Licensing of biological products: biosimilars, ATMPs and PMFs in a no-deal Brexit

This guidance sets out the procedures that the MHRA will introduce to regulate biological medicines in the event of no-deal Brexit.

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Guidance for UK Marketing Authorisation Applications for similar biological products (biosimilars) post Brexit

If the UK leaves the EU without a deal, the MHRA will continue to regulate biosimilar products according to the same principles that are applicable now. These are covered in regulation 58 of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 amending Reg 53 of The Human Medicines Regulations 2012.

New applications will be assessed at national level and should be submitted using existing procedures for national applications.

Applications for biosimilar products will also be eligible for the targeted assessment procedure after a final opinion from the European Medicines

Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has been obtained.

For biosimilar applications submitted after exit day, the application can only be made with reference to a product that complies with regulation 48 of the Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

These will include products that are authorised, or have been authorised for at least 8 years in the UK and those authorised by conversion from EUMarketing Authorisations (MA). It also includes products for which an EUmarketing authorisation was in force on exit day but which did not convert into UK marketing authorisations as the holder opted out of that process.

Data and market exclusivity period entitlements for reference medicinal products approved before the date of UK exit from the EU will continue to be applicable in the UK.

As part of the supporting data package, the UK will continue to accept data generated on reference product sourced in accordance with the 'Guideline on similar biological medicinal products CHMP/437/04 Rev1'.
We have more information about biosimilar products on our website.

Guidance for UK Marketing Authorisation Applications for Advanced Therapy Medicinal Products (ATMPs) after Brexit

If the UK leaves the EU without a deal, ATMPs will be regulated nationally by the MHRA according to the same principles that previously applied. These principles are covered in regulation 4 of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/XXXX); Reg 2A of The Human Medicines Regulations 2012 (SI 2012/1916) as amended).

This means that marketing authorisation applications for ATMPs will be assessed in accordance with the general provisions in place for the licensing of medicines, taking the specific requirements for this group of medicines into account.

Data, traceability, exemptions from licensing, packaging and post-authorisation requirements will remain unchanged from the current EUrequirements and will be transposed into UK law.

Definitions of individual classes of ATMPs will remain unchanged and classification of ATMPs in the UK will be undertaken by the MHRA in accordance with the legislation and current guidance.

Accordingly, ATMPs will continue to be classified into either:

- gene therapy medicinal products
- somatic cell therapy medicinal products
- tissue engineered products

What to do if you are uncertain about classification

If you are uncertain about the classification of your product fill out the ATMPadvice form or consult the Reflection paper on classification of advanced therapy medicinal products (EMA/CAT/600280/2010 rev.1).

Guidance for Plasma Master Files (PMFs) and Vaccine Antigen Master Files (VAMFs) after Brexit

If the UK leaves the EU without a deal, the MHRA will continue to recognise the existing PMF and associated inspections until further notice.

The supervision of the PMFs may eventually be fully transferred into a national system. This will be communicated by the MHRA at a later date. In the interim, we require the PMF holder to notify the MHRA of the

outcome of the annual updates within 4 weeks of the completion of the update.

For variation applications submitted to the EMA, the PMF holder must notify the MHRA of the submission and determination outcome of such an application within 4 weeks of the submission and determination dates, respectively.

MHRA reserve the right for further review where an EU assessment report is deemed to indicate significant public health issues that are insufficiently addressed at European level.

MHRA will issue guidance on the transfer of PMFs to the MHRA database when this becomes relevant, but the data requirements will be in accordance with those currently in place in the EU.

No VAMF is in use in the UK at present. Applicants proposing such a submission, which will be subject to the same standards and criteria as apply now, should contact the MHRA for further guidance.

This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019.