

# **Cooperative relationships for bio-medical science post- Brexit: The legal landscape**

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**Note:** This analysis must not be treated as formal legal advice, not least because its authors are not insured to give such advice. Anyone seeking such advice should consult a solicitor.

## Summary

Post transition (after 31 December 2020), the future relationship(s) between the EU and the UK will have to be embodied in some kind of legal form(s). This briefing paper focuses on possible legal forms for post-Brexit cooperation in bio-medicine.

Post-Brexit, the level of EMA/MHRA cooperation and mutual recognition *will fall short* of the present EMA-MHRA relationship, which, during transition, is based on the deepest type of legal integration of different systems/economies that falls short of a federal state, that is, membership of the European Union. EMA/MHRA cooperation will be *conditioned by the broader EU/UK (trade) relationship(s)* within which it sits. In general, from the point of view of the EU, bio-medical science cooperation is an aspect of trade relations, *not a severable part of the economy/society*.

Post-Brexit, the UK is formally a 'third country', like any other non-EU Member State. There is no formal legal category of 'ex Member State'. The EU's power or *competence* to enter into agreements with 'third countries' must be understood as an important legal *constraint* on what is politically possible for the EU-UK future relationship(s). But EU competence must also be understood as *dynamic*. This means that the current models of EU-third country relationships cannot be seen as an exhaustive list of types of EU-UK relationship that could be negotiated, although they will be an important source of inspiration. In particular, the EU's competence to enter into the EEA was untested at the time the EEA was agreed. A similarly unprecedented type of agreement might be legally permissible for the EU, if it were politically acceptable.

Scope for cooperation between the EMA and third country agencies is restricted by broader EU competences, and the EMA's powers as an EU agency, *as interpreted by the EU's Court of Justice (CJEU)*. Specific and bespoke agreements for some small elements of cooperation between the EMA and MHRA would be legally possible without an EU-UK trade agreement being in place. But for anything less piecemeal, more ambitious, nearer to the current position, to go beyond ordinary 'third country' cooperation between the EMA and MHRA, and to have an over-arching EMA/MHRA agreement, a relatively deep underpinning free trade agreement would be necessary.

EU law does not at present grant full or partial access to the Clinical Trials Information System for all entities incorporated in any non-EEA third country. Rather, access is on a trial-by-trial basis. In the event that no agreement is in place covering this matter by 1 January 2021, alternative legal bases for data sharing, such as an adequacy decision, will immediately become necessary for data flow from the EU to the UK. As a non-EU/EEA State, the UK cannot lawfully be the lead assessor for marketing authorisations. While the EU may not lawfully recognise MHRA marketing authorisations post-Brexit, the UK may lawfully unilaterally recognise the EMA's marketing authorisations.

In short, the choice for the UK – in this policy area as in others – is between depth of integration and corresponding loss of regulatory control, or the regaining of regulatory control accompanied by a loss of access to the EU market. This trade-off is the critical question which successive UK governments have failed to settle. If shared standards and deep collaboration are the preferred outcomes, the UK must look to models such as the EEA Agreement for inspiration in its negotiations with the EU.

## 1. Background

This report comprises a detailed response to the queries raised by Cancer Research UK (CRUK) following a meeting with the *HGAB* team in March 2019. CRUK's particular interest arises from the EU level regulation of clinical trials and medicines licensing: both critical for CRUK's ongoing work. As requested by CRUK, the report maintains a legal – as opposed to political – focus throughout. It is however important to note that the legal and political spheres are sometimes unavoidably intertwined. Moreover, the extraordinary fluidity of contemporary politics makes it difficult to be certain about future legal positions.

The report is led by CRUK's questions. These essentially centre around the extent to which non-EU Member States ('third countries') can enjoy cooperation with the EU and its institutions, specifically the European Medicines Agency (EMA). The report therefore begins by outlining the options available for a future relationship between the UK and the EU post-Brexit. This primarily entails outlining the EU's competence to negotiate trade agreements with third countries. The second part of the report focuses on the EMA at agency level. This includes consideration of the legal bases of the agency, its activities, and its relations, as well as existing case studies that can be applied analogously to the post-Brexit EMA-MHRA relationship.

The report's presumptions about the UK's third country status post-Brexit are consistent with the EMA's position and reflect the current absence of clarity regarding future EU/UK relations.

We note from the outset that **the level of cooperation and recognition will be limited in all of the examples explored and will fall short of the present EMA-MHRA relationship**, by virtue of the fact that the UK is no longer an EU Member State. The options for the future EMA-MHRA relationship will be largely contingent on the future EU-UK trading relations. A deep EU-UK FTA would provide a strong platform for inter-agency cooperation going forward (noting that it will not be possible to replicate everything associated with EU Membership). The EEA was an unprecedented model of deeply integrated EU-third country relations which shows the promise of the dynamism of EU competences, and the ways in which political agreements that the EU seeks to make can be embodied in novel (at the time) legal forms. While EEA membership itself is unlikely to be the basis of future EU-UK (trade) relationship(s), the case of the EEA provides inspiration for potentially productive novel legal relationships going forward.

We note the EU's legal obligation under Article 9 TFEU to promote a high level of human health protection in all its policies and activities. We also note the European Commission's proposed commitment to a level playing field, and cooperation and dialogue in economic sectors where in the EU's interest<sup>1</sup>. Continued cooperation with the UK in biomedicine is in the EU's interest, and will help to secure a continued high level of health protection in the EU.

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<sup>1</sup> European Commission's Recommendation for a Council Decision authorising the opening of negotiations for a new partnership with the United Kingdom of Great Britain and Northern Ireland COM(2020) 35 final, 3 February 2020.

## 2. Post-Transition UK-EU Relationship

There is an important correlation between what level of cooperation and integration a third country has with the EU *in general* and what level of cooperation and integration can be achieved between *agencies* in that third country with its EU counterpart. Hence we consider the possibilities for a general post-transition UK-EU relationship before exploring the options available at the agency-level.

### 2.1 EU-third country relationships: legal limitations

This section will address the following questions from CRUK:

What is the legal limit of what competency looks like? Are there certain activities for which third country involvement is (either explicitly or by implication) formally legally ruled out? Or is this simply a political decision on where to set the acceptable limit of third country participation?

It has been stated that the EEA is the only existing precedent of a relationship with the EU that goes 'beyond' third country cooperation. In this context, is 'third country' defined in relation to existing practice or is there a formal legal definition of what this 'third country' relationship can/cannot look like?

In order to answer these questions, we first provide some basic definitions of the two key participants we are considering: the European Union and the 'third country'.

The EU is not a state. The EU is a legally created entity comprising 27 Member States, by the agreement of the governments of those Member States. This agreement (now embodied in the Treaty on European Union (TEU) and Treaty on the Functioning of the EU (TFEU), and all the law that flows from those international instruments) informs the EU's objectives of economic and political union. But the TEU and TFEU, as interpreted by the CJEU, also comprise the legal bases by which the EU's powers and competence are constrained. These legal texts are crucial to determining the EU's competence to enter into agreements with what are known as 'third countries'.

The TEU and TFEU envisage two types of country: EU Member States and 'third countries'. The only commonality between all third countries is that they are not Member States of the EU and therefore they cannot enjoy the same cooperation with and participation within the EU as the Member States. Other than being an EU Member State, it is in principle not legally possible to 'go beyond third country cooperation'. Even the closest cooperation, for instance, within the EEA, or association agreements with countries seeking to join the EU, is still, legally speaking, 'third country cooperation' from the point of view of the EU. But there is significant variation in the types and levels of cooperation between the EU and different 'third countries' or groups of third countries. The US, Switzerland, and the EEA, for example, all fall on different points of the spectrum of cooperation and participation.

Legal limits to the EU's competency are outlined in the TEU and TFEU.

They are of two broad types:

- Substantive limits to the contents of what the EU may lawfully agree with third countries;
- Procedural limits to how those agreements must be negotiated, ratified and enter into force.

Cooperative relationships in bio-medical science fall within the broad parameters of the EU's external trade policy – the various bases on which the EU agrees to trade with the rest of the world.<sup>2</sup> The EU's competence in external trade policy determines:

- To what extent the EU may lawfully negotiate trade agreements with third countries;
- To what extent the EU may do this without the involvement of its Member States (known as 'exclusive competence')? (*procedural* points);
- What legal limits there are on the *contents* of trade agreements that the EU negotiates (a point of *substance*).

The TFEU's aim is 'the progressive abolition of restrictions on international trade.' The EU aims to be 'a strong and united player on the international scene, rather than a more or less effective coordination platform'<sup>3</sup> for its Member States.

Under the Common Commercial Policy (CCP), Article 207 TFEU sets out the scope of trade to include goods, services, commercial aspects of intellectual property, and foreign direct investment.

*Procedurally*, Article 3 TFEU confirmed these as the exclusive competence of the EU. Where a FTA includes areas outside of these (such as non-direct investment or investor-state dispute settlement (ISDS)), the EU may not conclude the agreement alone, but the Member States also have to agree it (known as a 'mixed agreement').<sup>4</sup>

Areas requiring a mixed agreement are irrelevant to the EMA-MHRA relationship. Nonetheless, the possibility that an EU-UK FTA may have to be a mixed agreement should be borne in mind, given that a broader FTA between the EU and the UK would have to encompass areas beyond those relevant to CRUK and the bio-medical sector.

*Procedurally*, the CCP allows the EU acting alone to agree FTAs that extend EU standards to third countries. So, if the UK was willing to continue to comply with EU rules in return for internal market access, albeit in a more limited form than EU Membership permits, the EU could negotiate such an agreement with the UK without the need for each Member State to have a veto.<sup>5</sup>

However, even if it is within the EU's remit to negotiate and conclude an agreement independently, this does not guarantee that its content adheres to the limitations on EU competence set out in the TEU and TFEU. *Substantively*, the EU may not agree FTAs that are incompatible with the Treaties, including fundamental rights. FTAs, for instance, must respect the autonomy of the EU and its legal order. However, it is permissible for the EU to agree to establishing a new institution to interpret and apply provisions of a FTA, as is the case in the EU-Canada FTA (CETA).<sup>6</sup>

Furthermore, *substantively* the EU may not agree other types of cooperation agreements that undermine the EU's CCP. If an agreement to cooperate in science and technology, for instance, grants access to the EU's market in products or services, then it is a FTA in the terms of EU law, and EU law on FTA competences applies.

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<sup>2</sup> Aspects of bio-medical science cooperation may also fall within the EU's R&D policy, and its international development policy. The former relates directly to trade policy, and the latter does not apply to the EU-UK relationship as the UK is not a developing country.

<sup>3</sup> [https://epin.org/wp-content/uploads/2019/02/EPIN\\_wp43-Erlbacher-External-Competences.pdf](https://epin.org/wp-content/uploads/2019/02/EPIN_wp43-Erlbacher-External-Competences.pdf)

<sup>4</sup> Note that, for political reasons, the EU sometimes negotiates agreements as 'mixed agreements' even where legally this would not be required.

