Royal Pharmaceutical Society - Response ID ANON-8JP8-J26U-H (version for RPS website)

Submitted to **MHRA EU Exit no-deal contingency legislation for the regulation of medicines and medical devices**

4 What is your organisation?If you represent a business, please indicate if you are a small or micro business (1-9 or 10-49 employees)

Organisation:
Royal Pharmaceutical Society

How to complete this consultation

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 :
We agree a transition period is required and this should be sufficient to permit recruitment of appropriately trained individuals.

We would support a single, grouped, Type IA variation to register a new UK QPPV for all impacted MAs held by the same MAH.

Change M2: New Marketing Authorisation (MA) assessment routes

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

Yes

Please explain your answer:
It is essential to have an assessment procedure for new medicines and new indications for existing medicines for the UK to ensure patients have appropriate access to new treatments.

It is considered rationale to accept the same scientific dossier as that submitted to the EMA as companies manage trials for licensing above country and on a global basis.

The proposal to use the same dossier does appear to contradict later statements in the consultation around orphan disease and paediatric implementation plans (PIPs).

It does need to be accepted that comparators in clinical trial studies may not be available and/or standard clinical practice in the UK.

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

Yes

Please explain your answer:
If the MHRA consider the proposed fees are reasonable then the RPS is unlikely to have any objection.

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?

Yes

Please explain your answer:
This approach appears to be sensible if the data can't be obtained from the EMA.

If marketing authorisation holders (MAHs) of centrally authorised products choose not to make these products available in the UK then the MHRA must have a process in place to notify the relevant bodies including the RPS so that the impact on patient care can be minimised

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

Yes

Please explain your answer:
This appears to be a sensible approach but there is likely to still be confusion over where variations are in the process i.e. are they at the late stage. This may be aggravated by the number of variations that the MHRA could be managing at this point in time

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

Yes

Please explain your answer:
A Brexit 'no deal' cannot be considered in isolation as it will have implications for the Falsified Medicines Directive.

Change M4: Packaging

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

Yes

Please explain your answer:
The RPS recognises its important to give the industry until the end of 2021 to amend packaging as for some companies the UK MAH and address will need to be agreed first.

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

Yes

Please explain your answer:
It is important that the UK can still accept packs with FMD safety features as the RPS would not want further potential medicines shortages as a result of being unable to accept these packs.

The RPS does have major concerns about the risk to patient safety in the UK in not implementing the FMD. The RPS is concerned that the UK may become a target market for counterfeit medicines.

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?

Yes

Please explain your answer:
The RPS considers it is important to support and encourage pharmaceutical companies to develop paediatric indications for their products.

It would seem reasonable to maintain the same level of reward as that granted in the EU.

It is envisaged that EU PIPs should be accepted for most cases and the need to modify for the UK should be seen as the exception.

Pharmaceutical companies should not be deterred from launching products in the UK market.

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?

Yes

Please explain your answer:
The RPS supports the incentivising of companies to develop products for orphan diseases.

The RPS is not convinced of the need to have a separate orphan designation for the UK, as pharmaceutical companies operate on a global basis. Having a separate orphan designation for the UK is likely to lead to confusion rather than act as an incentive to develop products as the market would be considered too small.

Change M7: Abridged applications

16 Do you agree with the proposal for abridged applications?

Yes

Please explain your answer:
The RPS agrees to abridged procedures where appropriate as they do not want any unnecessary barriers put in place for pharmaceutical companies launching products in the UK.

Moving forward the RPS does have concerns, due to being unable to access data from the EMA, about only being able to use reference products which have been approved in the UK. They consider this is a risk and could act as a deterrent to pharmaceutical companies launching some products in the UK.

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:
There is a clear need for transitional arrangements.

The RPS has concerns over how long it will take wholesalers to implement this and wants any requirements to support patient safety but have minimal impact on medicines supply. The RPS is already concerned about medicine shortage.

Change M9: Recognition of prescriptions

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

Yes

Please explain your answer:
The RPS believes it is important for pharmacies still to be able to dispense privately at no cost to the NHS. Patients who are unable to access their medicines may end up in hospital.

The RPS would prefer prescriptions to be written in English if it is intended for them to be dispensed in Great Britain as pharmacists can only dispense prescriptions that they understand.

The RPS does have concerns as to whether they will still be able to confirm whether the prescription comes from an eligible prescriber within the EU/EEA.

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 :
The RPS agrees with the identified costs, however, there are likely to be additional costs in terms of health care professional (HCP) time, especially pharmacy, to manage stock shortages, reassurance to patients as a result of medicines changing.

There is the risk of increased cost of medicines to the NHS and potential risk of stock-piling by patients.

