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Health systems, medical products and innovation

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By email only

To whom it may concern,

Subject: Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products

This information is addressed to the EU27 Heads of Medicines Agencies and to the Executive Director of the European Medicines Agency (EMA).

The United Kingdom 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. This means that as from 30 March 2019, 00:00h (CET) ('the withdrawal date')[1] the United Kingdom will be a 'third country'.[2] [3]

The pharmaceutical industry has been informed early by the Commission, the European Medicines Agency and national competent authorities about the impact of United Kingdom's withdrawal and the need to adapt processes and to consider changes to the terms of marketing authorisations in order to ensure their continuous validity and exploitation, once the United Kingdom has left the Union.[4] This contributed to a high level of preparedness of the sector.

In particular, according to Article 51(1)(b) of Directive 2001/83/EC and Article 55(1)(b) of Directive 2001/82/EC, medicinal products imported into the EU have to undergo quality control testing ('batch testing') in the EU/EEA.

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1 In accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

2 A third country is a country not member of the EU.

3 This is without prejudice to the transition period provided for in the draft Withdrawal Agreement subject to the timely ratification of the draft Withdrawal Agreement. Cf. Part four of the draft *Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community*, as agreed at negotiator's level on 14 November 2018 (https://ec.europa.eu/commission/publications/draft-agreement-withdrawal-uk-eu-agreed-negotiators-level-14-november-2018-including-text-article-132_en)

4 See the notice to stakeholders published in May 2017.

The requirement of a batch release site established in the Union is a fundamental pillar of the Union system of ensuring quality of medicinal products being placed on the Union market. With regard to the batch release sites currently located in the United Kingdom marketing authorisation holders therefore need to comply with this requirement at the latest by the withdrawal date.

However, with regard to the quality control testing there may be objective reasons beyond control of the marketing authorisation holders that may prevent timely transfer of such testing activities to the Union by the withdrawal date.

In these cases, Article 20(b) of Directive 2001/83/EC and 24(b) of Directive 2001/82/EC provide that competent authorities may allow importers of medicinal products coming from third countries to have in justifiable cases certain of the controls carried out by third parties.

In applying these provisions, competent authorities may allow marketing authorisation holders, for a limited period of time, as a justified case, to rely on quality control testing performed in the United Kingdom (hereafter "**the exemption**"), under the following conditions:

1. A batch release site in the EU27 is identified by the marketing authorisation holder by the withdrawal date.

2. The batch release site is supervised by a qualified person established in the EU27 by the withdrawal date.

3. The establishment designated by the third party conducting the quality control testing may be verified by a competent authority of the EU27, including on the spot checks.

4. All necessary steps have been taken to prepare the transfer of the quality control testing site from the United Kingdom to the EU27.

In order to make use of this exemption, affected marketing authorisation holders must immediately notify the relevant national competent authority that granted the marketing authorisation (or EMA in case of centrally authorised products). The notification must be submitted without undue delay but in no case later than on 29 March 2019. In the notification the marketing authorisation holder must:

- specify the batch release site in the EU27.
- confirm that the qualified person established in the EU27 is responsible for the quality control testing site in the United Kingdom.
- confirm and set out their precise timetable for transfer of the quality control testing site (which should allow the process to be completed quickly and in principle by the end of 2019 at the latest).
- specify the period of time and batches (packs and quantities) that are requested to be exempted. This should be strictly restricted to what is necessary.
- commit to providing batch testing results for those batches from the existing facilities within the United Kingdom.
- transfer samples of those tested batches together with the testing results to the batch release site in the EU27 in due time to make them available for inspection.

The national competent authority or EMA should assess the request for such an exemption. If the national competent authority or EMA considers that the request is justified it should grant the exemption to rely on the quality control testing conducted in the United Kingdom for the time period strictly necessary and for the specific batches identified. Such request would fall

outside the procedural requirements of Commission Regulation (EC) No 1234/2008 (variation regulation).

A copy of the letter granting the exemption should be sent by the marketing authorisation holder to the competent authority that granted the manufacturing authorisation for the batch release site in accordance with Article 40 of Directive 2001/83/EC and Article 44 of Directive 2001/82/EC.

On the basis of the above, the qualified person would then be able to release the batches concerned for placing on the Union market.

In the absence of such an exemption, if the testing of the batch does not take place in the EU27, as of the withdrawal date,

- the marketing authorisation will become non-compliant and the competent authorities may take action in accordance with Articles 116-118 of Directive 2001/83/EC and Articles 83-85 of Directive 2001/82/EC to suspend or revoke such authorisation;
- medicinal products coming from the United Kingdom can no longer be imported into the EU27.

In this context, marketing authorisation holders are reminded of their obligation under Article 23a of Directive 2001/83/EC, Article 27a of Directive 2001/82/EC and Article 13 of Regulation (EC) No 726/2004 to notify any issue that may cause disruption of supply two months in advance to the competent authorities. This means, where companies expect to encounter problems as of the withdrawal date, they would have to submit the respective notification now.

Of note, in case the Withdrawal Agreement, which provides for a transition period, is ratified, the marketing authorisation holders will be able to continue to rely on quality control testing conducted in the United Kingdom until the end of the transition period. In that case, there will be no need for an exemption as described in this letter.

In order to ensure stakeholders' awareness this letter should be published on the websites of the European Medicines Agency, the Coordination Group on Mutual Recognition and Decentralised Procedures – Human (CMDh) and the Coordination Group on Mutual Recognition and Decentralised Procedures – Veterinary (CMDv).

[Electronically signed]

SANTE Pharmaceuticals