JAZMP
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES OF THE REPUBLIC OF SLOVENIA
Slovenčeva ulica 22
1000 Ljubljana, Slovenia
www.jazmp.si info@jazmp.si
T +386 (0) 8 2000 500 F +386 (0) 8 2000 510

Dear Marketing Authorisation Holders,

The United Kingdom (UK) submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. Following the ratification of the Withdrawal Agreement by the United Kingdom and the European Union in January 2020, the United Kingdom formally left the European Union on 31 January 2020 and became a third country to the EU. A transition period started on 1 February 2020, which ended on 31 December 2020.

Since May 2017, the pharmaceutical industry has been reminded by the European Commission and the CMDh/CMDv about the impact of UK's withdrawal from the Union and its legal repercussions. Industry has been continuously informed of the need to adapt processes and to consider changes to the terms of marketing authorisations in order to ensure their continuous validity and exploitation, after the United Kingdom has left the Union.

Information notices and guidance documents on legal, regulatory and procedural requirements for companies have been published and regularly updated. We would like to refer you again to the European Commission Notice to stakeholders, the CMDh Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP and the CMDv Practical guidance for procedures related to Brexit for veterinary medicinal products approved via MRP/DCP.

According to our records, some medicinal products **have one or more of the following activities and/or entities still located in the UK**:

- **Marketing authorisation holder,**
- **Pharmacovigilance system master file,**
- **Qualified Person for Pharmacovigilance,**
- **Batch control site(s) for finished product (in absence of an agreed time-limited exemption[1]),**
- **Batch release site(s) for finished product,**

Taking into consideration that to our knowledge some of you have not made the necessary submissions or have not undertaken the relevant actions to ensure full compliance with the EU Pharmaceutical *Acquis*, we would like to inform you that **you must no longer place new batches on the market until the situation with non-compliant medicinal products is rectified[2]**.

You will therefore need to rectify as soon as possible the above listed non-compliant aspects of the marketing authorisation to ensure batches continue to be released in line with the legal requirements of Directive 2001/83/EC and **submit the corresponding marketing authorisation transfer**

[1] With the agreement of the NCA for a product deemed essential by the NCA;

[2] However, if all outstanding changes have already been implemented and all changes are subject to type IA variation(s), the ability to place new product batches on the market is not impacted, provided that the corresponding type IA_{IN}/IA variations are submitted as per timelines indicated in the above mentioned practical guidance.

application / type IA_{IN} / IB / II variation(s) / update to the Article 57 database concerning the QPPV and / or PSMF no later than by 1.3.2021 and / or submit the corresponding type IA variation(s) no later than by 1.4.2021. If you will not be able to comply with these requirements, you are requested to give us a status update no later than 1.3.2021.

If the necessary submission(s) will not be received within the above referred timelines, the Agency for Medicinal Product and Medical Devices of the Republic of Slovenia will consider taking appropriate regulatory action. The appropriate action could be to suspend or revoke the marketing authorisation(s) concerned on the basis of Article 116 and 118 of Directive 2001/83/EC / Article 83 and 85 of Directive 2001/82/EC or to prohibit the supply of the medicinal product on the basis of Article 117 of Directive 2001/83/EC / Article 84 of Directive 2001/82/EC and the corresponding national provisions.

The letter is without prejudice to any further changes that might be required for your medicinal product (e.g. removal from the dossier of importation, batch control and batch release sites located in Great Britain, change of local representatives if currently still located in UK).