<sup>5</sup> See, eg, Steve Peers (2016) The EU's future trade policy starts to take shape: the Opinion on the EU/Singapore FTA. <https://eulawanalysis.blogspot.com/2016/12/the-eus-future-trade-policy-starts-to.html> . Last accessed 11 August 2019.

<sup>6</sup> Opinion 1/17 ('CETA'), EU:C:2019:341

To summarise:

- An EU-UK FTA could lawfully encompass cooperation in bio-medical research
- Those aspects of such a FTA would be within the EU's exclusive competence
- But the FTA as a whole would have to be considered to determine whether *procedurally* each EU Member State would, in effect, have a veto
- *Substantively*, an EU-UK FTA must respect the Treaties, including fundamental rights, and the autonomy of the EU legal order
- An EU-UK FTA could not lawfully give the UK identical access to the EU market as an EU Member State
- An EU-UK FTA could lawfully extend EU standards to the UK
- An EU-UK FTA could lawfully include an institution for dispute settlement.

Note, however, that all of the above rules have been fleshed out by decisions of the CJEU, as well as changing over time as the EU's foundational treaties changes. Neither the procedural nor the substantive aspects of EU competence are static. Rather, they should be understood as dynamic. **The legal constraints on the EU's competence are important: nothing is 'simply a political decision' because of the nature of the EU. But the way those legal constraints are interpreted changes over time, and in response to non-legal (political) situations.**

## 2.2 EU-third country relationships: possible models

The EU has trade agreements with 71 countries.<sup>7</sup> There is evidently a range of options along the spectrum of integration and cooperation within the broad umbrella terms of 'third country relationship', and 'FTA'. An EU-UK FTA could in principle occupy any point on that spectrum.

For those seeking a deeply cooperative relationship, however, the FTA on the European Economic Area offers a particularly useful case study. Outside of EU Membership, the EEA EFTA States (Iceland, Liechtenstein and Norway) have the closest cooperative relationship with the EU, and full access to its internal market.

The Agreement on the European Economic Area has been in force since 1 January 1994. It creates a single market encompassing the EU, Iceland, Liechtenstein and Norway. The Agreement on the EEA gives all entities within that single market equal rights to access the market and imposes equal obligations on them. EU legislation on free movement of products, services, persons and capital applies throughout the EEA single market, including in Iceland, Liechtenstein and Norway. The Agreement covers EU cooperation with those states in related areas, which include research and innovation, and public health.

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<sup>7</sup> European Commission (2019) A balanced and progressive trade policy to harness globalisation. [https://ec.europa.eu/commission/priorities/balanced-and-progressive-trade-policy-harness-globalisation\\_en#background](https://ec.europa.eu/commission/priorities/balanced-and-progressive-trade-policy-harness-globalisation_en#background) Last accessed 11 August 2019.

The Agreement represents a compromise: Iceland, Liechtenstein and Norway agree to apply EU legislation which they do not participate in creating, in exchange for access to the EU's market. Unlike for EU Member States, in Iceland and Norway,<sup>8</sup> measures of EU law have to be implemented domestically: they do not automatically become part of the 'law of the land' (as is the case with the EU doctrine of direct applicability). Moreover, the doctrine of 'primacy' of law (where a piece of national law that is inconsistent with applicable EU law must be 'disapplied' by national courts<sup>9</sup>) does not apply under the EEA. Nor are domestic courts obliged to refer questions of EEA law to the EFTA Court, and if they do ask for an Advisory Opinion from that Court, the Advisory Opinion is not formally binding on domestic courts.<sup>10</sup>

Compliance by the EU Member States with this agreement is secured by the European Commission and CJEU. Compliance by Iceland, Liechtenstein and Norway is secured by the EFTA Surveillance Authority and the EFTA Court. This 'two pillar' or 'twin track' institutional architecture, and especially the independent EFTA Court compensates those countries' restriction of sovereignty.<sup>11</sup> But the EFTA Court is formally obliged to interpret EEA provisions in conformity with rulings of the CJEU before the EEA, and to take account of its rulings thereafter. And domestic courts in Iceland and Norway interpret domestic law consistently with EEA law not because of EEA law obligations, but because they are obliged to do so in domestic law.<sup>13</sup>

At the time the Agreement on the EEA was concluded, it was unprecedented.

Until the EU entered into the EEA, it was not clear that the EU had the competence to do so. This competence was tested before the CJEU, which held that the originally-proposed EEA was, in part, beyond the EU's competence.<sup>14</sup> In particular, the EU had no substantive competence to agree to the originally proposed EEA Court. The EEA Agreement was renegotiated, and the CJEU found that the new arrangements (including an EFTA Court) were within the EU's competence.<sup>15</sup>

As well as offering a model of an existing agreement, which could provide a blueprint for the 'deep and special relationship' the UK seeks with the EU, the EEA also illustrates that events in the non-legal (political) realm *can* forge new paths for the law to follow – as opposed to the law *entirely* constraining the politics.

### 3. Post-Transition EMA-MHRA Relationship: EMA cooperation with third countries and international coalitions

Having explored what can legally be achieved at the UK-EU level, and noting the dynamic nature of EU competence, we now turn to CRUK's questions regarding the possibilities of a future EMA-MHRA relationship at the agency-level. This section considers the extent of the EMA's competence to build cooperative relationships with third country agencies.

Any agency of the EU derives *its* competence from the EU itself.<sup>16</sup> This means that the broader trade agreement between the EU and the respective third country – e.g. post-Brexit UK – is thus fundamental to outlining what agreements can be undertaken at the agency level. The next

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<sup>8</sup> Liechtenstein is different because its constitution means that international legal obligations are automatically part of its domestic law. That is not the case in UK constitutional law.

<sup>9</sup> See *Factortame Ltd v Secretary of State for Transport* [1991] 1 AC 603.

<sup>10</sup> In practice, the threat of proceedings before the EFTA Surveillance Authority means that domestic courts would usually follow the EFTA Court's Advisory Opinions. See further C Franklin, ed, *The Effectiveness and Application of EU and EEA Law in National Courts* (Intersentia 2018).

<sup>11</sup> See further C Baudenbacher, ed, *The Handbook of EEA Law* (Springer 2016).

<sup>12</sup> Article 6 EEA which obliges the EFTA Court to interpret EEA provisions consistently with the relevant CJEU case law prior to signature of the EEA (2 May 1992). Article 3 (2) of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice requires the EFTA Court to 'take due account' of the principles of EU Law laid down in rulings of the CJEU after that date. In practice, the EFTA Court consistently follows the CJEU's approach, even in post-1992 CJEU rulings. See C Franklin, ed, *The Effectiveness and Application of EU and EEA Law in National Courts* (Intersentia 2018), p8-10.

<sup>13</sup> See C Franklin, ed, *The Effectiveness and Application of EU and EEA Law in National Courts* (Intersentia 2018), p16-18; 322-332; 392-408.

<sup>14</sup> Opinion 1/91 ECLI:EU:C:1991:490.

<sup>15</sup> Opinion 1/92 ECLI:EU:C:1992:189. See Barbara Brandtner, 'The Drama of the EEA: comments on Opinions 1/91 and 1/92' (1992) 3 *European Journal of International Law* 300-328 <http://www.ejil.org/pdfs/3/2/2042.pdf>

<sup>16</sup> Case C 9/56 *Meroni* ECLI:EU:C:1958:7.

section will outline this in further detail by considering the EMA's competence to negotiate bilateral agreements with its third country counterparts.

This section addresses the following questions from CRUK:

With a particular interest in the EMA-FDA relationship, what are the legal precedents for cooperation between EMA and third countries? What activities do these cover?

What broader legal requirements must be in place for countries to go beyond third country cooperation with the EMA?

Is there any legal basis for EU Agencies to strike agreements with third country agencies that go beyond existing "third country" provisions on an ad hoc / case-by-case basis?

### 3.1 EMA relationships nested in context of broader EU relationships

To answer these questions, we must first understand the scope of the competences afforded to the EU's institutions and agencies. The foundation for these legal principles was set in the 1958 *Meroni* case,<sup>17</sup> in which the CJEU held that it is not lawful for the European Commission to delegate to another body powers that it does not possess itself.<sup>18</sup> Authors disagree as to how the *Meroni* case applies to modern-day EU agencies.<sup>19</sup> But they agree that EU law imposes legal limitations on agencies' powers, for a range of reasons to do with how the EU works as a constitutional system: accountability of public bodies for their actions, balance of powers between different institutions and bodies, and judicial reviewability of decisions that have legal effects.<sup>20</sup> The ultimate source of those legal limitations is the TEU and TFEU themselves: which we have already noted are subject to dynamic interpretation by the CJEU.

That dynamic interpretation complicates matters somewhat. The CJEU understands the TEU and TFEU as 'living' instruments. At the same time, the Treaty provisions on the EU's external powers have changed over time. This has resulted in a 'legal framework of complexity verging on the byzantine'.<sup>21</sup> The CJEU's interpretation of the EU's founding Treaties follows an approach attentive to its perception of the aims of the EU: ever closer union between the peoples of Europe. Thus, rather than adopting a literalistic approach to the EU's competences and those of its institutions, the CJEU established (in the 1971 'ERTA doctrine'<sup>22</sup>), and the TFEU has now consolidated,<sup>23</sup> the principle that the EU has *implied* competence (in the absence of an express provision in the Treaties) to take *external* acts (involving agreements with 'third countries') where its *internal* powers (for instance, as expressly stated in EU legislation) necessitate such action. 'Necessitates' here is to be strictly interpreted: mere political convenience of external powers would not be enough. Implied external competence can only flow from internal powers where *the only way* to carry out those internal powers involves entering into agreements with third countries.<sup>24</sup> Moreover, the key principle that EU's competence is constrained is confirmed in the *ERTA* doctrine.

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<sup>17</sup> Case C 9/56 *Meroni* ECLI:EU:C:1958:7.

<sup>18</sup> Case C 9/56 *Meroni* ECLI:EU:C:1958:7, para 150 subpara 1 – 151 subpara 2.

<sup>19</sup> Merijn Chamon, 'EU agencies between *Meroni* and *Romano* or the devil and the deep blue sea' (2011) 48 *Common Market Law Review*, Issue 4, pp. 1055–1075 and literature cited therein.

<sup>20</sup> See, eg, Bart Van Vooren and Ramses Wessel, *EU External Relations Law* (Cambridge University Press, 2014); Craig and de Burca, *EU Law* (Oxford University Press, 2015); Panos Koutrakos, *EU International Relations Law* (Hart, 2015); Damien Chalmers, Gareth Davies, Giorgio Monti *European Union Law* (Cambridge University Press, 2019).

<sup>21</sup> Geert de Baere, 'EU external action' in C Barnards and S Peers, eds, *European Union Law* (Oxford University Press 2017).

<sup>22</sup> Case C 22/70 *Commission v Council (European Road Transport Agreement)* ECLI:EU:C:1971:32.

<sup>23</sup> In Article 216 (1) (b) TFEU, to the effect that the EU may conclude an agreement with a third country where 'necessary in order to achieve, within the framework of the Union's policies, one of the objectives referred to in the Treaties, or is provided for in a legally binding Union act ...'

