Parliamentary Briefing

Draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2019
Draft Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019
House of Lords – 7 March 2019

UK BioIndustry Association

Overarching comments and recommendations

- **BIA supports the approval of these Statutory Instruments as they are essential for UK patients. Although these regulations are needed for a no-deal Day 1 Brexit they will adversely impact UK industry and patients, therefore BIA would like Government to commit in Parliament to a review of these regulations in the next months after Exit day.**
- BIA recognises the MHRA's consultation and ongoing engagement on both regulations.
- Despite the expertise and efforts of the MHRA, BIA is concerned that with 22 days (on 7 March) until Brexit, being prepared for a "no deal" is an impossible task – not only does the MHRA have a huge amount of detail and system change to deliver, but companies (including SMEs with less resource) need to understand and implement new guidance and systems.
- Additional red tape and costs have already taken funding and resource away from research & development, and the draft impact assessment shows that this will continue.
- Regulatory cooperation between the MHRA and EMA is clearly in the best interests of industry, patients and public health both in the UK and EU – and UK government should seek this whether there is a Brexit deal or not.

Draft Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

- In the event of no deal there will be an impact on industry that could have a knock-on impact on maintaining R&D activities in the UK.
- Section 18 of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 will add another layer of red tape and is a step back from Government assurances.
- Specifically, **industry does not understand the need for the requirement for an additional UK-based quality assurance system to verify QP certification of investigational medicinal products (IMPs) imported from EU/EEA countries on the approved country list given that the clinical trial sponsor is responsible for ensuring the integrity of the IMP supply chain**.
- The August 2018 Government Technical Notice on batch release of medicines and IMPs stated that the UK would unilaterally recognise EU batch release for IMPs.
- In a speech in July 2017, then Health Minister Lord O'Shaughnessy said that "In the event that it is not possible to reach a deal that secures ongoing, close collaboration between the UK and Europe, we will set up a regulatory system in the UK that protects the best interests of patients, and supports industry to grow and flourish. We will ensure that our system is robust, efficacious and does not impose any additional bureaucratic burdens." www.gov.uk/government/speeches/speech-given-by-lord-oshaughnessy-on-brexit-and-medicines-regulation
- Despite these assurances, **a new layer of red tape has been introduced which will reduce the benefit for the sector of that batch release recognition and will impact the attractiveness of the UK as a location for clinical trials**.

Draft Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

The regulations are as expected by industry following the MHRA's response to submissions into its 'no deal' consultation. However, a number of issues raised by industry in its submission to the MHRA (https://www.bioindustry.org/uploads/assets/uploaded/15aae797-85e6-4c6c-9c9286434ad9ba38.pdf)

remain and we continue to be concerned about the impact of these regulations on industry and patients. The impact of these are highlighted in the MHRA's draft impact assessment.

Draft Impact Assessment

BIA welcomes the inclusion by MHRA of a draft impact assessment with the SI – unlike many other SIs. However, we also note comments within the assessment of the impact on industry and patients, including the below:

- "After the UK's withdrawal, the **start of data and/or market exclusivity will be the date of authorisation in the EU or UK, whichever is earlier**…… It has been adopted **to encourage companies to submit applications for innovative products to the UK as soon as possible…. There will be no additional cost to industry unless individual businesses decide to delay their UK market authorisation applications.** In this case, they will lose any additional revenue in the UK as a result of a shortened UK exclusivity period and earlier possible generic entry, there would also be a social cost for society from delayed access to medicines." Many BIA members tell us that in reality the linking of data and/or market exclusivity to the EU/EEA will not have the impact that Government is seeking. It is impacting the reputation of the UK globally as well as leading to further launch delays.
- "**cost to industry** in establishing a contact person, MAH and QPPV presence in the UK for those who do not already have a UK presence, compared to the static acquis baseline, including a direct cost to change the MAH to a UK MAH."
- "an **additional direct cost to industry** for each application for a new active substance or biosimilar compared to the status quo of applying through the European centralised procedure at the EMA and receiving approval across all EU countries".
- "anticipates there would be **additional administrative costs to industry**….. There are **also costs to these businesses** of maintaining their UK MA"
- Clinical trials - "There would be the **cost to clinical trial sponsors** of engaging the services of an MIA(IMP) for assurance to check IMPs have been certified in the EU or EEA".
- **Medicines prices and trade effects -** "In the event of no deal, **duplicating regulatory processes between the EU** could have a number of effects on pharmaceutical businesses and other organisations. For manufacturing authorisation holders (MAHs) of generics, biosimilars, and established new medicines authorised through the centralised procedure, there would be duplication of MA maintenance for CAPs and other additional processes to comply with as outlined in this Impact Assessment. It is likely manufacturers would seek to recoup these additional **regulatory costs through price increases, which would affect NHS budgeting and spending choices**, however the exact effects are uncertain.
- **Public health impacts -** "In the event of the UK leaving the EU without a deal, some third-party analysis has suggested that there **could be delays in new innovative medicines coming to the UK market, once the UK has legislated to become a standalone regulator."**
- "Centre for Innovation in Regulatory Science (CIRS) data analysed by the Office for Health Economics for authorisations in the years 2013-2015 shows a 2-3 month median submission lag between applying to the EMA versus selected third country authorities, namely Health Canada, SwissMedic, and Australia's Therapeutic Goods Agency (TGA)…… between 5% and 15% of submissions were submitted one year after the EMA…. **45% of submissions to EMA were not submitted to all three of the above comparators – SwissMedic did not receive 22%, TGA did not receive 29%, Health Canada did not receive 38%."**

The UK Ecosystem is Thriving – but has much to lose

- On 24 January 2019 the BIA published *Confident capital: backing UK biotech*[1] that showed that the UK biotech sector raised a record £2.2 billion from investors in 2018. This is almost double that raised in 2017.
- Across Europe, UK companies accounted for 40% of all biotech venture capital raised and 45% of funding raised through IPOs
- The figures show that global investors continue to see the quality of the science and businesses in the UK as a great investment opportunity.
- The UK remains the leading life sciences cluster in Europe and continues to challenge clusters in California and Massachusetts.
- The ability to conduct clinical trials in the UK is essential to maintaining ongoing R&D investment.

BioIndustry Association

- The BioIndustry Association (BIA) is the trade association for innovative life sciences organisations in the UK.
- BIA members include emerging and more established bioscience companies, scaling companies, large pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector.
- Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.
- BIA has about 370 member companies, over 150 of them have at least one R&D site in the UK.

Further Information

Please contact Laura Collister, Brexit Lead, lcollister@bioindustry.org

The BIA recently published a series of explainers on strategic technologies coming out of the biotech sector – these can be downloaded by clicking on the images below:

[1] https://www.bioindustry.org/resource-listing/confident-capital-backing-uk-biotech.html