BREXIT preparedness of our industry: As it looks increasingly likely that the UK will withdraw from the EU Internal Market on 1 January 2021. The President would like to remind members of the remaining issues to be assessed to limit potential risks for supplies of medicines to patients in the UK and in the EU/EEA. Where members see a major risk for patient supply, they are strongly encouraged to contact the European Commission and relevant regulatory authorities based on the procedure indicated in this letter.

6 October 2020

Dear members,

I am writing to encourage members to conduct a review of the aspects of your business that could be affected by Brexit as we approach another milestone in this process. In accordance with the Withdrawal Agreement, Union law continues to apply to and in the UK for a 'transition period' lasting until 31 December 2020 meaning that the UK remains a part of the EU Internal Market with all of its rules and regulations. As of 1 January 2021, the UK will, unless the transition is extended, which looks increasingly unlikely, exit the EU Single Market and Customs Union, no longer participate in Union policies and programmes, and no longer benefit from EU international agreements. From that period onward, the UK will apply its own pharmaceutical legislation although much of it will be imported from EU law. It is important to note that Northern Ireland (part of the UK) will continue to apply EU Internal Market rules for pharmaceuticals and continue to be a part of the EU Customs Union.

EU-UK negotiations on a free trade agreement are very slow and there is limited political momentum to conclude a deal. For this reason, both parties have issued guidance[1][2] for stakeholders and authorities on how to best prepare for a no deal withdrawal from the EU Internal Market.

Despite joint industry efforts to prioritise health and access to medicines for patients, there are numerous outstanding issues that will affect trade in medicines between the EU and the UK and business continuity (Regulatory transfers, quality testing and release sites transfers, supply chain and logistical alternatives, legal and contractual changes, etc.).

I therefore kindly request that members affected by this issue should step up efforts and prepare for the high risk of a no deal withdrawal to ensure that our supply chains continue to function with minimal disruption and interruption of medicines supply to patients.

[1] On 7 July 2020 the European Commission published a communication "On readiness at the end of the transition period between the European Union and the United Kingdom"

[2] The UK Government published the following guidance:

- "How to prepare if the UK leaves the EU with no deal"
- import goods from the EU
- export goods to the EU
- Trading in drug precursors from 1 January 2021

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I **strongly recommend that you re-activate internal contingency plans – if not already done – to assess compliance with Brexit related guidelines from authorities**.

In particular, companies are encouraged to review:

- GMP and import testing issues, as the EU and the UK have failed to agree on a Mutual Recognition Agreement (MRA) which the EU has in place with most other highly regulated markets (US, Japan, Canada, etc.).

- Customs formalities, as the UK will become a third (foreign) market.

- FMD serialization, as the UK will cease to apply FMD legislation in England, Wales and Scotland although it will continue to apply in Northern Ireland. Therefore, any decommissioning for export to the UK should not include medicines destined for Northern Ireland. Medicines for Europe is in the process of collecting detailed guidance from EMVO on this matter for manufacturers.

Recognising the complexity of this issue, Medicines for Europe strongly encourages members to rapidly inform EU or UK authorities of any identified critical, lifesaving medicines which might face supply issues and for which no or limited alternatives are available for patients.

Wherever possible, please keep Medicines for Europe informed or in cc. of these concerns indicating, if necessary, that the information is confidential[3].

Medicines for Europe will continue to advocate for a Mutual Recognition Agreement and subsequently for an EU-UK free trade agreement. However, as we cannot count on this, each company is encouraged to take responsibility and review the risks for patient supply. I count on your prompt reaction and commitment to this important task.

Medicines for Europe remains of course at your disposal for any clarification or questions you might need.

Best regards,

Christoph Stoller
President

[3] It is also important to indicate "confidential" for any such information sent to the Commission or EMA as this can be the subject of access to document requests from the general public.