<sup>24</sup> Cases 3, 4 & 6/76 *Kramer and Others* involving EU powers to conserve marine biological resources. This could not be carried out effectively without involving all relevant countries - some of which were not EU MS - hence the CJEU reasoned that the duties to do so of the EU institutions conferred by EU legislation implied a power to enter into agreements with third countries to do so. The CJEU has applied this principle in other cases, and the legal position is now consolidated in Article 216 (1) (b) TFEU.

It follows that **the scope for cooperation between the EMA and third country (non-EU) country agencies is restricted by the EU's powers to enter into agreements with third countries, and the EMA's powers as an EU agency, as interpreted by the CJEU.** Neither the European Commission, nor Council, can confer powers it does not have onto the EMA. As much as Brexit will create major inconveniences, the internal powers that the European Commission has, to establish an internal market for pharmaceuticals and other products, and to secure safety of patients and others within that market, including through regulating bio-medical research, do not *necessitate* agreements with the UK as a third country to the effect that a third country would in effect be part of that internal market. This legal conclusion is echoed in the EU's core guidelines for negotiating Brexit to the effect that a 'non-member of the Union, that does not live up to the same obligations as a member, cannot have the same rights and enjoy the same benefits as a member.'<sup>25</sup>

As we have already seen, the EU is competent to enter into a range of agreements with third countries, either for trade in products and services generally, or in a specific sector, such as science and technology, as desired by the May government<sup>26</sup> but none can lawfully involve as close integration as EU membership itself. Further, a sectoral agreement (such as in science and technology) cannot permit access to the EU's market without being, in the terms of EU competence, a FTA.

### 3.2 The legal bases for an EU-UK Agreement affecting the EMA

The EMA's powers to cooperate with agencies in third countries are limited and must be exercised within the parameters of the broader trade agreements that the EU shares with any third country, or other arrangements that the EU is legally competent to agree.

The key provisions of the TFEU in this regard are:

- Article 216 (1) TFEU: 'The Union may conclude an agreement with one or more third countries ... where the Treaties so provide or where the conclusion of the agreement is necessary in order to achieve, within the framework of the Union's policies, one of the objectives referred to in the Treaties, or is provided for in a legally binding Union act or is likely to affect common rules or alter their scope'
- Articles 206 and 207 TFEU '... the Union shall contribute ... to the harmonious development of world trade, the progressive abolition of restrictions on international trade ... and the lowering of customs and other barriers.
- '... shall be based on the conclusion of tariff and trade agreements relating to trade in goods and services ... the achievement of uniformity in measures of liberalisation ...'
- Articles 179 and 180 TFEU: 'The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely ...
- 'In pursuing these objectives, the Union shall carry out the following activities, ... (b) promotion of cooperation in the field of Union research, technological development and demonstration with third countries ...'
- Article 168 (3) TFEU: 'The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.'

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<sup>25</sup>Council of the European Union (2017) European Council (Art. 50) guidelines for Brexit negotiations.

<https://www.consilium.europa.eu/en/press/press-releases/2017/04/29/euco-brexit-guidelines/> Last accessed 2 August 2019.

<sup>26</sup>UK Government. (July 2018). *The Future Relationship Between the United Kingdom and the European Union* [White Paper]. Last accessed 10 August 2019: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/786626/The\\_Future\\_Relationship\\_between\\_the\\_United\\_Kingdom\\_and\\_the\\_European\\_Union\\_120319.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/786626/The_Future_Relationship_between_the_United_Kingdom_and_the_European_Union_120319.pdf)

Mirroring this, the UK Government expressed an ambition to negotiate a "Science and Innovation Accord" with the EU in its July 2018 Brexit White Paper. This sought to enable 'continued cooperation through joint participation in networks, infrastructure, policies and agencies which are to the UK's and the EU's joint benefit'. It should be emphasised, however, that this was a unilateral expression of the UK Government's hopes as opposed to reflecting the negotiation of an agreement between it and the EU. Moreover, this White Paper is significantly out of date considering the change of government that has taken place since.

Any agreement between the EMA and an entity in a third country must have an underpinning legal power, and this power will be based in the relevant agreement between the EU and the relevant third country. **Even if existing EMA agreements appear to be ‘free standing’, and based solely on political expedience, the nature of EU legal competence means that this is not so.**

### 3.3 EMA-MHRA Relationships: possible models

That said, the EMA's powers to enter into bilateral agreements with third countries encapsulate a broad range of options. These are explored further below. All of these options provide only a limited level of cooperation and recognition, and fall short of the present EMA-MHRA relationship.

After summarising the options, we outline the key differences between the EMA-FDA and EMA-EEA country agencies' relationships, to illustrate the paramount importance of the broader free trade relationship between the EU and respective third country, in understanding the powers available to the EMA in its relations with UK bodies, in a post-Brexit scenario.

#### 3.3.1 Confidentiality arrangements

Agreed via an exchange of letters, confidentiality arrangements enable the exchange of confidential information between the EMA and third countries, including e.g. non-public information on products, safety information (e.g. SUSARs concerning adverse reactions) and GMP and GCP inspection findings. They also provide a framework for regulatory cooperation, with aims to provide market access and increase harmonisation.<sup>27</sup>

There are currently seven confidentiality arrangements in total, with the most recent with Switzerland and the WHO in 2015. Australia, Canada, and the US all also have such agreements in place. They all follow a very similar format and share very similar content, with the odd discrepancy, including how long the arrangement is to be in place prior to review and conditions of termination.

For further insight, we have provided an example of what such a confidentiality arrangement might look like with the UK's MHRA post-Brexit within the annex.

#### 3.3.2 Mutual recognition agreements

Regarding specific aspects of medicines regulation such as Good Manufacturing Practice, mutual recognition agreements (MRAs) essentially aim to allow two respective agencies to use the findings in each other's inspection reports to ground their decision-making.<sup>28</sup> Their scope varies depending on the particular agreement.

Obligations in MRAs are fundamentally different to the mutual recognition of standards embedded in EU law and required of all EU Member States, which sets minimum standards at EU level, allows MS to set higher standards but requires that all Member States recognise each other's standards, subject to proportionate objective public interests.<sup>29</sup> This same principle means that EMA standards must be legally recognised by all EU Member States – including, at present, the UK. A key difference between EU law (the EU's *internal* trade agreement) and its external trade agreements is the direct enforceability of EU law by individual market actors before national courts, and ultimately by reference, before the CJEU. Free movement of goods and services within the EU is predicated on these legal arrangements, which prevent free-riding and rent-seeking. Essentially, the whole of EU economic law is based on a trade-off between efficiency gains of operating within a larger market and loss of regulatory control at national level. EEA law makes similar, though not identical, arrangements.

There are seven MRAs on aspects of medicines regulation presently in place with different countries. Australia, Canada and the USA all have MRAs in addition to confidentiality arrangements.

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<sup>27</sup> European Medicines Agency (2017) International Agreements. <https://www.ema.europa.eu/en/partners-networks/international-activities/international-agreements> . Last accessed 20 July 2019.

<sup>28</sup> European Medicines Agency (2017) Mutual recognition agreements (MRA). <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra> . Last accessed 20 July 2019.

<sup>29</sup> See UK Government guidance here <https://www.gov.uk/guidance/mutual-recognition-regulation-across-the-eea>.

### 3.3.3 'Other cooperation schemes'

This umbrella term encapsulates less 'dense' forms of cooperation or mutual recognition and concerns pharmaceuticals.<sup>30</sup> China, India, and Russia currently have this type of arrangement with the EMA. They vary slightly in scope and form; for example, the agreements with China<sup>31</sup> and India<sup>32</sup> entail that the EMA supports them to implement similar GMP and GCP standards, as well as establishing annual meetings between the parties to facilitate dialogue on pharmaceuticals. In Russia, however, the agreement is limited to a regulatory dialogue subgroup on pharmaceuticals set up in 2007 that is simply used when scientific or technical issues arise.<sup>33</sup> In any case, all existing examples of such schemes illustrate that the level of cooperation and recognition is highly limited.

### 3.3.4 Multilateral international coalitions and initiatives

The EMA participates in a range of multilateral coalitions and initiatives which offer another – albeit less direct and more remote – means for third countries who wish to collaborate in some capacity with the EMA. The most significant examples include:

- the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

The ICH brings regulatory authorities and the pharmaceutical industry together to determine how best to achieve their shared objective of greater global harmonisation of pharmaceuticals. Perhaps its most significant output is the ICH Guidelines. Certain provisions within these must be implemented in order for the respective country/region to become an ICH Regulatory Member.<sup>34</sup> However, it is only an aim that all Guidelines are implemented by all Members – as opposed to mandatory, or in any way legally binding. Thus, while membership does allow some part in contributing to international harmonisation, it is necessarily limited in this respect. However, the ICH does note that membership helps to strengthen relations with other members and 'provides a strong common foundation to develop bilateral regulatory cooperation'.<sup>35</sup> This is evident in some of the EMA's confidentiality arrangements with third country agencies, which refer specifically to the latter's mutual membership in the ICH as reason for increasing their cooperation.

- the Council of Europe's European Directorate for the Quality of Medicines and Health Care (EDQM)

The EDQM's mission is similar to that of the ICH in that it seeks to develop and support the implementation of global quality standards for medicines. It covers areas including 'blood transfusion, organ cell and tissue transplantation and consumer health issues'.<sup>36</sup> Membership gives access to the European Pharmacopoeia Commission sessions and a vote on technical matters.

- the International Pharmaceutical Regulators Programme (IPRP)

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<sup>30</sup> European Medicines Agency (2017) International Agreements. <https://www.ema.europa.eu/en/partners-networks/international-activities/international-agreements> . Last accessed 20 July 2019.

<sup>31</sup> European Medicines Agency (2017) China. <https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/china> Last accessed 20 July 2019.

<sup>32</sup> European Medicines Agency (2017) India. <https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/india> Last accessed 20 July 2019.

<sup>33</sup> European Medicines Agency (2018) Russia. <https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/russia> Last accessed 20 July 2019.

<sup>34</sup> The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2019) ICH Guidelines Implementation. <https://www.ich.org/products/ich-guidelines-implementation.html> Last accessed 20 July 2019.

<sup>35</sup> The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (2017) Value of Membership. <https://www.ich.org/about/value-of-membership.html> . Last accessed 20 July 2019.

<sup>36</sup> European Directorate for the Quality of Medicines (2012) Vision, Mission and Values. <https://www.edqm.eu/en/EDQM-mission-values-604.html> Last accessed 20 July 2019.

The IPRP provides a forum whereby pharmaceutical regulators can exchange information to address issues of mutual concern and advance regulatory cooperation. It includes a variety of working groups. The EMA is involved in eight of these.<sup>37</sup>

The EMA is a member of each of these initiatives (ICH, EDQM, IPRP) because they reflect its ethos and objectives to some extent.

However, it is crucial to emphasise that membership of any of these initiatives would not equate to having a relationship with the EMA that is equivalent to EU membership. While, as outlined above under the ICH, it can offer a gateway to building or sustaining a relationship with the EMA, and ultimately constitute a preliminary step towards a longer term goal of greater cooperation, it cannot promise much more than this.

