How does Brexit impact the medical devices market of Ukraine?

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News under the tag "Brexit" appear in Ukrainian mass media more and more frequently, describing various aspects of the UK politics and economics. Considering new development vector of any country, first of all we must consider the political process with hardly predictable multi-level impact on certain economic realm, industries and production. It is important not to miss in this variety of information and analytics the provisions which can be applicable to the certain industry. In this assay we highlight those aspects of Brexit that can directly or indirectly affect medical devices industry in the EU and Ukraine.

Background and what we know about Brexit

The European Union currently has 28 member states (EU28) aimed at integration in manufacturing, politics, law and economics. Achievement of common goals and building up relationships between Member States is governed by two main Treaties: The *Treaty on the Functioning of the European Union* and the *Treaty on European Union*, which are used comprehensively and integrated into the *Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union*. The right of a state to join or leave the EU is stipulated by the *Treaty on European Union* (hereinafter - TEU).

In Article 50 of the TEU, procedure for exit from the EU is described, which conditionally consists of three stages:

Stage I: Making decision by the member state to withdraw from the Union in accordance with its constitutional requirements,
Stage II: Notification of the European Council on its withdrawal,
Stage III: Discussion within the Union and conclusion of an Agreement with the leaving state to set out exit procedures and transitional periods taking into account its future relations with the Union.

In the history of the United Kingdom, there was already an attempt to leave the union of European states (at that time, the EEC), but according to the results of a public referendum it was decided to remain in the Community. In almost 40 years, on June 23, 2016, another referendum was carried out, related to the exit from the EU. With a majority of votes, the exit from the Union was determined, that marked the beginning of the UK exit procedure (**Br**itain **exit** = Brexit).

The second stage, i.e. notification of the European Council on the intention to leave the EU by the United Kingdom, took place on March 29, 2017, when the British Prime Minister Theresa May signed a letter addressed to the head of the European Council with a notification on the beginning of the exit procedure.

According to the provisions of Article 50 of the TEU, the third and final stage of exit should have been general agreements between the EU and the UK that would describe transitional periods, exit procedures and smooth transition of the UK to the status of a "third party" for the EU. As of today an Agreement defining the relationship between the UK and the EU has not been concluded.

Hard Brexit

There are two possible scenarios for an exit of a country from the EU:

- At the time of exit, signing by the country and the EU of the Agreement establishing post-exit economic and political relations, possible transitional periods, etc.;

- Automatic, 2 years after the second stage (announcement of the exit), without coordination of relations and transitional periods.

Since no consensus was reached in the discussion of the Agreement defining the relationship between the UK and the EU, the second scenario comes into force, i.e. the automatic exit of the country from the EU, also called *Hard Brexit*. The Brexit becomes hard because the UK will acquire the status of **a third country** on the day of exit, and all the social, economic and political consequences of the break in relations occur instantly without any transitional period. Therefore, on April 10, 2019, the EU state heads decided to provide Britain with another deferment, this time until October 31, 2019.

Business response
Prolonged discussions and the lack of completed decisions, the uncertain political status of the UK in relation to the EU, forced many market participants to examine the risks of the worst-case scenario and act based on the assumption of a possible *Hard Brexit.*

In the event of *Hard Brexit*, the "third country" status in relation to the EU significantly affects the established relations in the field of technical regulation:

- Exclusion of British notified bodies from the Nando (New Approach Notified and Designated Organizations) database;
- Inability to place products on the EU (EU27) market on the basis of EU certificates issued by the UK notified bodies;
- Certificate transfer or re-certification to the one of the EU (EU27) notified bodies;
- Designation of an Authorized Representative (EC REP) in EU27 both for the UK manufacturers and for the manufacturers who have previously appointed EC REPs the United Kingdom.

Therefore, the risks of Hard Brexit could affect the designation of the Authorized Representative in the EU, conformity certificates and selection of the notified body, product labeling and the Technical file. All these factors are crucial for the UK manufacturers and foreign manufacturers, if involved UK Authorized Representatives or UK notified bodies.

Notified bodies
Historically, a significant part of medical devices in the EU passed conformity assessment in the UK notified bodies. At the beginning of 2019, there were four such authorities:
0086 BSI Assurance UK Limited
0088 Lloyd's Register Quality Assurance – LRQA
0843 UL INTERNATIONAL (UK) LTD
0120 SGS United Kingdom Limited

The exclusion of the UK bodies from the integrated Nando database means that such organizations lose their right to perform conformity assessment to the EU Directives, and conformity certificates grant no rights to affix CE mark and place the products on the European market. This significantly influenced the regulatory strategy of many manufacturers.

