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Life after Brexit: A brief estimation of particular issues raised in Greece in the pharmaceuticals sector following the December 2020 Trade Agreement.

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Brexit is now the new reality and obviously several legal issues have been raised after the end of negotiations, looking for answers to be provided by all "interested parties" such as companies, their advocates and competent authorities, both national and European. The major change after the UK left the EU is in the trade of goods. Transfers of medicinal products from the UK to EU countries, which until now were considered as intra-EU transactions, are now imports from a third country and according to the dated 13 March 2020 REV3 Notice to Stakeholders, which replaces the notice (REV2) dated 1 February 2019 and the Q&A document (REV4) dated 1 February 2019 UK, they should be treated in all their aspects as such.

Marketing Authorization

Marketing authorization is the first issue that comes to mind when searching for Brexit-Pharma consequences, since it is required by law in all Member States to issue an authorization specifically for each and every product in order to place a medicinal product on the market. In the UK, the Medicines and Healthcare Products Regulatory Agency ("MHRA") is the competent authority to issue such authorization. However, since the MHRA is no longer considered as a European competent authority, the authorizations issued are not automatically recognized in the EU. Of course, a transition period has been agreed between the EU and the UK and a list has been issued by the UK and updated 16 March 2021, describing the approved countries for:

- Importation of medicines under a wholesale dealer's license ("*approved country for import list*");
- Batch testing of medicines ("*approved country for batch testing list*");
- Manufacturing of active substances with regulatory standards equivalent to those of the UK ("*approved country for active substances list*").

From an EU perspective, regulations have been also set up regarding the recognition procedures and according to the "*Questions*

and answers to Stakeholders on the implementation of the Protocol on Ireland/Northern Ireland" issued by EMA on the 5th March of 2021, in order to provide "*additional practical guidance on the applicable rules in Northern Ireland after the transition period with respect to EMA activities and medicinal products for human and veterinary use within the framework of the centralized procedure*". From the 1st of January 2021 the medicinal products that are nationally authorized in the UK will be considered as non-EU/EEA products and the value of *'Non-EU authorization procedure'* should be referenced where the country of authorization remains as *'United Kingdom (GB)'*. Furthermore, since after Brexit's effective date and in the end of the transition period the main pharmaceutical legislation (Regulation (EC) No 726/2004,6 Directive 2001/83/EC,7 and Directive 2001/82/EC) will no longer be implemented in the UK, a marketing authorization holder currently established in the United Kingdom has to transfer its marketing authorization to another authorization holder established in the EU (since EU Regulations provide for the marketing authorization holder to be established in the European Union). Thus, the addressee of the marketing authorization decision changes to a new addressee. The transfer of the marketing authorization must be fully completed and implemented by the marketing authorization holder before the end of the transition period. Any application for marketing authorizations shall be submitted by applicants established in the European Union and any applications made by applicants established in the United Kingdom will need to change to an applicant established in the EU according to the EU Notice to Stakeholders, issued on the 13th of March 2020. Further instructions regarding how to transfer the marketing authorization and in which cases UK MAHs may keep their authorization status are provided by the "*Guidance Variations to Marketing Authorizations (MAs)*" issued by MHRA on the 31st of December 2020.

Imports Legislation

The regulatory framework implemented in pharmaceuticals imports from the UK was not introduced recently. In particular, in order to find out the procedure to be followed, a research in the Directives of 2001/83 and 82, articles 40(3) and 44(3) is required, leading to the basic obligation that the competent authorities of the European Union are to ensure that the import of medicinal products into their territory is subject to an authorization. The authorization is granted when a number of conditions, as defined in Articles 41 and 42 of Directive 2001/83/EC and Articles 45 and 46 of Directive 2001/82/EC, are fulfilled (e.g. availability of a qualified person within the EU, GMP inspection). The Greek

Import legislation framework is ruled by the Ministerial Decision 32221/2013 and the Circular 18013/2013, based on the abovementioned Directives.