Thus, while membership of these initiatives has its benefits, in terms of building a cooperative relationship with the EMA, they are quite limited in the context of post-Brexit UK, because of its pre-June 2016 relationship with the EU, unless a significant rupture between the EU and the UK takes place, necessitating a longer term strategy of rebuilding a relationship. That might be the case in the event of a No Deal Brexit.

### 3.3.5 EMA-FDA relationship

The EMA-FDA relationship provides an important case study for two main reasons:

- While the EU and the US have ‘the largest bilateral trade and investment relationship and enjoy the most integrated economic relationship in the world’ as well as agreements<sup>38</sup> and a forum<sup>39</sup> in place to facilitate this, they presently lack an overarching FTA.<sup>40</sup> This will be the case between the EU and the UK in the event of a No Deal Brexit.
- In spite of this lack of overarching FTA, increasing integration has still been pursued between the EMA and FDA.

EMA-FDA cooperation comprises an amalgamation of different agreements, gradually introduced over time in a piecemeal fashion. This highlights a crucial element of this relationship: in the absence of shared standards guaranteed by EU membership, any cooperation is an ongoing trust-building exercise which fluctuates depending on factors including political ones. To allow for this, temporary agreements are not uncommon. Generally, this is how most EMA-FDA agreements begin, albeit with an arrangement implemented to ensure their regular review, renegotiation, and renewal where both parties are happy to continue the particular collaboration. The ongoing nature of this process inevitably entails significant time and resource, such as administration costs.

One such example is an MRA on GMP inspections which had a transition phase spanning November 2017 to July 2019.<sup>41</sup> This included the exchange of information such as scientific advice, GMP and GCP inspection planning and reports, and marketing authorisation procedures. Similarly, the EMA-FDA ‘quality by design’ pilot scheme launched in March 2011 was agreed on the basis of an initial three year period. This was only extended again in April 2014 when the first phase had proved to be a success. Notably, the extension was only for two years. In contrast, the EMA-FDA confidentiality arrangement started under the monitor-and-review structure but,

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<sup>37</sup>European Medicines Agency (2018) International Pharmaceutical Regulators Programme (IPRP). <https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-organisations-initiatives/international-pharmaceutical-regulators-programme-iprp> Last accessed 20 July 2019.

<sup>38</sup>E.g. The Air Transport Agreement approved by Decision 2007/339/EC on the Air Transport Agreement between the EU and its Member States and the United States of America.

<sup>39</sup>The Transatlantic Economic Council.

<sup>40</sup>In April 2019, the European Commission issued a decision stating that the ‘negotiating directives for the Transatlantic Trade and Investment Partnership must be considered obsolete’ in light of the US’s intention to withdraw from the Paris Agreement. It was thus concluded that ‘a more limited agreement covering the elimination of tariffs on industrial products only’ would be pursued instead. See <https://www.consilium.europa.eu/media/39180/st06052-en19.pdf> . Last accessed 20 July 2019.

<sup>41</sup>European Medicines Agency (2015) United States. <https://www.ema.europa.eu/en/partners-networks/international-activities/bilateral-interactions-non-eu-regulators/united-states> Last accessed 20 July 2019.

since being signed again in 2010, remains indefinitely effective with no need for renewal.<sup>42</sup> This allows the two agencies to share information including scientific advice, marketing authorisation procedures, and post-marketing surveillance.

Furthermore, the EMA and FDA have engaged in a range of collaborative activities in the areas of GMP and GCP inspections. These include regular teleconferences, regarding drug shortages due to GMP non-compliance, for example, and issues pertinent to the EMA/FDA GCP initiative. In addition to the substantive aims of these projects, such as reducing duplication of inspections, they also have a secondary purpose: to build understanding between the EMA and FDA. This facilitates their ever increasing cooperation – albeit within the parameters imposed by the broader US-EU relationship and agreements. For these purposes, the ultimately fruitless TTIP negotiations are illustrative. As is the EU's continued emphasis on their 'different regulatory systems, payment methods and market conditions' in the health sector. Nonetheless, the EU and the US have also jointly acknowledged their 'combined market for healthcare of more than 800 million people' and 'similar health problems, i.e. aging population and exploding public health care costs'.<sup>43</sup> This is within the context of Article 168 (3) TFEU which provides for cooperation between the EU and its Member States and third countries in the sphere of public health.<sup>44</sup> In simplified summary then: there is recognition that their overlapping goals and interests mean there is value in collaborative efforts via e.g. the Transatlantic Economic Council, but the failure to agree on key shared standards means that these cooperative efforts have to be restricted.

Logically, therefore it would seem that a combination of a cooperative council model and shared standards would be one possible future basis for securing some regulatory alignment between the EU and UK – without the UK accepting regulatory oversight from EU institutions or shared EU-UK institutions, as is the case in the EU-EEA context. One might argue that, because the two are currently fully aligned, this would be more straightforward than the EMA-FDA equivalent and thus require less time and resource to negotiate and maintain.

However, this does not account for the remaining issue of legal enforceability. It is the absence of CJEU jurisdiction that underpins the EU's safety mechanisms in such arrangements. Where the other party to the agreement is not bound by EU law and jurisprudence, the ability to monitor, review and, where necessary, terminate such arrangements provides a back-up. Thus, unless the UK was willing to abandon its red line on CJEU jurisdiction, submit to the oversight of the EU's legal system, and require its courts to recognise and enforce CJEU jurisprudence, these mechanisms would still be necessary and time and resource costly.

### 3.3.6 EMA-EEA agencies

In contrast to the FDA, the equivalent agencies in the EEA countries<sup>45</sup> enjoy a much greater level of integration and cooperation with the EMA. Indeed, based on the Regulation creating the EMA<sup>46</sup> and the outlining of its collaborative activities,<sup>47</sup> the EU Member States and EEA Member States and their respective medicines regulatory authorities are legally and practically equal in terms of the activities related to medicines licensing of interest to CRUK.

Comprising the European medicines regulatory framework and known as the 'national competent authorities', Norway, Iceland and Liechtenstein all have such an agency performing this role – as do the present 28 EU Member States.<sup>48</sup> No non-EU/EEA third countries have agencies participating in this regulatory framework. The national competent authorities are responsible for authorising medicines, as well as providing members of the EMA's committees, working parties, and assessment teams in the form of European experts.

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<sup>42</sup> See [https://www.ema.europa.eu/en/documents/other/statement-authority-confidentiality-commitment-european-medicines-agency-not-publicly-disclose-non\\_en.pdf](https://www.ema.europa.eu/en/documents/other/statement-authority-confidentiality-commitment-european-medicines-agency-not-publicly-disclose-non_en.pdf) Last accessed 20 July 2019.

<sup>43</sup> Transatlantic Economic Council (29 November 2011) Annexes to the TEC Joint Statement, p. 13. [http://trade.ec.europa.eu/doclib/docs/2011/december/tradoc\\_148391.pdf](http://trade.ec.europa.eu/doclib/docs/2011/december/tradoc_148391.pdf) Last accessed 20 July 2019.

<sup>44</sup> European Union, *Consolidated version of the Treaty on the Functioning of the European Union*, 13 December 2007, 2008/ C115/01.

<sup>45</sup> For present purposes, this refers to EEA Member States that are not also in the EU.

<sup>46</sup> European Medicines Agency (20 ) National competent authorities (human). <https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human> Last accessed 11 August 2019.

<sup>47</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council.

<sup>48</sup> European Medicines Agency (2016) European Medicines Regulatory Network. <https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network> Last accessed 11 August 2019.

This integration is a product of the Agreement on the EEA that underpins the relationship between the EU and Norway, Iceland and Liechtenstein. The EMA would not have the competence to negotiate such a close relationship with a third country agency in the absence of this, or an equivalent, overarching agreement.

### 3.3.7 Switzerland

To date, the EU-27 has been clear that a 'Switzerland-style' 'cherry picked' arrangement will not be available to the UK.<sup>49</sup> The politics of this are obvious: the UK is a significant market and geopolitical power, and while the EU may be able to tolerate a 'non-standard' relationship with Switzerland, this would be much more difficult to sustain with the UK.

In any event, the EMA/Swissmedic relationship does not provide an example of close integration. Swissmedic,<sup>50</sup> Switzerland's pharmaceuticals regulatory agency, has a mutual recognition agreement with the EU,<sup>51</sup> and memorandums of understanding on information exchange with the EU<sup>52</sup> and with several EU Member States.<sup>53</sup> These are significantly less dense cooperative arrangements than the EU has with the EEA states.

### 3.4 EMA-MHRA within the post-Brexit UK-EU relationship: summary

The questions CRUK asked us sought an understanding of the extent of the EMA's competence to enter into agreements with equivalent agencies in third countries. Agreements on the inter-agency level are constrained by EU legal precedent, which dictates that the European Commission may lawfully only confer upon the EMA powers that the European Commission legally possesses.<sup>54</sup> **The EMA-MHRA relationship will thus be determined by the nature of the UK-EU relationship more generally.** This relationship will be embodied in a FTA.

The purpose of a FTA is not agency cooperation: a FTA seeks to promote free trade between the relevant countries/economic entities. Rather, arrangements for agency cooperation follow the entry into a FTA. This is because free trade can only be based on mutual trust in regulatory standards, which requires information sharing, agreed levels of risk/consumer protection and so on. The agency cooperation supports the underlying agreement to open each other's markets to traders in the other party to the FTA.

The EMA-FDA relationship shows what cooperation can be achieved with a third country in the absence of an extensive trade agreement or broader integration, such as in the form of the EEA.

The main advantage of a less integrated relationship is regulatory control for each party to the arrangements for bio-medical research and pharmaceuticals regulation.

The disadvantages are as follows:

- First, the development of the EMA-FDA relationship indicates that one agreement is rarely sufficient to ensure deep integration and, thus, anything remotely close to the level of cooperation the UK currently enjoys as a Member State.
- Second, agreements are piecemeal and can comprise some arrangements that are only temporary.

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<sup>49</sup>The Independent (2018) Brexit: Michel Barnier 'strongly opposes' May's Chequers proposals, warning offer would be end of EU. <https://www.independent.co.uk/news/uk/politics/brexit-michel-barnier-theresa-may-chequers-proposal-no-deal-eu-a8519636.html> Last accessed 2 August 2019.

<sup>50</sup><https://www.swissmedic.ch/swissmedic/en/home.html>

<sup>51</sup>Agreement between the Swiss Confederation and the European Union on the mutual recognition of conformity assessments <https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/international-collaboration/bilateral-collaboration-with-partner-authorities/mutual-recognition-agreements.html>

<sup>52</sup>By exchange of letters in 2015, for an initial period of 5 years, with tacit agreement for renewal for subsequent periods of five years. <https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html>

<sup>53</sup>Ireland, Germany, UK, Austria, Netherlands <https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html>

<sup>54</sup>Case C 9/56 *Meroni* ECLI:EU:C:1958:7, para 150 subpara 1 – 151 subpara 2.

