

GPhC response to MHRA consultation on EU Exit no-deal contingency legislation for the regulation of medicines and medical devices

Online questionnaire response submitted on 1 November 2018

Medicines - Changes M1-M9

5 Do you want to complete the Medicines section of the consultation?

Yes

Change M1: Legal Presence

6 Do you have any views on how the proposed transition period for UK MAH and QPPV establishment should be managed by the MHRA in order to reduce any impact or burden in terms of meeting the requirements?

MAH QPPV:

Change M2: New Marketing Authorisation (MA) assessment routes

7 Do you agree with the proposed new targeted assessment process?

Not Answered

Please explain your answer:

8 Do you agree with the proposed new fees for targeted assessment? Please provide comments to support your yes/no answer.

Not Answered

Please explain your answer:

Change M3: Converting centrally authorised products (CAPs) to UK MAs – commonly referred to as ‘grandfathering’ of licences

9 Do you agree with the requirements for data provision for grandfathered CAPs?

Not Answered

Please explain your answer:

10 Do you agree with the proposed approach to handling variations for CAP grandfathered products?

Not Answered

Please explain your answer:

11 Do you envisage any problems with the proposed approach to packaging for CAP grandfathered products?

Not Answered

Please explain your answer:

Change M4: Packaging

12 Do you agree with the proposed approach on packaging, including the period of time proposed to allow for changes?

Not Answered

Please explain your answer:

13 Do you agree with the proposed approach regarding Safety Features under the Falsified Medicines Directive?

Not Answered

Please explain your answer:

Change M5: Paediatric investigation plans (PIPs) and studies

14 Do you agree with the proposal for UK paediatric investigation plans (PIPs) and newly completed paediatric studies?

Not Answered

Please explain your answer:

Change M6: Orphan designation

15 Do you agree with the proposal to explore incentivising submission of MA applications for products intended to treat rare diseases in UK?

Not Answered

Please explain your answer:

Change M7: Abridged applications

16 Do you agree with the proposal for abridged applications?

Not Answered

Please explain your answer:

Change M8: Increased requirements for needing a manufacturer's licence for import or a wholesale dealer's licence

17 The transitional provision for this area is still be considered. Have you views on the length of time that should be allowed for organisations to obtain MIAs, and what arrangements should be put in place during that period?

Please explain your views:

Change M9: Recognition of prescriptions

18 Do you agree with the proposal to enable continued recognition of prescriptions issued in an EU / EEA country?

No

Please explain your answer:

1. As mentioned above the provision permitting prescriptions issued in any EU / EEA country to be dispensed across the EU / EEA stems from the EU cross border healthcare directive. It is anticipated that this directive will cease to apply to the UK in the case of no deal. In view of this we do not agree that provision needs to be made to continue the recognition of EEA prescriptions. An exception to this may be made in the case of healthcare provision and recognition of prescriptions on the island of Ireland but others will be better placed to comment on this.

2. There are also patient safety implications of continuing the recognition of EEA prescriptions. This is for the following reasons:

- Currently under the Mutual Recognition of Professional Qualifications [MRPQ] Directive EEA qualified medical practitioners authorised to issue an EEA prescription in their home Member State are also eligible, if they so wish, to have their EEA medical qualification recognised for registration with the GMC. It is at present unclear what legislative provisions will cover the recognition of EEA medical qualifications in the case of no deal. Consequently, from a patient safety perspective legislation should not be drafted to permit the continued recognition of EEA prescriptions for dispensing here if the EEA qualified prescribers themselves would no longer be recognised as meeting the professional qualification requirements for registration in the UK.
- In the case of on-line consulting and prescribing services we are aware that some services are provided by businesses operating in other EEA countries such as Romania. Such consulting and prescribing services have developed because of the legislative provisions on recognition of electronic EEA prescriptions. In certain models, the prescribers and/or the prescribing services fall outside the UK regulatory remit of the GMC, CQC and the other devolved regulators put in place to ensure patient safety throughout the healthcare system. Continuing the recognition of electronic EEA prescriptions when the cross border healthcare directive no longer applies fails to ensure patient safety in the digital healthcare environment and poses significant risks to patient safety.

It is however important to point out that in our view removing the recognition of EEA prescriptions should not affect the emergency provisions in the Human Medicines Regulations, namely Regulation 225 and 226. These provisions arguably do not require the recognition of EEA prescriptions. Rather they

enable a pharmacist to provide patient centred care and, in the absence of a prescription, supply a patient with medicinal products if the pharmacist is satisfied that the medicinal products had been previously prescribed for the patient by a 'relevant prescriber'. In these limited situations the definition of 'a relevant prescriber' would need to include an EEA health professional.

This should be considered as an interim / transitional measure at least, so that patients from EEA countries presenting with an EEA prescription in person in Great Britain, which would no longer be legally valid, could receive the emergency medication and care that they need.

Impact Assessment - Medicines

19 If you have evidence to help quantify the costs to business of these proposed changes, please respond below

Please explain your answer:

20 If you have any additional costs that you think have not been included, or would like to challenge the cost analysis included in the Impact Assessment, please give your views below

Please explain your answer:

21 If you would like to attach any evidence to support our assessment of the impacts, including internal business evidence, research reports or data please upload here

Please upload here:

No file was uploaded

Clinical Trials - Changes CT1 - CT3

22 Do you want to complete the Clinical Trials section of the consultation?

No

Medical Devices - Change D1

30 Do you want to complete the Medical Devices section of the consultation?

No

Fees - Changes F1-F2

35 Do you want to complete the Fees section of the consultation?

No

NIBSC - Change N1

41 Do you want to complete the NIBSC (biological medicines) section of the consultation?

No

Impact Assessment - Further Comments

47 If you have any further comments about the content and analysis in the Impact Assessment, please provide them below.

Please give your views:

Public Sector Equality Duties

48 Do you foresee any impacts (positive or negative) of these proposals on groups with protected characteristics for the purposes of the Equality Act 2010 or on other groups of people who suffer health inequalities? If so, do you have any suggestions for mitigating negative impacts?

Not Answered

Please explain your answer:

Any further questions or comments on this consultation?

49 Please give any comments or questions below

Please explain your views: