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Brexit and Pharmaceuticals' Regulation: Optimising the UK's post-Brexit influence in global standards-setting

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Introduction

The implications of Brexit for the United Kingdom's (UK's) role in global standard-setting have been largely overlooked to date, but they deserve serious and urgent attention by policymakers.

One key global regulatory body in which the UK is set to lose its voice, post-Brexit, is the ICH. The ICH stands for the **International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.** The ICH is a highly influential international organisation which aims to harmonise the development and registration of pharmaceuticals across the world, including through standards on **good clinical practice relating to the quality, safety and efficacy of pharmaceuticals.**

This paper outlines why the ICH is so influential within the global pharmaceuticals market. The paper then highlights the role played within the ICH by the UK, through its **Medicines and Healthcare products Regulatory Agency (MHRA),** as part of the European Union (EU) delegation to the ICH, and how the UK's influence will be lost when it leaves the EU.

Finally, this paper proposes a solution to this issue: after Brexit, the MHRA could apply for initial Observer status in the ICH, which could pave the way to eventual membership of the ICH in its own right.

While the MHRA would never achieve the level of influence held by the EU within this body, MHRA membership of the ICH could enable the UK to have a voice in global standard-setting for the development and registration of pharmaceuticals post-Brexit.

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Why is the ICH so important?

The ICH was set up in 1990 by the EU, Japan and the United States (US). Its aim is to achieve greater global harmonisation in the development and registration of pharmaceuticals to help ensure that they are **safe, effective and of high quality,** while also enabling the pharmaceutical industry, consumers and regulators to benefit from the resource efficiencies which can be achieved through harmonisation.

The ICH's membership comprises the regulatory bodies of the **EU, Japan and the United States**, a number of national regulatory bodies, and also various umbrella industry associations. The greatest influence is accorded to the EU, Japan and the US, as the ICH's Founding Regulatory Members.

Although the international guidelines produced by the ICH are not, in themselves, legally-binding, they are usually adopted into law by member countries or organisations such as the EU.

The influence of the ICH is demonstrated by the fact that ICH guidelines are de facto binding in the law of its member countries and the EU, and compliance with them is effectively required by those who export pharmaceuticals to them. In other words, **compliance with ICH guidelines is a de facto requirement for the development and registration of pharmaceuticals in any of the member countries and the EU.**

However, the ICH's influence extends much further. The effect of this legal and regulatory influence within the territories of its founding members is to oblige those countries that export pharmaceuticals into the EU, Japan or US to comply with ICH guidelines as well.

Moreover, the influence of EU law extends to clinical trials; if a company wants to draw on evidence from clinical trials conducted outside the EU, it must ensure that those trials are carried out to the legal standards required by EU legislation. Thus, the influence of both ICH guidelines and of relevant EU legislation conforming to those guidelines extends beyond ICH members across the globe, including other large, wealthy markets such as Australia, New Zealand and Brazil. In addition, ICH guidelines receive further legal backing through the World Trade Organisation's rules for the resolution of trade disputes.

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What influence is the UK set to lose?

If, once it has left the EU, the UK is to forge an economy that trades globally and builds on its strengths, including in clinical trials and pharmaceutical development, it will almost certainly need to comply with EU law and ICH guidelines.

Ironically, however, the UK has, to date, played a significant role in shaping both ICH and EU policy and practice.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) participates in the ICH as part of the EU's delegation. As a Founding Regulatory Member, the EU, together with the other two Founding Regulatory Members (Japan and the US) has greater decision-making power within the ICH than any other ICH Members. In addition, MHRA staff also participate in several ICH Expert Working Groups on the elaboration of ICH scientific and regulatory guidance.

Further, as an EU Member State, the UK helps to make decisions on standards via its say in the form and content of EU law and policy, including through the European Medicines Agency (EMA). The latter EU agency is based in London and oversees clinical trials, pharmaceutical development, marketing and post-marketing surveillance. The UK contributes significant expertise and knowledge towards the EMA's work, particularly through the MHRA, which has played a key role in shaping EU policy and practice.

What steps can the UK take to restore its voice post-Brexit?

Once the UK leaves the EU, the UK is set to forego both the influence it exercises, via the EU, on the decisions made by the ICH, and the influence it wields on EU law and policy, including through the EMA. However, while there appears to be little that the UK government can do about the demise of its influence within the EMA, there is a path by which the UK might be able to regain a voice within the ICH within a matter of a few years.

This path consists of a simple, two-step process which could take place after the UK's departure from the EU: (i) an application by the MHRA/UK to be granted Observer status at the ICH and then, two years later, (ii) an application by the MHRA/UK to be granted membership (see Figure 1).