- Third, and partly because of this, agreements lack the clarity, consistency, and certainty that regulatory entities operating in EU/EEA Member States enjoy. In short, there is no such guarantee of on-going extensive cooperation.

The EMA-FDA agreements are products of long processes that ensure there is sufficient trust and understanding between both participants. In this regard, they are only a near-analogy with the EMA-MHRA relationship. Before June 2016, that mutual trust between the EU-27 and the UK was already in place. Depending on the nature of the Brexit negotiations and the broader post-Brexit EU-UK relationship as it unfolds, that mutual trust can be part of the environment in which EMA-MHRA relations are built.

To summarise: the key point is that the third country agreements the EMA undertakes are reflective of the broader relationship between the EU and the respective third country. As the EEA countries demonstrate – particularly in contrast to, e.g., the US's FDA – **there really needs to be a broader overarching FTA with the particular third country to base any relationship that goes “beyond (ordinary) third country” integration with the EMA. The EMA does not possess sufficient competence to negotiate bilateral agreements to ensure the level of cooperation that CRUK is seeking in the absence of such an underpinning trade agreement.** Of course, this presents difficulties in the sense that this will necessitate an agreement that concerns a much wider breadth of areas than those concerning the health and biomedicine sector; while there are strong arguments for integration in this particular field, there is likely to be some political resistance regarding other areas.

Thus, as things stand at present, **the choice for the UK is between the depth of integration (and corresponding loss of regulatory control) implied by a model similar to EEA membership, or the regaining of regulatory control accompanied by a loss of access to the EU market implicit in less dense arrangements.** The current position of the EMA vis a vis regulatory agencies in the EEA states, is reflected in EU-EEA relationship as opposed to a product of EMA negotiations. Indeed, with regard to EMA activities specifically, it is rather a direct product of the establishing Regulation which outlines that it is ‘of EEA relevance’.<sup>55</sup> As such, meaningful consideration of this option necessitates looking at options for the EMA-MHRA relationship via a EU-UK free trade agreement.

A final alternative might be for the UK to instead look to broader global opportunities and seek involvement in multilateral international coalitions and initiatives.<sup>56</sup> A resulting effect may be that, if the MHRA could gain a substantial platform within these forums already occupied by the EMA, it might facilitate a closer cooperation between the two in the future. It must be acknowledged, however, that this would be no easy feat.<sup>57</sup> Indeed, like the option above, it would demand significant time and resource.

#### 4. One overarching agreement with the EMA

This section will address the following questions from the CRUK:

Given the practical barriers in terms of time/resource needed to set up and maintain a number of agreements between the EMA and the respective third country agency, would it be preferable to have one overarching agreement with the EMA?

For the most part, a single (preferably ongoing) agreement to create and refer to is significantly simpler and more accessible in the long term. This would also ensure greater certainty and consistency. However, the reason for the piecemeal approach of the agreements between the EMA and equivalent third country agencies such as the FDA is because there is no overarching agreement between the EU and the respective third country that provides adequate security and consistency of shared standards. As such, by implementing several agreements and placing time limits on them, modification, non-renewal and termination are usually options. These

<sup>55</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council.

<sup>56</sup> Ref section above.1

<sup>57</sup> M Flear, Charting a roadmap towards membership and formal voice in global bioethics standard-setting: Health research and the case of the International Council on Harmonisation (2018) 18(2-3) 157-178 <https://doi.org/10.1177/0968533218804598> Last accessed 2 August 2019.

provide alternative safeguards. Further, this approach is a trust-building exercise in the absence of this certainty.

Thus, while there are significant practical barriers in maintaining a number of agreements, there are also practical and, indeed, legal barriers to having one overarching agreement with the EMA. The crucial point is competence. While the EU has the competence to negotiate extensive FTAs in a large number of areas, the EMA is restricted to the powers it has been endowed with and can only operate within the agreements the EU has negotiated with the respective third countries. This explains the disparity between the EMA's relationship with the FDA and its relationship with EEA member state agencies. The relationship with the latter is built upon the Agreement on the EEA<sup>58</sup> and this underpinning agreement to share certain standards and regulations manages the risk of a cooperative relationship within the health sector.

As such, **whether one overarching agreement is feasible from a legal and regulatory perspective will hinge on the broader relationship between the EU and the UK post transition.**

## 5. Specific Post-Transition EMA Functions and Activities in the UK

Having set out the options for what the broader EMA-MHRA/UK-EU relationship might look like, this final part of the report addresses CRUK's questions regarding the future of two specific aspects of the EMA in the post-Brexit UK: namely, centralised marketing authorisations and access to the Clinical Trials Database. Crucial to and underpinning future collaboration between the MHRA and the EMA, the last section considers the future of UK-to-EU and EU-to-UK data sharing post-transition.

### 5.1 Access to Clinical Trials Regulation database

This section will address the following questions from the CRUK:

Would ECJ jurisdiction be required to access the portal and database associated with the CTR?

Are there existing EU agency databases which third countries have full/partial access to and what is the legal basis for this access?

#### 5.1.1 The Clinical Trials Information System

A new database called the Clinical Trials Information System (CTIS) was set up under the Clinical Trial Regulation EU No. 536/2014.<sup>59</sup> Its predecessor, the EU clinical trial portal and database, was created under Directive 2001/20/EC. It is understood that the latter system is the one presently in use by CRUK in light of ongoing EU-wide issues with the implementation of the CTIS. Thus, two developments are concurrently occurring: the phasing in of the new system and the process of negotiating the UK's exit from the EU. As such, analysing how CRUK's *present* situation will change after December 2020 is of limited value. The forthcoming CTIS and the question of third country access is instead considered.

As confirmed by the EMA's website, the overarching purpose of the CTIS is to provide for '[i]mproved collaboration, information-sharing and decision-making *between and within Member States*' (emphasis added).<sup>60</sup> Thus, access to the secure part of the database is predicated on EU membership.

However, it is acknowledged that, due to third countries' involvement in some clinical trials, it is necessary for them to have some access to this database and the information contained within it. This is known as a sponsor workspace which allows the clinical trial sponsor (that is, the company or organisation which conducts a clinical trial) limited access to enable them to submit data to the system for Member States' assessment. The sponsor workspace allows sponsors to,

<sup>58</sup> The European Free Trade Association, based on the Agreement on the European Economic Area OJ No L 1, 3.1.1994, p. 3.

<sup>59</sup> Council Regulation (EU) No 536/2014 on Clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC of 16 April 2014 OJ 2014 L 158/1.

<sup>60</sup> European Medicines Agency (Last updated 2019) Clinical Trial Regulation. <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation> Last accessed 20 July 2019.

inter alia, 'search and access clinical trials', 'supervise their own clinical trials and check progress', and 'respond to requests for information and view deadlines'.

Moreover, the Regulation outlines the process in cases where clinical trials are carried out between one or more EU Member States and third countries. In these multi-state clinical trials involving the EU, sponsors in third countries must have a legal representative established in the EU somewhere, who is responsible for compliance.<sup>61</sup> That legal representative would have full access to the database so as to comply with EU law obligations. They would be liable for compliance breaches, and subject to EU law and CJEU jurisdiction as established in an EU Member State.

Where a clinical trial is to be conducted solely on one Member State's territory, or on theirs and a third country's, a legal representative as per above is not necessary 'provided that they ensure that the [trial] sponsor establishes at least a contact person on their territory'.<sup>62</sup>

Finally, there is a website that is publicly accessible which includes, for example, an overview of clinical trial statistics, data and reports, and an advanced search.<sup>63</sup> This is a last resort option for UK researchers post-transition assuming no unique access is negotiated, and in the event that the individual is not a sponsor.

### 5.1.2 Other EU agency databases and access conditions

Looking at other EU agency databases, there is no perfectly analogous case study to determine whether it is possible for third countries to ever have equal access to data available to Member States.

There are many examples whereby the agency's database is publicly available – e.g. the EU-OSHA's dangerous substance database,<sup>64</sup> or the EMCDDA's best practice portal and evidence database.<sup>65</sup> The European Institute of Innovation and Technology (EIT) offers one example whereby, although documents are available to all members of the public – within and outside the EU – there is an application process that one must complete before being able to access the respective document(s).<sup>66</sup> In contrast, the European Fisheries Control Agency (EFCA) has a collaboration tool and database called Fishnet in which 'different context areas' can be configured so as to limit access to only certain Member States.<sup>67</sup>

### 5.1.3 Access to CTIS for Post-Transition UK

Open access is a last resort option for UK researchers post-transition assuming no unique access is negotiated, and in the event that the individual is not a sponsor.

Could the EU and UK agree a UK-EU/EMA-MHRA agreement whereby full access to the CTIS is provided to the UK as a non-EEA third country? There is no existing precedent for this. That applies to both the CTIS and other EU agencies. No other EU agency database provides an analogous example. In most cases, because of the competencies and responsibilities of the agency, they start from the point of full public access (either with or without an application process). By contrast, the competencies of the EU in medicines regulation are understood to include a requirement to honour industry secrecy in terms of clinical trial data.<sup>68</sup> This is controversial among some, such as patient groups, but the law has evolved to reflect practices in the pharmaceutical industry, and, it is argued, to support the EU's common research area by

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<sup>61</sup> Clinical Trial Regulation EU No. 536/2014, Article 74 (1).

<sup>62</sup> Clinical Trial Regulation EU No. 536/2014, Article 74 (2).

<sup>63</sup> European Medicines Agency (Last updated 2019) Clinical Trial Regulation. <https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation> Last accessed 20 July 2019.

<sup>64</sup> European Agency for Safety and Health at Work (2018) Practical tools and guidance on dangerous substances. <https://osha.europa.eu/en/themes/dangerous-substances/practical-tools-dangerous-substances> Last accessed 20 July 2019.

<sup>65</sup> European Monitoring Centre for Drugs and Drug Addiction (2010) Best practice portal. [http://www.emcdda.europa.eu/best-practice\\_en](http://www.emcdda.europa.eu/best-practice_en) Last accessed 20 July 2019.

<sup>66</sup> Regulation (EC) No 1049/2001, Article 2(2). See <https://eit.europa.eu/public-access-documents> Last accessed 20 July 2019.

<sup>67</sup> European Fisheries Control Agency (2015) EFCA Fisheries Information System. <https://www.efca.europa.eu/en/content/efca-fisheries-information-system> Last accessed 20 July 2019.

<sup>68</sup> It is untested as to whether this is legally mandated (for instance, in order to protect the 'European Research Area', or whether it is simply a matter of political practice.

allowing the inventors of technological developments to recoup their investments through exclusive IP rights, as well as retaining control over the data they create, for instance through clinical trials. The EFCA's Fishnet offers one precedent whereby varied access is implemented. Its collaborative areas are available to those involved in the particular project. However, only Member States are included within this, so it does not provide an analogy for third countries.