Considering the first wave of alerts for a possible *Hard Brexit* scenario, manufacturers most often made their decisions in favor of change of the notified body. The UK bodies faced with a massive outflow of customers, whereas an additional challenge became the transition to the new Medical Device Directives in 2020. In August 2019, these and other factors resulted to cancellation by the UL International of its designation for the Medical Devices Directive and, in early October, the LRQA also canceled its designation for the Medical Devices and Medical Devices for In Vitro Diagnostics Directives.

In November 2018, the BSI Group The Netherlands B.V. has been designated, that allowed transfer of the certificates from the BSI Assurance UK Limited to the Netherlands via the transfer procedure. Similarly, SGS United Kingdom Limited recommends their customers to transfer certificates for medical devices to the SGS Belgium NV.

Despite the extreme efforts and success of the BSI and SGS in the transfer of certificates, the LRQA and UL INTERNATIONAL (UK) LTD certificates have lost their validity, and the authorities stopped working on the Medical Device Directives even before the official decision on Brexit.

Position of the European Commission

It is fair to note that the European Union provided ongoing support and information to market entities regarding the *Hard Brexit* scenario. During two years, several alerts have been published only on medical devices, the main of which are the following:

- *Notification to market participants - the UK exit and the EU rules for industrial products (published on January 22, 2018)*
- *Questions and answers related to the exit of the UK from the EU in relation to industrial products (published on February 1, 2019)*
- *Completion of preparations for the United Kingdom's exit from the European Union on November 1, 2019 (published on September 4, 2019)*

It can be assumed that such early information from the beginning of 2018 could increase pressure on manufacturers and notified bodies, but it also provided the possibility to prepare in advance for a possible *Hard Brexit* and prevent from the surplus of medical devices on the market. A recent European Commission's report states that as of September 4, 2019, most manufacturers managed to transfer their certificates to one of the EU27 notified bodies, with the proviso that the situation has not been fully resolved and is under the control of the Commission and competent organizations.

Brexit and conformity assessment procedures in Ukraine

Ukraine has a separate system of technical regulation, however, a change in the UK status within the EU could affect the imported products on the national market. Based on our practice, we identified two main groups of medical devices according to the degree of possible Brexit influence:

1. Class I medical devices, in-vitro diagnostic products of the "other" group and medical devices that have passed the conformity assessment without the partial recognition procedure in accordance with Art. 45 of the Law of Ukraine "On Technical Regulations and Conformity Assessment".

For these products, the UK exit from the EU will not have a significant impact, but non-critical aspects should be assessed: has the EC certificate or EC REP changed? Changing the number of the authority next to the CE mark, changing the Authorized Representative in the EU obliges the manufacturer to make changes into the labeling and instructions, the Essential Requirements checklist etc. Usually the manufacturer, when making changes to the technical documents, also implements previously "accumulated" changes, which together can affect the documents for Ukraine.

The UK manufacturers' Authorized representatives in Ukraine are recommended to check the relevance of the technical documents, and if there are any changes, to examine their impact on national requirements, and if necessary, notify the appointed authority and/or update the Declaration of Conformity.

2. Medical devices whose conformity assessment procedure in Ukraine was performed with partial recognition of EC certificate according to Article 45 of the Law of Ukraine "On Technical Regulations and Conformity Assessment".

Three of four the UK bodies, i.e. UL, BSI and LRQA, have signed the Agreement on the Recognition of Conformity Assessment Results with the Ukrainian conformity assessment bodies. Accordingly, national certificates issued under the partial recognition procedure for the results of these notified bodies are at risk.

The change of the body in the EU is usually carried out via the transfer procedure, it implies a transitional period with the possibility to affix the number of the previous body on the labeling. Concomitantly, conformity certificates have to be reissued on behalf of the new notification authority.

When carrying out the procedure of partial recognition, the Ukrainian authority takes into account the results of the assessment performed by the EU notified body and must take steps to analyze and evaluate changes and the overall impact on the Ukrainian certificate. Such analysis can result in re-issue or changes to the certificate, as well to the switch to audit procedure if the Agreement on recognition has not been signed between with new EU notified body.

Please note that the manufacturer must inform the Ukrainian conformity assessment body on the changes related to certified products, and on any changes to EU certificate for partial recognition procedure. We strongly recommend to evaluate changes and develop a balanced professional approach.

We are preparing this notification a few weeks before the final Brexit decision. We already see the changes affecting general situation in the technical regulation in the EU and Ukraine. Inapplicable or indirect at first glance changes in the overall vector of the country's development may have a significant impact on all areas of activity, not only the country, but also its partners.

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