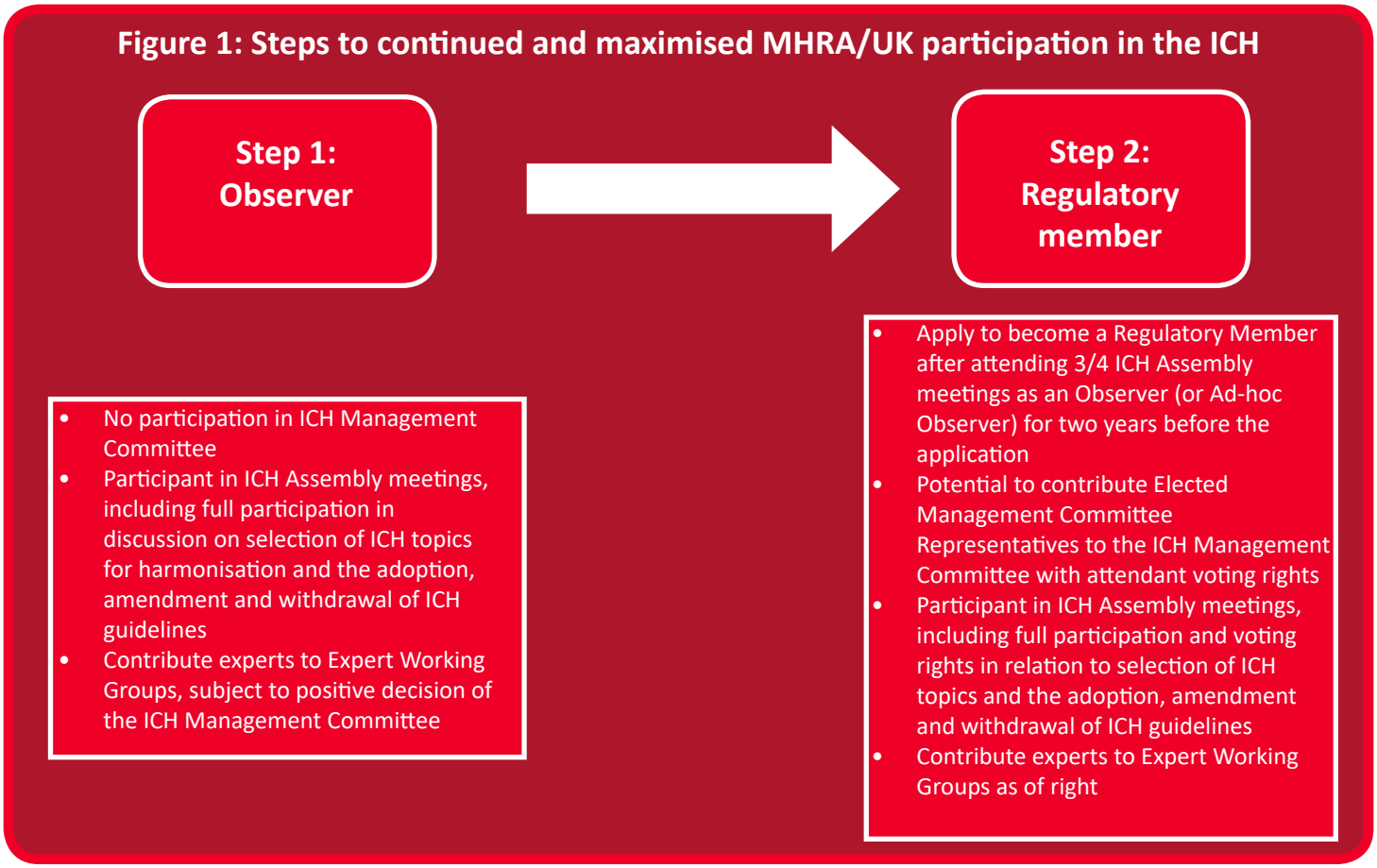
While the MHRA would not regain its status as part of one of the ICH's Founding Regulatory Members, it could become a Regulatory Member if its application were to be accepted by the ICH; this would give it voting rights, including access to the influential ICH Management Committee, which among other things decides on the areas for harmonisation through ICH guidelines. However, individual MHRA membership of the ICH would provide one thing that might be of benefit which the Agency does not currently enjoy; it would be able to speak with a clear, distinct voice rather than as part of the EU.

One obvious question is why the MHRA should need to wait until Brexit to apply to become an ICH Observer and why it should need to wait a further two years after attaining that status before it could apply to become a member.

The requirement to wait for two years after attaining Observer status is bound up with the organisation's rules; the ICH's rules require that any potential member has to participate in a certain number of the body's meetings of a particular type for two years prior to applying for membership, and this requirement is most easily followed by attaining Observer status.

The need for the MHRA to wait until the UK exits the EU is a consequence of EU law, which states that it is the EU and not its Member States which are competent in the fields of good clinical practice covered by the ICH's guidelines.

Figure 1: Steps to continued and maximised MHRA/UK participation in the ICH



Conclusion

In terms of the growing global pharmaceutical marketplace, Brexit not only means UK withdrawal from the EU, it also effectively means withdrawal from the highly influential international pharmaceuticals regulatory forum, the ICH. However, due to the increasingly harmonised nature of the global market for pharmaceuticals and the pivotal position of the ICH within that drive for harmonisation, the UK cannot afford to lose its influence permanently within this key organisation.

The MHRA/UK should therefore take immediate action to ensure it becomes an Observer at the earliest possible opportunity post-Brexit. Once the MHRA/UK becomes an Observer it will be able to build up the necessary participation to support an application to become a Regulatory Member as soon as possible after the UK officially leaves the EU. As a Regulatory Member of the ICH, the MHRA/UK will, in principle at least, be far less of a 'taker' and more of a 'maker' of ICH guidelines. This proposed solution would help mitigate the loss of the UK's influence both within the ICH, via the EU, and on EU law, as an EU Member State.

It is also possible that there may be some benefits to this course of action, should it prove successful, as individual membership of the ICH would enable the MHRA/UK to speak with a clearer and more distinct voice than is possible at present.

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