

MHRA issues new post-Brexit transition guidance on medicinal products, clinical trials and medical devices

Life Sciences analysis: Grant Castle and Sarah Cowlshaw, Partners at Covington & Burling and Marie Doyle-Rossi, Katharina Ewert and Ellie Handy, associates at Covington & Burling discuss the key points of the MHRA's new post-transition guidance on medicinal products, clinical trials and medical devices. They also consider the differences between the current guidance and the previous guidance issued in case of a no deal Brexit.

The Medicines and Healthcare products Regulatory Agency (MHRA) has published new guidance on medicines, clinical trials and medical devices to help stakeholders prepare for the end of the transition period and beyond. Further new and updated guidance may be issued as the transition period progresses, so stakeholders are advised to monitor these pages for updates.

This analysis was first published on Lexis®PSL on 25 September 2020 and can be found [here](#) (subscription required).

What are the key points of the MHRA post-transition information on medicinal products, clinical trials and medical devices?

The MHRA has published [guidance](#) on the regulation of medicinal products, clinical trials and medical devices applicable from 1 January 2021.

Medicinal products

The guidance on medicinal products sets out the requirements stakeholders need to comply with from 1 January 2021 regarding licensing, importing and exporting, pharmacovigilance and paediatric medicinal products. Anyone involved in the manufacture and supply chain of medicinal products placed on the market in the UK, Northern Ireland (NI) or Great Britain (GB) needs to consider this guidance.

Clinical trials

From 1 January 2021, much of the framework for clinical trials will stay the same, including the general obligation to publish details of clinical trials and publish summary results. However, the guidance sets out certain new requirements, eg it [confirms](#) at the end of the clinical trial, sponsors should send a confirmatory email to CT.Submission@mhra.gov.uk once they have uploaded the summary results to the public register. Also, [substantial amendments](#) might be required for changes of legal representatives and amendments to the identity of manufacturing and import authorization holders for investigational products (MIA(IMP)s).

Medical devices

The guidance on medical devices provides that from 1 January 2021, different rules will apply to medical devices placed on the market in GB and those placed on the market in NI, where EU law will continue to apply. That will largely remain the case in GB until 30 June 2023, manufacturers may continue to rely on EEA Notified Body certificates and the CE-mark will be recognised in GB. All medical devices have to be registered with the MHRA, there will be certain grace periods for registering existing devices. Manufacturers based outside the UK will need to appoint a UK Responsible Person.

What are the main differences (if any) between the current information and the previous guidance, which was issued in case of a no deal Brexit (ie before the Withdrawal Agreement was concluded)?

Medicinal products

Following the Northern Ireland Protocol, the new guidance notes that different rules will apply for products placed on the market in GB and NI, whereas previous guidance referred to the UK as a whole. Additionally, due to the transition period, deadlines and grace periods have changed.

Specific changes include a 24-month transition period for holders of centralised marketing authorizations (MAs) grandfathered to UK MAs, and companies holding a Parallel Import Licence, to establish in the UK. Also, there has been amendments to the review processes for pending centralised MAs, the definition of homeopathic medicines, the validity period for a Written Confirmation for export of an active substance, and pharmacovigilance procedures (including rules regarding QPPVs and PSMFs).

Medical devices

The new guidance clarifies that the UK will continue to recognise EEA Notified Body certificates and the CE-mark until 30 June 2023. After that date, all devices placed on the GB market, will have to bear the new UKCA mark and manufacturers will require a certificate from a UK Approved Body. The new guidance also sets out special rules, which will apply to devices placed on the NI market.

Are there any relevant gaps in the current guidance?

Medicinal products

The new guidance provides some additional information, but notably it no longer provides details on Applying for a Certificate of Pharmaceutical Product and how the UK will manage orphan medicinal products from 1 January 2021. The new guidance also does not address certain issues eg placing finished medicinal products on the market in NI. Further, the new guidance no longer sets out MHRA 'new assessment routes' for MA applications (ie it no longer refers to the Targeted Assessment process, Accelerated Assessment pathway and Rolling Review route). However, the new guidance does set out two processes for applications for centrally authorised products pending on 1 January 2021 (ie the 'In-flight' assessment or the 'Reliance Route').

Clinical trials

The new guidance no longer refers to the UK having an IT 'hub' for electronic filings and submissions equivalent to the EU's portal being developed under the Clinical Trials Regulation.

Medical devices

In the EU, changes to the medical device and in vitro diagnostic regime will enter into force in 2021 and 2022 respectively. In anticipation of a potential no deal Brexit, the Medical Devices (Amendment etc) (EU Exit) Regulations 2019, SI 2019/791 had implemented these changes into domestic UK law. The guidance notes that the UK government intends to consult on a revision of the existing regime, but is silent on the implications for the 2019 Regulations.

What are the foreseeable amendments and additions to it?

The MHRA guidance notes that there will be further guidance and possibly amendments to the 2019 Regulations on human medicines and medical devices.

Also, the Medicines and Medical Devices Bill is currently pending before Parliament. The Bill provides the Secretary of state with certain powers to make regulations concerning medicines and medical devices. Moreover, the UK government intends to consult on a revision to the medical devices regime. These upcoming legislative changes may impact the MHRA guidance.

The Internal Market Bill (the Bill), if and when adopted into law, may have significant implications on the guidance insofar as it relates to goods circulating between NI and GB and vice versa (see questions on circulation of products in the UK and UK Internal Market Bill below).

What does the guidance provide for products to be marketed in Northern Ireland and Great Britain and for their circulation across the UK countries?

Medicinal products & medical devices

The guidance sets out the position for devices intended for the NI market, to which special rules apply, but does not address the circulation of finished medicinal products within the UK internal market. In general, the guidance suggests devices for the NI market will remain more aligned with the EU regulatory requirements, whereas those for the GB market will be regulated under GB requirements. However, the guidance pre-dates the publication of the Bill (see question on UK Internal Market Bill below) and therefore, may be subject to change.

Clinical trials

The guidance on clinical trials notes that further information will be provided regarding the Northern Ireland Protocol. The guidance clarifies that comparator products imported into GB from outside the UK, which have a MA from approved countries or for NI, do not need to be re-certified.

What is the possible impact of the UK Internal Market Bill on the life sciences sector?

The precise implications are difficult to predict as the Bill is still in its early stages and will likely be subject to change over the coming weeks. In its present form, the Bill creates significant uncertainties for life sciences companies on the circulation of products between NI and GB and vice versa. For example, the Bill clarifies that the UK's internal free market access principles of mutual recognition and non-discrimination apply to the sale of goods in the UK, excluding NI. However, the Bill is silent as to the mutual recognition of GB compliant goods, such as finished medicinal products, shipped to NI intended for the UK internal market only. The Bill does not include any provisions on customs in relation to the movement of goods from GB to NI. Finally, the Bill gives significant powers to ministers to adopt regulations that can expressly override provisions of the Northern Ireland Protocol.

What are the practical implications of the current MHRA guidance for life sciences businesses?

The new MHRA post-transition guidance provides those in the life sciences sector with some additional certainty, for example, clarity on transition/grace periods the MHRA will apply. However, there are still a number of significant gaps and evolving developments (such as the ongoing negotiations with the EU, the proposed and pending UK legislation and additional MHRA guidance due to be published) that may affect the continued supply of products and the conduct of clinical trials.

Interviewed by Sabina Habib

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