Guidance on new provisions for traditional herbal medicinal products and homoeopathic medicinal products in a no deal Brexit

How herbal and homoeopathic medicines will be treated by the MHRA if there is a no-deal Brexit

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Herbal medicines

The policy for herbal medicines will follow that for marketing authorisations (MAs) in areas including place of establishment, variations and any other matters ongoing at EU-level on exit day.

In the event of no deal, the MHRA will expand the list of countries from which it will accept traditional evidence for herbal medicines. Currently for traditional herbal registration evidence has to be provided that the product or a corresponding product has been used for a period of 15 years within the EU/EEA.

In the event of a no deal Brexit, the MHRA will be able to accept the 15 years of traditional evidence from a wider range of countries in addition to EEA countries. Suitable countries will be those that have a level of pharmacovigilance equivalent to that of the UK. This is to ensure that

any safety issues have been properly identified to support the traditional use of the product.

The MHRA may publish its own list of herbal substances, preparations and combinations for use in traditional herbal medicines. This will include the entries in the existing EU List and the list will be updated as new entries arise.

Homoeopathic medicines

The policy for homeopathic medicines will follow that for MAs in areas including place of establishment, variations and any other matters ongoing at EU-level on exit day.

In the event of a no deal Brexit, the MHRA will expand the definition of a homoeopathic medicinal product. The definition will cover products prepared from homoeopathic stocks made in accordance with a homoeopathic manufacturing procedure described in a pharmacopoeia used officially in a country that is included in a list published by the MHRA.

The list will include the:

- British Pharmacopoeia
- European Pharmacopoeia
- Pharmacopoeia used officially in an EEA country
- United States Pharmacopoeia
- Swiss Pharmacopoeia
- any other Pharmacopoeia used officially in a country to be included for this purpose

The above list will be updated as new entries arise.

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