Health and Social Care Committee

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From Dr Sarah Wollaston MP, Chair

Rt Hon Jeremy Hunt MP,
Secretary of State for Health & Social Care

26 March 2018

Dear Jeremy,

I am writing further to my letter on behalf of the Health and Social Care Committee of 15 February regarding Brexit transitional arrangements, and also further to the publication of the Fourth Report of the Health and Social Care Committee, Brexit: medicines, medical devices and substances of human origin, on Wednesday 21st March. I am writing to seek further clarity following the publication on Monday 19 March of the Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.

The Committee stated in our 15th February letter that:

> We are encouraged that both sides of the negotiations are now discussing the terms of a transition period

The publication of the Draft Agreement is welcome confirmation of this discussion, and negotiators on both sides should be congratulated on having achieved this. However, several questions arise from the Draft Agreement, which I would like to seek clarification from you on. The key areas are:

1. The Draft Agreement appears to set out that during transition, UK agencies and industry will continue to have to abide by European Medicines Agency (EMA) laws and regulations. However, unlike currently, it appears that the UK will have no formal method of engaging with the decision-making process of the EMA. Does this limit the UK to becoming a 'rule taker' rather than a 'rule-maker' with regards to the EMA during the transitional period?

2. What degree of transparency will be afforded by the Government regarding those EMA meetings which the UK continues to be invited to during transition, to allow for parliamentary, stakeholder and public scrutiny?

3. This Draft Agreement appears to outline that during transition, the UK will enjoy a more restrictive relationship with the EMA than the Prime Minister set out for 'associate membership'. If this understanding is correct, can the Government confirm how it will be seeking to negotiate 'associate

membership' after the transition period if, for the 21 months previously, the UK has accepted a significantly 'worse' deal from the EU?

Will the UK have a meaningful role in shaping future policy within the EMA?

Article 122 Scope of the transition (which is highlighted in the Draft Agreement in green and thus is "agreed at negotiators' level") states that "Unless otherwise provided in this Agreement, Union law shall be applicable to and in the United Kingdom during the transition period." This implies that as a starting point EU law, and membership of bodies such as the EMA will apply to the UK throughout a transitional period. However, *Article 6 References to the Union and to Member States* indicates that this does not apply to:

> (a) the nomination, appointment or election of members of the institutions, bodies offices, and agencies of the Union, as well as the participation in the decision making and the attendance in meetings of the institutions;
>
> (b) the participation in the decision-making and governance of the bodies and agencies of the Union
>
> (c) the attendance in the meetings of… Commission expert groups or of other similar entities…unless otherwise provided in this Agreement.

I would appreciate clarification of whether my understanding is correct that per this Draft Agreement, from the start of the transition period on 30 March 2019, the UK will be excluded from the EMA and other EU agencies, without permission to attend EMA meetings or contribute to decision making.

Moreover, *Article 122 Scope of the transition* suggests that the UK will still be subject to the decisions made by the EMA during this transitional period over the licensing and regulation of medicines and devices. In our report on Brexit: medicines, medical devices and substances of human origin, we argued that

> "…the worst outcome [post-Brexit] would be for the UK to become an isolated rule-taker."

However, my interpretation of the 19th March Draft Agreement suggests that this may be what the transitional period holds for the UK. UK agencies and industry will continue to have to abide by EMA laws and regulations, but, unlike currently, the UK will have no formal method of engaging with the decision-making process of the EMA. While *Article 91* is coloured as 'white' in the Draft Agreement, and therefore is not formally agreed by the EU and UK, it states:

> "Decisions adopted by institutions, bodies, offices and agencies of the Union before the end of the transition period, and addressed to the United Kingdom or to natural and legal persons residing or established in the United Kingdom, shall be binding on and in the United Kingdom."

Is my understanding correct that these Articles, if agreed, mean that decisions made by bodies such as the EMA concerning businesses, agencies and individuals established in the UK will be fully binding on the UK during the upcoming transitional period, but with no opportunity for the UK to influence the decision-making process?

Furthermore, *Article 41 'Making available of information in relation to past authorisation procedures for medical products'* claims that:

> The United Kingdom shall, upon a reasoned request from a Member State or the European Medicines Agency, make available without delay the marketing authorisation dossier of a medicinal product authorised by a competent authority of the United Kingdom before the end of the transition period.

Our recent Brexit report argued that continued EU-27 and UK collaboration on marketing authorisation would be mutually beneficial to public health on both sides of the Channel. **Can I seek clarification from you on whether the Government has plans to ensure that the provisions made in *Article 41* that the UK will share marketing authorisation dossiers with the EU-27 and EMA during any transitional period will be reciprocated?** My understanding of the Draft Agreement is that there is no provision for the UK to request marketing authorisation dossiers authorised in the EU-27 or the EMA, which could mean the regulation of medicines and devices in the UK, and potentially the safety of UK patients, could be in a relatively weaker position during a transition period than for the EU-27.

<u>Stakeholder scrutiny and Government transparency</u>

Article 123 (highlighted in green and therefore agreed by negotiators) states that:

> … during the transition period, representatives or experts of the United Kingdom may, upon invitation, exceptionally attend meetings of Commission expert groups or other similar entities, or of bodies, offices or agencies…provided that one of the following conditions is met:
>
> (a) the discussion concerns individual acts to be addressed during the transition period to the United Kingdom or to natural or legal persons residing or established in the United Kingdom; or
>
> (b) the presence of the United Kingdom is necessary and in the interest of the Union, in particular for the effective implementation of Union law during the transition period".

I would appreciate clarification from you on whether this provision includes the expert working groups through which the EMA takes many decisions, and, if the UK retains no voting rights in such meetings, what assessment your Department has made of the impact this will have on the influence of the UK both in the EU and internationally.

Further questions surround the details of such an approach:

- **If Parliament, stakeholders and the wider public is to conduct effective scrutiny of the Government throughout the transition period, what level of transparency can we expect around those meetings which representatives from the UK are invited to attend? What specific measures will be taken to ensure the full publication of all invitations to meetings that the UK receives, and which UK representatives attend these meetings?**

- **Has your Department, or the wider Government, sought clarification on the process by which the UK Government is to be invited to future EMA meetings? For example, will the Government receive a list of all meetings within EU agencies for a given time period, or only be notified of those meetings deemed relevant to the UK by the EU?** It seems likely that the UK will wish to negotiate access to certain meetings due to their political significance or UK expertise in an area. **Am I therefore correct in my understanding that if the Government is not presented with a full list of meetings taking place within EU agencies, this negotiation becomes impossible, and the UK could be excluded from pertinent meetings?**

- As this text has been agreed to by the UK (as demonstrated by its highlighting in green), **can you provide me with specific examples of the EMA meetings the UK is expecting to be invited to during the transition period? Will the Government publish its planning for establishing with the European Commission which meetings the UK will be invited to in advance of the start of the transitional period?**

<u>Whether 'associate membership' of EU agencies is a realistic ambition</u>

Finally, the Health and Social Care Committee in our latest report on Brexit welcomed the Government's desire to seek associate membership of the EMA. The Prime Minister's 2nd March speech outlined that 'associate membership':

> "…is the only way to meet our objective of ensuring that these products only need to undergo one series of approvals, in one country."

She went on to argue that:

> "[with] associate membership we would be able to ensure that we could continue to provide our technical expertise"

However, from my understanding, the Draft Agreement negates these aspirations for the duration of the transition period, with *Article 123* limiting the technical expertise the UK can continue to provide, *and Article 41* implying that the UK's aspiration for a single market authorisation system are improbable during the 21-month period. If this understanding is correct, I would appreciate clarification from the Government on how the UK is anticipating achieving 'associate membership' of the EMA after a transition period when, for the 21 months previously, the UK's relationship with the EU will have been significantly more restrictive. If the EU is to offer the UK 'associate membership' on the terms the Prime Minister has set out, this will, it appears to me, include substantially greater UK freedom from EU and

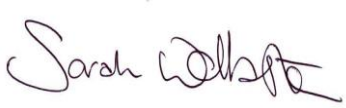
EMA regulations in comparison to during the transition period. **What assessment has the Government made on whether such an offer would be politically acceptable for the EU? Or does this Draft Agreement mean the Prime Minister's aspirations of associate EMA membership will be impossible to realise?**

I would welcome a response from your department on the points in this letter. In the meantime, I reiterate the conclusion of our report on Brexit: medicines, medical devices and substances of human origin, where we argued that:

> …our view is that the worst position for the UK is that it becomes isolated from, but dependent on, a European Union which, adopts a more precautionary attitude to regulation of the life science industry.

I would appreciate clarification from you on how the Government will look to ensure that this situation is not one which manifests itself during the transition period.

With best wishes,



Dr Sarah Wollaston MP
Chair of the Committee