# Guidance on Reference Medicinal Products (RMPs) if there is a no-deal Brexit

This guidance should be considered by applicants when selecting the reference medicinal product for applications for new generic medicines and other abridged marketing authorisations.

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After Brexit there will be changes to the legislation of reference medicinal products used to support abridged marketing authorisation applications.

## Reference Medicinal Product

In the event of a no-deal Brexit reference medicinal products for new generic medicines or other abridged marketing authorisation applications submitted after exit day will be required to comply 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, or have been, authorised for at least 8 years in the UK (including those authorised by conversion from EU marketing authorisations)

- products that had an EU marketing authorisation 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 apply in the UK.

## How to check if your authorisation based on‘European Reference Medicinal Product’ as described in Article 10.1 of Directive 2001/83 (as amended) is valid

Authorisations based on a ‘European Reference Medicinal Product’ that have been granted, and applications that have been submitted to MHRA prior to exit day, will continue to be valid.

Applications submitted to MHRA will need to comply with regulation 48 of the Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

## Non-UK comparator products

Where a comparator product used in bioequivalence and therapeutic equivalence studies is not sourced from the UK market, the applicant should provide evidence that it is representative of the reference medicinal product.

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