In reality, the varying levels of access available for the CTIS offers the best model to answer this question. Full access is only available to Member States – regardless of their involvement in clinical trials. In contrast, sponsors in third countries only have access to a separate 'sponsor workspace'. Their level of access is restricted and predicated on which clinical trials they sponsor. There is no present option in EU law to grant full or partial access to the database for a whole third country outside the EEA; it is instead on a sort of case-by-case (trial-by-trial) basis. Even then, this is just to a specified 'sponsor workspace', implying that this is a designated area for such third countries as opposed to access to part of the primary database. This is partly due to the limited competence of the EMA, as well as the EU itself. But it is also important to note that, due to the pharmaceutical industry's consistent opposition, persuading the EU/EMA to make clinical trials data open is likely to prove politically impossible. Thus, the "next best" option to full access is the hypothetical scenario whereby a third country sponsor was involved in enough (and sufficiently varying) clinical trials to cumulatively access the entire 'sponsor workspace'. Again, however, the delays in introducing the new system means that we cannot know precisely what amount of information and functions (e.g. in terms of information-sharing) this would entail access to.

Failing that, the last resort option for UK researchers post-transition – assuming no unique access is negotiated, and in the event that the individual is not a sponsor – is simply accessing the very limited public website. In any event, any data sharing would have to comply with the EU's GDPR.<sup>69</sup>

## 5.2 Data sharing and the GDPR

This section will address the following questions from the CRUK:

What measures would be needed for data-sharing between the EMA and MHRA//EU and UK agencies?

What measures would be needed for data-sharing between the MHRA and EU national competent authorities?

What legal underpinnings would need to be in place to allow data sharing on issues like PCV, GMP, and GCP?

The Withdrawal Agreement secures legal continuity for data sharing until the end of transition (currently 31 December 2020).<sup>70</sup> Under the Withdrawal Agreement, the EU is obliged to continue to treat data obtained from the UK before the end of transition the same as data obtained from an EU Member State, or rather, not to treat it differently 'on the sole ground of the UK having withdrawn from the Union'.<sup>71</sup>

After that date, if any data is to flow from the EU to the UK, the EU will have to recognise the UK's regulatory environment as 'adequate', and vice versa. Data sharing without such an adequacy decision, or alternative basis for information flow (see further below), would breach the GDPR, as a provision of EU law (applicable in the EU-27) and 'retained EU law' (applicable in the UK).

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<sup>69</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ 2016 L 119/1.

<sup>70</sup> WA, Article 126.

<sup>71</sup> WA, Article 73.

In terms of data flow *from* the UK to the EU, as ‘retained EU law’, the GDPR will in principle be part of UK law in January 2021, under the terms of the EU (Withdrawal) Act 2018. However, the GDPR will be subject to amendments adopted on the basis of powers in the EU (Withdrawal) Act 2018, as well as the Data Protection Act 2018 and the European Communities Act 1972. These amendments will take effect through secondary legislation: the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019,<sup>72</sup> and any subsequent secondary legislation. The majority of the changes to the existing law involve removing references to EU institutions and procedures that will not be directly relevant when the UK is outside the EU. But the Regulations do make some changes to the legal position beyond removing references to the EU and its institutions and procedures.

The key issue of relevance to CRUK, however, is the different bases for information flow to and from third countries set out in Articles 45 through 49 of the GDPR and Sections 18 and 74 through 76 of the DPA 2018. These are outlined below.

- Adequacy decisions
- Appropriate safeguards, including standard data protection contractual clauses
- Special circumstances/derogations

#### a) Adequacy decisions

**Data flow from the UK to the EU.** The EU Exit Regulations add new sections 17A and 17B, and 74A to the Data Protection Act 2018. These give the Secretary of State power to adopt adequacy decisions by regulations, and oblige the Secretary of State to keep such decisions under periodic review. An adequacy decision may be taken in respect of a third country (which in this context, contrary to its meaning in EU and international law, means a country outside of the UK<sup>73</sup>); a territory or one or more sectors within a third country; an international organisation (such as the EU); or a description of such a country, territory, sector or organisation. Transfer of personal data from the UK to such a country, territory, sector or organisation would not be lawful in the absence of an adequacy decision, or other basis for lawful transfer, such as ‘standard data protection clauses’, or ‘special circumstances’ (see below).

When assessing the adequacy of protection in a third state or international organisation, the Secretary of State must take into account a list of factors outlined in new section 74A of the Data Protection Act. These are for things like whether the state or entity (the EU in this case) receiving data from the UK respects human rights, has a robust data protection environment, and adequate dispute-resolution mechanisms in the event of a breach. The Secretary of State must monitor developments in such third countries, sectors etc, and amend or revoke adequacy decisions accordingly, having given the country etc the opportunity to remedy any lack of protection. In addition, each adequacy decision must be reviewed at least once every 4 years.<sup>74</sup>

The UK government’s guidance explains that the UK ‘will transitionally recognise all EEA countries (including EU Member States) and Gibraltar as “adequate” to allow data flows from the UK to Europe to continue,’ and ‘preserve the effect of existing EU adequacy decisions,’ including the EU-US Privacy Shield, on a transitional basis.<sup>75</sup> The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) (No. 2), Regulations 2019, schedule 2, article 102, inserting a new Schedule 21 into the UK GDPR provides that all EEA states (which of course include all EU27 Member States), Gibraltar, EU and EEA institutions, and all the third countries, territories, sectors or international organisations which the EU recognises with adequacy clauses (Switzerland, Canada, Argentina, Guernsey, Isle of Man, Jersey, Faroe Isles, Andorra, Israel, Uruguay, New Zealand, and the USA) are regarded as countries etc which the UK recognises as having an adequate level of protection for personal data transferred from the UK into that country.

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<sup>72</sup> SI No 419 28 February 2019.

<sup>73</sup> New provision in Article 4 GDPR, after para 26.

<sup>74</sup> Data Protection Act 2018, new Sections 17B and 74B.

<sup>75</sup> Department for Digital, Culture, Media & Sport (updated 11 April 2019) Amendments to UK data protection law in the event the UK leaves the EU without a deal. (UK Government, Guidance Note) <https://www.gov.uk/government/publications/data-protection-law-eu-exit/amendments-to-uk-data-protection-law-in-the-event-the-uk-leaves-the-eu-without-a-deal-on-29-march-2019> Last accessed 18 June 2019.

**Data flow from the EU to the UK.** Obviously the UK's EU Exit Regulations can make no provision for the transfer of personal data into the UK from another country. Non-EU countries will each need to decide how to treat the UK as a non-EU Member State, when, up to Exit Day, they have been recognising the UK's treatment of personal data as adequate because the UK is an EU Member State. It was reported in April 2019 that some countries have indicated that they will continue to allow free data flow into the UK, even in the event of a No Deal Brexit.<sup>76</sup> These include Switzerland, Israel, and the USA. The legal source of these permissions is domestic law within each third country.

Transfer of personal data from EU Member States into the UK post-transition remains subject to EU law; the UK's unilateral adequacy decision is irrelevant to data flowing from the EU to the UK. In the absence of any other provision being in place (but see further below in terms of other bases for lawful data sharing), for data being shared from the EU to the UK, the UK will be treated as a 'third country' in the terms of the GDPR. This will mean that transfer of data to the UK will in principle be unlawful, unless there is a lawful basis for that transfer as provided for under the GDPR.

The GDPR provides that the Commission may decide that a third country, or one or more specified sectors in that third country, ensures an adequate level of protection of personal data. Transfer of personal data from the EU to a country or sector within a country that is subject to such an adequacy decision is lawful under the GDPR without any further specific authorisation.<sup>77</sup> The UK is a 'third country', but its law, up until the end of transition, will have been (at least presumptively) compliant with EU data protection law. Indeed, under the EU (Withdrawal) Act 2018, the GDPR will become 'retained EU law', a part of the law of the UK. An adequacy decision seems the logical and practical approach.

The EU has signalled that it would like to take an adequacy decision for the UK during transition, so long as to do so will be to fully respect the EU's data protection law.<sup>78</sup> Adequacy decisions are formal acts, taken by the Commission, assisted by a committee and according to a specified procedure,<sup>79</sup> lasting for a period of up to 4 years, at which point they are reviewed.<sup>80</sup> The GDPR sets the procedures through which adequacy decisions must be taken, and the EU institutions are not competent to depart from those procedures. To do so would be *ultra vires*.

It is not yet clear what the EU's position will be on data transfer into the UK from the EU in the event that no EU-UK agreement that respects EU data protection law has been reached. On duly justified imperative grounds of urgency, there is a power to adopt immediately applicable implementing acts *revoking or withdrawing* adequacy decisions.<sup>81</sup> Failure to reach an EU-UK agreement might constitute such a ground of urgency, if the UK's regulatory arrangements post-transition involved significant regulatory drift from EU data protection law.

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<sup>72</sup> SI No 419 28 February 2019.

<sup>73</sup> New provision in Article 4 GDPR, after para 26.

<sup>74</sup> Data Protection Act 2018, new Sections 17B and 74B.

<sup>75</sup> Department for Digital, Culture, Media & Sport (updated 11 April 2019) Amendments to UK data protection law in the event the UK leaves the EU without a deal. (UK Government, Guidance Note) <https://www.gov.uk/government/publications/data-protection-law-eu-exit/amendments-to-uk-data-protection-law-in-the-event-the-uk-leaves-the-eu-without-a-deal-on-29-march-2019> Last accessed 18 June 2019.

<sup>76</sup> Linkomies L (April 2019) UK Secures post-Brexit data flow deals with nine countries. Privacy Laws & Business International Report 8-9.

<sup>77</sup> GDPR, Article 45 (1).

<sup>78</sup> For example, see European Commission's Recommendation for a Council Decision authorising the opening of negotiations for a new partnership with the United Kingdom of Great Britain and Northern Ireland COM(2020) 35 final, 3 February 2020, para 12.

<sup>79</sup> GDPR, Article 93 (2), Regulation (EU) No 182/2011, Article 5.

<sup>80</sup> GDPR, Article 45 (3).

<sup>81</sup> GDPR, Article 45 (5); Article 93(3).

To our knowledge, there is no formal statement from the EU on its likely position on data adequacy in the event of no EU-UK agreement at the end of transition. However, we might extrapolate from the European Data Protection Board's February 2019 note regarding Brexit without a Withdrawal Agreement. That statement outlines that the UK will be treated as a third country and 'the transfer of personal data to the UK has to be based on one of the following instruments' at the point of exit:

- Standard or ad hoc Data Protection Clauses
- Binding Corporate Rules
- Codes of Conduct and Certification Mechanisms
- Derogations<sup>82</sup>

An adequacy decision is not presented as an option under the listed bases of lawful transfer of personal data to the UK in the event of Brexit without a Withdrawal Agreement. This might also be the case in the event of No Deal at the end of transition. In short, adequacy decisions are not suitable for the immediate legal ruptures implied by No Deal Brexit: to adopt an adequacy decision would be, in effect, to create a (partial) 'Deal', and would thus undermine the EU's negotiating position.

#### **b) 'Appropriate safeguards': Standard data protection contractual clauses**

In the absence of an adequacy decision, transfer may take place where 'appropriate safeguards' are provided. One such appropriate safeguard is the use of standard contractual clauses. Article 57 of the GDPR provides for each supervisory authority to create standard contractual clauses, which businesses can use in their agreements for data processing and transfer.

