# News story: MHRA update to pharmaceutical companies on exit preparations

### Update on negotiations

The European Council formally agreed on 15 December that sufficient progress has been made to move on to the second stage of the negotiations, and adopted guidelines for that second phase.

This followed the publication of a Joint Report on progress during the first phase by the Government and the European Commission on 8 December.

These are important steps forward for both sides and demonstrate the shared interest in managing our exit smoothly, and in moving on with our negotiations.

In the context of ensuring continuity in the availability of goods placed on the market under Union law before withdrawal, the Joint Report makes clear that “goods placed on the market under Union law before the withdrawal date may freely circulate on the markets of the UK and the Union with no need for product modifications or re-labelling; be put into service where provided in Union law, and that the goods concerned should be subject to continued oversight.”

The guidelines set out the need for the EU and the UK to complete work on all withdrawal issues and to start drafting the Withdrawal Agreement. The UK looks forward to continuing these discussions.

The EU guidelines also acknowledge the proposal put forward by the UK for a time-limited implementation period, based on the existing structure of EU rules and regulations. The aim is for access to one another’s markets to continue on current terms throughout this period, and for it to be based on the existing structure of EU rules and regulations.

Both parties have recognised the importance of such a period in the interests of providing certainty and continuity to businesses and individuals, and the EU is expected to adopt additional negotiating directives on transitional arrangements in January 2018. The UK expects to be able to rapidly agree the detail with the EU in 2018.

Finally, the guidelines reconfirm the EU’s desire to establish a close future partnership with the UK. As the UK enters the second phase of negotiations, its position on medicines regulation remains clear. The UK is fully committed to continuing the close working relationship with its European partners, in the interests of public health and safety. Its aim is to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines and be assured that their safety is protected through

the strongest regulatory framework and sharing of data.

## Preparing for all outcomes

MHRA is aware that companies who market pharmaceuticals in the EU and UK will need to plan and make decisions in advance of the UK's departure from the EU in March 2019.

As noted above, the UK's intention remains to secure an implementation period based on the existing structure of EU rules and regulations as quickly as possible, and to agree a deep and special future partnership.

We will continue to advise businesses on the basis of the UK position and will continue to work with the European Medicines Agency in planning for the UK's withdrawal from the EU and future relationship.

## Current regulatory relationship between UK and European network

It is also important to note that the UK's current regulatory relationship with the European network remains unchanged. The UK has underlined to Member States and to the EMA on several occasions that at present:

- the UK continues to be a full member of the EU: we will fulfil our responsibilities, and, in turn expect to be treated as such.

- the UK continues to bid for EMA work and expects its bids to be respected and considered on merit. There are simple, pragmatic solutions to manage the possibility of various outcomes in March 2019: we are, for example, putting forward UK bids in conjunction with other Member States, in the centralised procedure, to ensure business continuity where procedures are likely to run beyond this date.

- MHRA have committed to complete all assessments under evaluation at the time that the UK departs from the EU and will make assessment reports available to the network.

- the UK continues to carry out its Official Control Authority Batch Release (OCABR) responsibilities as part of the Official Medicines Control Laboratory (OMCL) network for human biologicals.

- the UK will continue to put candidates forward for leadership roles where appropriate and expects the committees with responsibility for electing chairs to do so on merit.

## UK regulatory requirements after March 2019 in the event of no

## ongoing relationship with EMA networks

Companies have been asking for detail about UK legislative requirements in different scenarios. We have been working closely with industry associations and other stakeholders and further details on all these issues and more – both our Day One and longer-term proposals – will be published when appropriate.

As stated above, the UK intends to agree a time-limited implementation period with the EU, and both parties have recognised its importance. Should however there be no implementation period, MHRA's approach would be in line with the following principles:

- the European Union (Withdrawal) Bill will convert the existing EU legislative framework into UK law at the moment of exit, so there would be no sudden changes to the UK regulatory framework.

- we would be pragmatic in establishing UK regulatory requirements. We would give adequate notice and ensure that companies had sufficient time to implement any changed requirements.

- where possible, we would be making use of the information we already have to complete administrative tasks for continuity of work and licences.

- we would ensure the minimum disruption and burden on companies as the UK exits the EU, while building on the existing relationship between MHRA and firms.

We will continue to engage with business, patient groups and other stakeholders to help plan ahead with certainty, and will look to publish more technical detail if appropriate.