Medicines & Healthcare products Regulatory Agency

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Third Sector Stakeholders

By Email

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Dear Colleague,

I wanted to draw your attention to several published pieces of information which aim to provide further clarity to the sector on our work in preparing for exiting the EU.

- At the March European Council, the UK and EU agreed the terms of an implementation period, from March 2019 to the end of December 2020. The period will enable businesses and organisations in the UK and across the EU to operate as now, giving them time to plan with confidence for life after our withdrawal. For the life sciences sector in particular, an update has been published which sets out what the implementation period agreement would mean, once finalised as part of the Withdrawal Agreement. Continued market access, opportunities to attend committees and groups, and ongoing data sharing during the implementation period will ensure that access to medicines and medical devices continues and patient safety is maintained in both markets.

- To support this update, we have published a document, which answers specific questions the sector has asked us about the terms of the implementation period for the sector. We will update and expand this over time.

- We have also given clarity on how the implementation period affects upcoming EU regulation, in particular the new EU Clinical Trials Regulation (CTR) here. As you may know, the CTR is expected to be implemented during 2020 and would therefore apply to the UK under the terms of the implementation period. However, if the new regulation does not come into force during the implementation period, the Government has confirmed that UK law will remain aligned with parts of the EU's CTR legislation that are within the UK's control, in order that researchers conducting clinical trials can plan with greater certainty.

- Finally, I wanted to draw your attention to the joint statement of 19 June 2018 which provides an update on the latest areas of agreement on the draft legal text of the Withdrawal Agreement. Since March new agreements have been reached on matters including goods on the market, Euratom related issues and judicial cooperation in civil and commercial matters.

Progress is being made to finalise the Withdrawal Agreement as a whole. The aim is to agree this by October, alongside the framework for our future relationship with the EU. We are confident of a positive outcome from the negotiations with the EU and we will continue to act in the best interests of patients, recognising that this will require continued close cooperation between the EU and the UK.

I hope you find this helpful. We are always open to feedback. If you have any, please email engagement@mhra.gov.uk.

Yours sincerely,

Dr Ian Hudson
Chief Executive
Medicines and Healthcare products Regulatory Agency