One of the most important elements of acquiring the imports authorization is the requirement to appoint a Qualified Person (QP). The qualified person of the manufacturing and importation authorization holder is responsible to certify the quality of each batch of medicinal product before the release in an EU market.

More detailed and updated information on the general QP duties and responsibilities may be found in the recently issued, "Annex 16: Certification by a Qualified Person and Batch Release" (dated 12th October 2015).

Qualified Persons

In accordance with Article 51(1) of Directive 2001/83/EC and Article 55(1) of Directive 2001/82/EC, its Greek implementation, the Ministerial Decision 32221/2013 art.67-73 and the relevant Annex 16, the qualified person of the manufacturing and importation authorization holder is responsible to certify that each batch of a medicinal product intended to be placed on the EU market was manufactured in accordance with EU GMP requirements and the marketing authorization. Each batch imported into the EU has to undergo upon importation a full qualitative analysis, a quantitative analysis of at least all the active substances and all other necessary quality checks to ensure compliance with the requirements of the marketing authorization. According to EOF's relevant announcement, Qualified Persons in Greece have to attest to the following qualifications:

a) Holding a Bachelor Degree of the University Division of Biology, Pharmaceuticals or Medicine or any other designated University Division mentioned in art. 65 of the J.M.D. DYG3(α)/83657/05 (GG 59Β΄/24.01.2006);

b) Not operating a pharmacy or a pharmaceutical warehouse or an agency, and not holding any other public, municipal, or compensated private position;

c) Having served or lawfully discharged from military obligations;

d) Being registered with a Municipality in Greece;

e) Not being convicted for one of the felonies of art.2 L.517/68 or otherwise punished for violating pharmaceutical regulations;

g) Declaration that the production unit he will be responsible for, fulfills the requirements to function properly and to produce scientifically approved products;

h) Professional experience of no less than 18 months in the specific field of medical products' quality.

Therefore, UK-based importers have now to re-examine whether the quality responsible person that is already employed meets these standards, or in case they don't, to find and appoint one in accordance with EOF's procedure.

Certificate of Analysis

When a Mutual Recognition Agreement regarding the conformity assessment required for medicinal products provided by the GMPs is succeeded, the signatories recognize that a designated testing body, such as a 'conformity assessment body' in state A (the *export* country in our case the UK) can perform testing on the basis of technical requirements of state B (the *import* country, in our case Greece), and *vice versa*. This allows a product produced and certified in state A to be exported to state B without undergoing further testing in state B, to assess whether the product meets state B's technical requirements – thus reducing barriers to trade. The importer of the batch is, therefore, to receive and maintain the certificate of analysis issued by the fabricator/manufacturer. Upon request, it has to be readily available to the staff of the Regulatory Authority of the importing country, according to EOF's Circular no.58446/20.10.2004. Such Agreement, however, has not been achieved between the UK and the EU yet through the provisional Trade and Cooperation Agreement of 24 December 2020, creating thus a "double obligation" for the UK manufacturers, since along with the certificate of analysis, the importer of UK products remains obligated to have its own QP in Greece or any other European country of products' first entry, who still has to proceed with its own safety testing (e.g. inspection, testing, certification, and licensing), according to the technical regulations and standards.

The same applies to the Market Authorizations, for which no Mutual Recognition Agreement was achieved, leaving the MAHs with lots of extra burdens and issues, related to their place of establishment, as described above. One of the main issues arising from the non-agreement in the context of the provisional Trade and Cooperation Agreement of 24 December 2020 is that a Qualified Person responsible for Pharmacovigilance established in the UK shall not be accepted in the EU Member States (Guidance on handling of Decentralized and Mutual Recognition Procedures which are approved or pending).

The pharmaceutical sector is just one of many public health sectors affected by Brexit. Medical devices, cosmetics and other

regulated products are also facing different quality-check or trade issues, when it comes to their distribution in Greece and the EU. Further legislative developments should be therefore anticipated, not just in Greece, but in the EU and the UK as well, in order to clarify the framework for placing UK medicinal and generally healthcare products in the single market.

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