes) regarding the evolution of the Regulation. Therefore, the economic players located in the EEA, could benefit Switzerland and Turkey by yielding the same economic advantages in the European Union. This means, a legal manufacturer located in Switzerland would not need to have an Authorized Representative in the territory of the Union.

The replacement of the Medical Directives by the MDR has different implications on the countries below: for Norway, Iceland and Lichtenstein, as those countries belongs to the EEA, they should implement the requirements of the MDR in their own national laws: The Directives were covering the EEA[1]and the MDR is covering those countries too[2]. Therefore, on this subject as part of the preparation of the implementation of the new MDR in Norway, the Norwegian medicines agency took over the responsibility for medical device since January 1st 2018[3]. Regarding Switzerland and Turkey, these countries were bounded with the EU through a series of separate bilateral agreements which are most likely going to be (or have been) updated, in addition of implementing the requirements of the MDR in their own national laws.

---

[1] ("**Council Directive 93/42//EEC of 14 June 1993 concerning medical devices**. The council of the European Communities, having regard to the Treaty establishing the **European Economic Community**")

[2] ("REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. (**Text with EEA relevance**)")

[3] http://eudracon.eu/the-norwegian-medicines-agency-takes-over-the-responsibility-for-medical-device-in-norway/

The Turkish Medicines and Medical Devices Agency ("TITCK") announced that the legislative process for the adoption of the MDR was initiated. In addition, the Turkish Medicines and Medical Devices Agency was present during the first meeting of the Medical Device Coordination Group on November 2017 in Brussels (which was established by the new MDR and IVDR) and belongs to this MDCG such as a third of the other countries (Switzerland, Norway, Lichtenstein and Iceland)[4]. As of today, the Turkish Notified Bodies are not able to start the designation process until the MDR is transposed in the Turkish national law.

Following the publication of the new MDR, Switzerland implemented a step-by-step plan in order to modify its national laws to comply with the new requirements introduced (or reinforced) by the MDR in order for them to be applicable at the same time of the MDR (May 26th 2020) and IVDR (May 26th 2022)[5]. The Mutual Recognition Agreement (MRA) detailing the mutual obligations of both parties (Switzerland and EU) in link with the anticipated revision of the Swiss law, has already been updated and entered into force on December 22nd 2017. This allowed the Swiss Notified Bodies to apply to be designated under the MDR, beginning November 26th, 2017.

WHAT ABOUT THE UK?

In the framework of the Brexit, the question of the future relationship between the UK and EU has been raised several times (and is still ongoing) regarding the Post-Brexit as well as the impact on all economic players involved. After 17 months of negotiations, an agreement has been approved by the 27 EU Members-States on November 14th, 2018 with the British Prime Minister[6]. After a rescheduling of the vote (initially planned for December 2018) to January 15th 2019, the outcome was a massive reject by the British Parliament. Therefore, the British Government should present on January 21st, 2019 a new agreement to the British Parliament which should vote again of its acceptance or not. Until then, the true impact of Brexit remains to be seen and different scenarios are still possible:

- A deal which could be built as Mutual Recognition Agreement
- A deal with limited conditions
- No deal without any kind of agreement
- New elections
- A report of the Brexit

An agreement has been reached for a transitional period between March 29th, 2019 and December 31st, 2020 in which the UK will keep many arrangements with the EU the same, but will lose its authority to vote on the new EU rules. This also means that CE-certificates issued by UK-based Notified Bodies may

[4] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565&news=1
[5] https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html
[6] https://ec.europa.eu/commission/publications/draft-agreement-withdrawal-uk-eu-agreed-negotiators-level-14-november-2018-including-text-article-132-text-subject-final-legal-revision-coming-days_en

lose their validity on March 30th 2019 if no deal is finalized by that time[7]. It is also important to note, that the UK becoming a third party country, could mean, medical devices incorporating an ancillary medicinal substance for which the review of the usefulness was done by MHRA might also be affected by Brexit. The European Commission released a Questions and Answers document[7], to bring this issue to manufacturers who could be affected.

Closer we get to the end of the clock, and more uncertainties remains about the withdrawal of the United Kingdom of the European Union. On January 3rd, 2019, the MHRA released a response to a "hard Brexit" with no deal concluded with the EU. This document provides guidance about the regulatory impact of this no-deal scenario on medicines, medical devices and clinical trials. For medical devices, the key arrangements include:

- for a time-limited period, devices that have a CE mark from a notified body based in the UK or an EU country will continue to be recognized by UK law and allowed to be placed on the UK market
- the expansion of the MHRA's registration system to all classes of medical device"[8].

The question of the recognition of UK's legislation by the EU on medical products – especially if the UK is (temporarily) following the EU legislation, is however, still undetermined.

WHAT ABOUT OUTSIDE EUROPE?

CE-marking will continue to be recognized worldwide. The EU Commission recently released a guidance document for Authorities outside of the EU regarding the update of the CE-marking with the new MDR and IVDR[9]. This document gives details about the transition to the MDR with the different deadlines related to the implementation of this regulation. Last but not least, details regarding the impact of the MDR on other agreements (such as the MRA between EU and Australia) have not been released, and therefore the website of the EU commission should be watched for more information.

[7] https://www.ema.europa.eu/documents/other/questions-answers-related-united-kingdoms-withdrawal-european-union-regard-medicinal-products-human_en.pdf
[8] https://www.gov.uk/government/news/mhra-releases-response-to-consultation-on-eu-exit-no-deal-legislative-proposals
[9] https://ec.europa.eu/docsroom/documents/32604?locale=en

NORTH AMERICA

GMED LNE GROUP

ABOUT THE WRITER:

Waiss Faissal, Pharm.D

Certification Project Manager at GMED North America

Waïss Faissal is a Certification Project Manager and the Drug Usefulness subject matter Expert at GMED North America. He is a Doctor of Pharmacy (and graduated from the University of Paris Sud where he also completed a Biomedical Engineering Master Degree at the Engineering School of l' Ecole Normale Supérieure des Arts et Métiers (Paris, France).

Prior to joining GMED North America, Waïss was working as Regulatory Affairs and Clinical Studies Manager in the Medical Device Industry, for a company specialized in orthopedic implants.

His responsibilities involved but were not limited to the maintenance and monitoring of Post Market Surveillance (PMS) activities, the Clinical Evaluation and Clinical Investigations data collection and reporting, the evaluation of the new Medical Device Regulation (745/2017) requirements on the company's activities.