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:
Cost in HCP time to manage medicine shortages.

Some patients may require hospital admission to manage changes to medication or the complications of not receiving medicines.

To manage the risk of stock shortage it has been proposed to hold an additional six-week of stock in the UK. Cost of holding six-week supply – who will pay for the storage, who will pick up the cost of the stock? The feasibility of producing an additional six-week of stock in such a short time frame?

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 :
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Clinical Trials - Changes CT1 - CT3

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

Yes

Change CT1: Legal presence – clinical trials

23 Do you agree with the approach proposed, for a sponsor or legal representative to be established in the UK or a designated country?

Yes

Please explain your answer:
It seems a sensible approach to continue to permit the legal representative or sponsor to be based in the UK or on the designated list. It is stated that this would initially include the EU and EEA countries, however, if possible it would seem sensible to continue with this approach.

24 Do you agree with the additional requirement on the sponsor to ensure that, where both the sponsor and legal representative are not UK-based, a CI is continuously available to assist with the actioning of any relevant licensing authority or sponsor required changes to the conduct of the trial?

No

Please explain your answer:
The RPS believes it is important that the MHRA has a point of contact based in the UK, however, this may not necessarily be the CI as it may be more appropriate for it to be another individual nominated by the commercial sponsors.

Change CT2: Transparency

25 Do you agree with this approach?

Yes

Please explain your answer:
The continued transparency of information on clinical trials is essential and should be made available to the UK public.

It is stated an UK information system will be developed it is important that there is no delay in the development of this system.

Change CT3: Use of designated country lists, including for legal presence and importation of investigational medicinal products (IMPs)

26 Do you agree with the proposed designated country lists?

Yes

Please explain your answer:
The RPS believes it is important to minimise the barriers to setting up clinical trials in the UK but it is also important to protect patient safety.

Impact Assessment - Clinical Trials

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

Please explain your answer:

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

Please explain your answer:

29 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

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Medical Devices - Change D1

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

Yes

Change D1: Registration of medical devices

31 Do you agree with this approach and what do you think the timetable for transition period should be?

Yes

Please explain your answer and also give any views on the timetable for a transition period:
The transitional time period should be until at least May 2022.

Impact Assessment - Devices

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

Please explain your answer:

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

Please explain your answer:

34 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

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Fees - Changes F1-F2

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

Yes

Change F1: Fee waivers for orphan products

36 Do you agree with the proposal to consider offering new fee waivers for orphan products?

Yes

Please explain your answer:
It is important to offer incentives to companies to undertake research and development in orphan disease areas.

Change F2: New/amended MHRA fees for six processes/services previously provided centrally by EC or EMA

37 Do you agree with the proposed new/amended MHRA fees for six processes/services previously provided centrally by EC/EMA?

Not Answered

Please explain your answer:
Unable to comment on whether the proposed fees are reasonable.

Impact Assessment - Fees

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

Please explain your answer:

39 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 views:

40 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

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NIBSC - Change N1

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

Yes

Change N1: Independent UK batch testing of biological medicines and associated fees

42 Do you agree that, as a standalone national control laboratory, NIBSC certifies batches of biological medicines used in the UK, taking a risk-based approach and accepting evidence of testing by an EU 27 OMCL as discussed above?

Yes

Please explain your answer:
The RPS agrees this should be undertaken on a risk-based approach.

43 Do you agree with this proposal for NIBSC OMCL batch testing fees?

Yes

Please explain your answer:
The RPS agrees there should be batch testing fee tariff, however, would be unable to comment on the level of fee.

Impact Assessment - NIBSC

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

Please explain your answer:

45 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:

46 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 :
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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:
While it is recognised all government departments must put in place processes for managing a ‘no-deal’ Brexit and the measures proposed by the MHRA appear to reasonable, the preferred option would see a negotiated settlement between the UK and EU.

The RPS has significant concerns about a no-deal Brexit and the impact this would have on medicine availability for patients. One solution could be for patients to be switched between branded medicines and generic alternatives. It is, however envisaged therapeutic substitution will be required as in some instances neither a brand nor a generic alternative will be available. For pharmacists to be permitted to do therapeutic substitution this may require changes to legislation.

A no-deal Brexit is likely to create significant additional work load for pharmacy in managing stock shortages and reassuring patients and the public about their medicines. Some patients will need to have their medicines changed and guidelines will need to be rewritten and prescribing systems changed. Information on alternative treatments will need to passed to other healthcare professionals, patients and carers.

The RPS has specific concerns about the continuation of the UK position in clinical research and would urge any additional processes are kept to a minimum in terms of complexity to complete and cost.