**Data flow from the UK to the EU.** The EU Exit Regulations 2019 purport to offer some level of legal continuity, as they amend the Data Protection Act to provide that standard contractual clauses that are authorised before Exit Day will remain valid.<sup>83</sup> It will therefore be possible for UK-based organisations, like CRUK, that currently transfer data to other organisations based in other countries, on the basis of standard data protection contractual clauses to continue to do so. Post-Brexit, standard contractual clauses become known as 'standard data protection clauses' in UK law.<sup>84</sup>

Schedule 2 of the EU Exit Regulations adds new sections 17C and 119A to the Data Protection Act. These provisions address standard data protection clauses. Such clauses are those which the Secretary of State considers provide appropriate safeguards for transfers of data to a third country or international organisation, in accordance with new sections 17A and 17B. Schedule 3 of the Regulations revokes existing EU law (that otherwise would become retained EU law) which provides for standard contractual clauses.<sup>85</sup> To replace this, the Information Commissioner is empowered, in consultation with the Secretary of State, and any other stakeholders the

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<sup>82</sup> European Data Protection Board, *Information note on data transfers under the GDPR in the event of a No Deal Brexit*, 12 February 2019, [https://edpb.europa.eu/sites/edpb/files/files/file1/edpb-2019-02-12-infonote-nodeal-brexit\\_en.pdf](https://edpb.europa.eu/sites/edpb/files/files/file1/edpb-2019-02-12-infonote-nodeal-brexit_en.pdf) accessed 19 June 2019.

<sup>83</sup> Data Protection Act 2018, new Schedule 21, sections 7, 8 and 9, added by Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 [http://www.legislation.gov.uk/uksi/2019/419/pdfs/ukxi\\_20190419\\_en.pdf](http://www.legislation.gov.uk/uksi/2019/419/pdfs/ukxi_20190419_en.pdf) Last accessed 19 June 2019. Presumably this will eventually be amended so that it applies to standard contractual clauses authorised before the end of transition.

<sup>84</sup> Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 [http://www.legislation.gov.uk/uksi/2019/419/pdfs/ukxi\\_20190419\\_en.pdf](http://www.legislation.gov.uk/uksi/2019/419/pdfs/ukxi_20190419_en.pdf) Last accessed 19 June 2019, Schedule 1 of Regulation 3, section 39.

<sup>85</sup> Commission Decision 2001/497/EC of 15th June 2001 on standard contractual clauses for the transfer of personal data to third countries, under Directive 95/46/EC OJ 2001 L 181/19;... (g) Commission Decision 2004/915/EC of 27th December 2004 amending Decision 2001/497/EC as regards the introduction of an alternative set of standard contractual clauses for the transfer of personal data to third countries OJ 2004 L 385/74; (i) Commission Decision 2010/87/EU of 5th February 2010 on standard contractual clauses for the transfer of personal data to processors established in third countries under Directive 95/46/EC of the European Parliament and of the Council OJ 2010 L 344/100;... and (q) Commission Implementing Decision (EU) 2016/2297 of 16th December 2016 amending Decisions 2001/497/EC and 2010/87/EU on standard contractual clauses for the transfer of personal data to third countries and to processors established in such countries, under Directive 95/46/EC of the European Parliament and of the Council OJ 2016 L 344/100.

Commissioner considers appropriate,<sup>86</sup> to specify ‘standard data protection clauses’ which are sufficient to provide adequate safeguards for the purposes of transfer of data to a third country or international organisation,<sup>87</sup> and also to amend or withdraw such standard clauses.<sup>88</sup> Documents issued by the Commissioner specifying standard data protection clauses are subject to a negative Parliamentary assent procedure.<sup>89</sup> For UK-based organisations, like CRUK, wishing to continue to conduct data transfers of UK citizens’ data and other data they hold, to organisations based in other countries, standard data protection contractual clauses are a potential basis for lawful transfer of data post-Brexit.

**Data flow from the EU to the UK.** Again, as with adequacy decisions, the UK’s EU Exit Regulations can make no provision for the post-Brexit transfer of data *from* EU-based entities, or those based in other countries, *to* UK-based organisations like CRUK. There is (as yet) no agreement on coordination or mutual recognition of such clauses between the UK and the EU, and in any event the nature of these clauses is currently the subject of litigation before the CJEU. Case C-311/18 *Schrems II* was referred to the CJEU for a preliminary ruling by the Irish High Court,<sup>90</sup> and the Irish Supreme Court has upheld that decision.<sup>91</sup> The hearing began on 9 July 2019 and the AG’s (advisory) Opinion was delivered on 19 December 2019.<sup>92</sup> The judgment is not due until Spring 2020.

One of the key questions of contention is the consistency of standard contractual clauses with the requirements under EU law for data subjects to access effective remedies for violations of their rights. An important element of standard contractual clauses as a basis for lawful data transfer under the GDPR is that the contract gives data subjects specific rights, even though the data subject is not a party to the contract. These questions engage application of both the GDPR’s requirements and those of the EU Charter of Fundamental Rights, Articles 7 (privacy); 8 (data protection) and 47 (right to an effective judicial remedy).

Here the UK’s amendments to the GDPR, as ‘retained EU law’, through the relevant EU Exit Regulations are important. Will the UK arrangements for remedies and enforcement suffice to secure adequate protection from the point of view of the EU? Bear in mind, first, that the EU Exit Regulations remove all obligations on the UK, or entities within the UK, to cooperate within the structures of the EU, or to exchange information with the European Commission, including in matters of enforcement. Further, and this would have been more serious in the event of a No Withdrawal Agreement Brexit, the EU Exit Regulations,<sup>93</sup> the amended Data Protection Act,<sup>94</sup> and the European Union (Withdrawal) Act,<sup>95</sup> all seek to prevent future developments of EU law that arise through interpretations of the CJEU becoming applicable in the UK. *Schrems II* will be decided after Exit Day, but is likely to be decided during transition. Under the Withdrawal Agreement, any principles of EU law deriving from that decision will thus be applied in the UK, and data subjects in the UK will be able to rely on those principles in seeking to remedy any breaches of their data protection rights. If the CJEU upholds its Advocate General, standard contractual clauses will continue to be recognised as a lawful mechanism for transfer of personal data from the EU to a ‘third country’, although the Opinion can be read as imposing an obligation on users of standard contractual clauses to check the consistency of the regulatory environment in the third country to which data is to be sent. It is not clear whether the CJEU will follow its Advocate General (although it usually does, it is not a foregone conclusion).

In view of those concerns, it may be preferable for the health research sector to move expeditiously to adopt a sector-specific code of conduct, and have this code approved under Article 40 of the GDPR. Such a code of conduct would provide a lawful basis for transfer of data

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<sup>86</sup> Data Protection Act 2018, new section 119A (4).

<sup>87</sup> Data Protection Act 2018, new section 119A (1).

<sup>88</sup> Data Protection Act 2018, new section 119A (2).

<sup>89</sup> Data Protection Act 2018, new section 119A (6). Under the negative Parliamentary assent procedure, a statutory instrument laid before Parliament becomes law on the day the Minister signs it, and automatically remains law unless a motion to reject it is agreed by either the House of Commons or the House of Lords within 40 sitting days. See <https://www.parliament.uk/site-information/glossary/negative-procedure/> Last accessed 20 June 2019.

<sup>90</sup> [2017] IEHC 545.

<sup>91</sup> [2019] IESC 46.

<sup>92</sup> ECLI:EU:C:2019:1145.

<sup>93</sup> Regulation 5 (3).

<sup>94</sup> DPA, section 205.

<sup>95</sup> EU (Withdrawal) Act 2018, section 4.

to relevant UK-based organisations from the EU in a No Deal Brexit scenario. Another possibility is that EU-based bio-medical research organisations transfer data to UK-based bio-medical research organisations on the basis of ‘special circumstances.’ This is explored below.

In any case, the ICO has, despite the question marks surrounding *Schrems II*, produced an interactive tool for organisations to deal with standard contractual clauses if the UK does leave the EU without a deal.<sup>96</sup> The ICO recommends that organisations that need ‘to maintain the free flow of personal data into the UK from Europe, in the event the UK exits the EU without a deal... should consider using standard contract clauses.’<sup>97</sup> But the ICO can only account for movement of data *out* of the UK, not *into* the UK. To write of ‘free flow’ of data, as the ICO’s recommendations do, is to misrepresent the formal legal position.

### c) Special circumstances/derogations

**Data flow from the UK to the EU.** Alternatively, it is permissible for a UK-based organisation to transfer data to a third country on the basis of special circumstances.<sup>98</sup> The most relevant circumstances that could be relied upon in the context of on-going clinical trials are those set out in DPA, section 76(1) (a) and (b), which allow for transfer in order to ‘protect the vital interests of the data subject or another person’ or ‘to safeguard the legitimate interests of the data subject.’

Corresponding to Article 49(1)(d) of the GDPR, section 18(1) of the DPA 2018 provides that the Secretary of State is empowered to specify ‘circumstances in which a transfer of personal data to a third country’ is ‘necessary for important reasons of public interest.’

**Data flow from the EU to the UK.** The GDPR permits derogations from the requirement for an adequacy decision or appropriate safeguards.<sup>99</sup> These may offer the most appropriate basis for lawful transfer of data from the EU to the UK following No Deal Brexit where data is being shared in the context of an on-going clinical trial.

If the patient (data subject) gives explicit consent for transfer of their personal data to the UK, transfer is lawful under Article 49 (1) (a) GDPR. Of course, such explicit consent may not be feasible in the context of CTs, and involves additional administrative and bureaucratic burdens.

Even if consent cannot be secured, it could be argued that a patient (data subject) already enrolled in that trial, and who perhaps cannot access any other licensed treatment for their condition, would need to secure continued data transfer ‘for important reasons of public interest.’<sup>100</sup> The GDPR outlines that ‘scientific research purposes’ include ‘studies conducted in the public interest in the area of public health.’<sup>101</sup> Thus, organisations seeking to transfer data relevant to this context could potentially rely on the derogation found in Article 49(1)(d) of the GDPR: where ‘the transfer is necessary for important reasons of public interest.’

## 5.3 MHRA as reporting MS for CT applications and lead assessor for MAs

This section will address the following questions from the CRUK:

What would be legally required to allow the MHRA to act as a reporting member state in clinical trials applications?

What would be required legally to allow the MHRA to act as Lead Assessor in applications for market authorisations submitted under the EMA’s centralised procedure after Brexit?

<sup>96</sup> ICO (2019) *Do I need to use standard contractual clauses (SCCs) for transfers from the EEA to the UK (if we leave the EU with no deal)?* <https://ico.org.uk/for-organisations/data-protection-and-brexit/standard-contractual-clauses-for-transfers-from-the-eea-to-the-uk/interactive-tool/> Last accessed 18 June 2019.

<sup>97</sup> ICO (2019) *How to transfer data from Europe (from the EEA) to the UK using standard contractual clauses (SCCs)* <https://ico.org.uk/for-organisations/data-protection-and-brexit/how-to-transfer-data-from-europe-from-the-eea-to-the-uk-using-standard-contractual-clauses-sccs/> Last accessed 18 June 2019.

<sup>98</sup> GDPR, Article 49; DPA, section 75.

<sup>99</sup> GDPR, Article 49.

<sup>100</sup> GDPR, Article 49 (1) (d).

<sup>101</sup> Para. 159 of GDPR preamble.

As per Article 128 (6) of the Withdrawal Agreement,<sup>102</sup> the UK is explicitly excluded from acting as lead authority in 'risk assessments, examinations, approvals or authorisations' from Exit Day. Logically, because they fall within the scope of 'risk assessments, examinations, approvals or authorisations', this includes CT applications and marketing authorisations for pharmaceuticals.

Article 5 of the Clinical Trial Regulation EU No. 536/2014 refers specifically to the 'reporting Member State' and sets out the process whereby this Member State is selected including, under Article 5 (1), where 'there is no Member State concerned willing to be the reporting Member State'. Thus, the Regulation indicates that there is no legal basis – as well as no precedent – for this 'reporting Member State' to be a non-Member State. (To be clear, 'Member State' here includes non-EU EEA Member States as the Regulation is 'with EEA relevance'.) Of course, the EU could change this Regulation but the ordinary revision procedure would be necessary to any amendment. Given that this requires both the European Council and European Parliament's agreement – and both may amend any proposals, with an opportunity for second amendments if an agreement cannot be reached - this can be a lengthy process.

Furthermore, as part of its efforts to prepare for Brexit, the EMA redistributed any products originally placed with marketing authorisation holders in the UK to the EU-27, Iceland, and Norway.<sup>103</sup> Cut-off dates for UK (co)-rapporteurships were also published in April 2018.<sup>104</sup> In addition to the lacking precedent of a third country undertaking such a role in marketing authorisations, these steps indicate that **a non-Member State/EEA State cannot be the lead assessor for marketing authorisations purposes and that the EU intends to treat the UK as a non-Member State/EEA for these purposes.** Of course, if the UK were to agree a FTA modelled on the EEA with the EU, the UK could potentially be treated as equivalent to an EEA State for these purposes, under the terms of that FTA.

#### 5.4 Application of EMA MAs in UK

This section will address the following questions from the CRUK:

What legal actions could the UK take to ensure EMA centralised marketing authorisations automatically apply in the UK? Could this be done unilaterally?

Where a centralised marketing authorisation is granted by the European Commission, it is valid in all EU and EEA Member States. Liechtenstein initially seems a possible analogous case, as it has a law that ensures automatic application of all EMA decisions.<sup>105</sup> However, it is important to note that EEA countries must transpose legally binding acts from the EU. As such, this was simply the means of legal transposition that Liechtenstein opted for and seems to essentially improve the speed and efficiency of an inevitable outcome by nature of their EEA membership. This context differs significantly from the UK.

**There is no legal barrier to the UK unilaterally recognising EMA MAs.** Potentially, it could even do so under the empowering provisions of the EU (Withdrawal) Act 2018, but that could be subject to legal challenge.<sup>106</sup> However, as already established, the UK will no longer be able to engage as (co)-rapporteur for new MA applications via the centralised procedure. Questions therefore arise as to how politically viable this legal route is.

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<sup>105</sup> Possibly implicit here: [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure\\_en-0.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure_en-0.pdf) p 13-14 which sets out the procedures for Norway and Iceland but is silent on Liechtenstein, merely noting that EMA CMAs apply.

<sup>106</sup> The EU (Withdrawal) Act 2018 permits changes to 'retained EU law' so as to deal with 'deficiencies' in UK law. Given that the MHRA can make marketing authorisation decisions, it is not clear that automatic recognition of EMA marketing authorisations would constitute an enactment remedying a 'deficiency'.

## 6. Conclusion

The future of the EMA-MHRA relationship post-transition will largely hinge on the broader relationship between the EU and the UK. Cooperation between agencies such as EMA and MHRA follows agreements between countries/entities to open their markets to each other, because free trade is based on mutual trust in regulatory standards, and agency cooperation builds and sustains such mutual trust. The level of cooperation and integration of regulatory standards at this level determines the parameters in which the EMA can negotiate agreements with the MHRA. It will not be lawfully feasible for bespoke piecemeal agreements to replicate the UK's position as an EU Member State: not in this policy area any more than in any other.

The EU has been clear in its negotiating principles for the EU-UK Withdrawal Agreement<sup>107</sup> that:

“Preserving the integrity of the Single Market excludes participation based on a sector-by-sector approach. A non-member of the Union, that does not live up to the same obligations as a member, cannot have the same rights and enjoy the same benefits as a member. In this context, the European Council welcomes the recognition by the British Government that the four freedoms of the Single Market are indivisible and that there can be no ‘cherry picking.’”

Some of these principles will apply to the future EU-UK (free trade) relationship(s). For instance, as a non-EU Member State, the UK will not be able to have the same rights or enjoy the same benefits as a Member State. The European Commission's proposed negotiating directives<sup>108</sup> state that:

“The envisaged partnership between the Union and the United Kingdom should be based on and refer, *inter alia*, to the following underlying principles and key objectives ... – reflect the United Kingdom's status as a non-Schengen third country, and that a non-member of the Union, that is not subject to the same obligations as a member, cannot have the same rights and enjoy the same benefits as a member.”

To agree otherwise would be to undermine the very fabric of the EU's legal order, and the autonomy of EU law, and is therefore not within the EU's legal competence.

But there are at present no *legal* barriers to future EU-UK relationship(s) that divide the internal market by sector: indeed many of the EU's trade relationships in the past covered, for instance, trade in goods but not services or capital, and many still differentiate between mutual access to markets depending on the specific economic sector concerned. Of course, the trade-off is the complexity of the EU-UK FTA(s), with corresponding time it/they take(s) to negotiate, and partiality of market access.

Options for cooperation between the EMA and third country agencies exist in the absence of extensive trade agreements. But these will not offer the same level of cooperative relationship as those enjoyed within the context of deeper FTAs. The UK is a ‘third country’, with all that entails, across all the options for the post-Brexit UK and its agencies and institutions including the MHRA. There is always a trade-off between sacrificing closer cooperation for regulatory control, or sacrificing regulatory control for closer cooperation. If shared standards and deep collaboration is the preferred outcome, the UK must look to models such as the EEA Agreement for inspiration.

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<sup>107</sup> <https://www.consilium.europa.eu/media/21763/29-euco-art50-guidelinesen.pdf> accessed 24 September 2019.

<sup>108</sup> European Commission's Recommendation for a Council Decision authorising the opening of negotiations for a new partnership with the United Kingdom of Great Britain and Northern Ireland COM(2020) 35 final, 3 February 2020, para 10.

## Annex

The MHRA on the one side the European Commission's Directorate General Enterprise and Industry and the European Medicines Agency (EMA) on the other side (collectively "the Participants") have identified a need to increase their technical and scientific cooperation as means to better protect health and facilitate the access to safe and high quality health products.

It is also our view that there is already considerable experience in the field of regulatory and administrative cooperation between the Participants in the pharmaceutical sector due to the UK's former membership of the EU and the cooperative relationship between the MHRA and EMA established therein.

The success of existing regulatory cooperative measures concerning the harmonisation of certain technical requirements has led to the desire from both sides to increase the range of information that can be shared in the interest of enhanced regulatory cooperation.

In this context, the Participants see value in establishing an arrangement to enhance the exchange of regulatory information, including draft regulatory guidance as well as information related to the authorisation and supervision of medicinal products for human and animal use. Because this type of information may include information of a non-public nature, both sides agree, to the extent permitted by their respective laws, to keep the information exchanged confidential.

The potential benefits of this exercise are expected to include e.g. improved performance and safety as a result of the involvement of the best regulatory expertise from both sides and resource savings due to reduced duplication of assessment. This cooperation shall not compromise each Participant's ability to carry out its responsibilities and shall not create any kind of legal obligation on the part of the Participants.

Therefore the European Commission and the EMA are pleased to cooperate with the MHRA to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal products for human and veterinary use, authorised or under review both in the UK and in the European Union (EU).

This arrangement covers medicinal products (as defined under Article 1 of Directive 2001/83/EC) for either human or animal use regulated by the Participants. In the context of this arrangement, the term 'medicinal product authorised in the European Union' refers to products subject to evaluation or authorised under the centralised procedure as well as medicinal products authorised at national level by the EU Member States that are subject to official European Community arbitration and referrals.

This cooperation activity will strengthen communication between public authorities involved in these activities and reinforce public health protection.

The type of information that may be shared includes, but is not limited to:

All legislation and guidance documents available under the rules and regulations governing medicinal products in the EU (<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/index.htm> ). This also includes all position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.

Post-authorisation pharmacovigilance data, particularly those of an urgent nature related to EU or non-EU originating adverse drug reactions as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.

Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and applications for agreement of paediatric investigation plans.

Good Clinical Practices (GCP) inspections for specific products and GCP Inspection reports available to the EMEA or the European Commission.

Information Technology systems supporting regulatory processes.<sup>109</sup>

At the EMEA, the information may be shared with national experts on secondment from the EU Member States, EEA countries, or EU candidate countries. These individuals will be required to sign a confidentiality undertaking with the EMEA.

The Participants reserve the right to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of the EU or the protection of the European Commission or the EMEA's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the companies concerned.

Participants note that it is an essential element of this international arrangement on regulatory cooperation that confidential information emanating from the other Participant will be treated as such.

On each occasion where there is a request for disclosure to third parties of non-public information received from the European Commission or the EMEA, the MHRA shall consult with the European Commission or the EMEA. Likewise, on each occasion where there is a request for disclosure of non-public information received from the MHRA, the European Commission or the EMEA shall consult with the MHRA.

The European Commission and the EMEA affirm that they have the authority to protect non-public information, including confidential commercial information, provided to their officials or representatives by the MHRA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001. The European Commission and the EMEA understand that the MHRA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between the Participants. For the purpose of this arrangement, sharing of information between the MHRA and its experts shall not be deemed as public disclosure. The MHRA affirms that they have the authority to protect non-public information, including confidential commercial information, provided to their experts by the EMEA, and that MHRA's experts can be prevented from unauthorised use and release of such information to any other party.

This arrangement is concluded for a period of NN years after which we will assess its effectiveness.<sup>110</sup>

The European Commission and the EMEA should be obliged if the MHRA would acknowledge the receipt of this letter and confirm that this letter and your reply constitute the arrangement set out above between our services.

We look forward to implementing this arrangement allowing for the sharing of non-public information and to continuing cooperative activities to further enhance the relationship between the MHRA, the European Commission, and the EMEA in the best interests of public health.

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<sup>110</sup> This example is taken from Health Canada's Confidentiality Arrangement. An alternative example is found in the EMA's Confidentiality Arrangement with Therapeutic Goods Administration (TGA) of the Australian Government Department of Health and Ageing: 'The arrangement can be varied via an exchange of letters and may be terminated on thirty days written notice by one Participant to the other.'

