



Norman Lamb MP  
Science and Technology Committee  
House of Commons

10 December 2018  
Our reference: 18509

**Medicines and Healthcare products  
Regulatory Agency**

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Dear Mr Lamb

### **E-cigarettes as medically licensed products**

Thank you for your letter of 26 November requesting the MHRA to set out their response to the recommendation at paragraph 46, of the House of Commons Select Committee on Science and Technology report on E-cigarettes. That is:

“The Government should review with MHRA and the e-cigarette industry how its systems for approving stop smoking therapies could be streamlined; to be able to respond appropriately should manufacturers put forward a product for licensing.”

To help address this recommendation, an Ad hoc working group will be set up under the sponsorship of the Commission on Human Medicines (CHM). A paper setting out the proposal was submitted by the MHRA and discussed by the CHM during their meeting on 6-7th December 2018. The CHM agreed that a group should be convened to advise, in the light of the further and emerging evidence, whether and if so, how the data requirements for the licensing of e-cigarettes as medicines could be further streamlined or simplified for companies applying to obtain a licence for e-cigarettes.

The draft terms of reference and membership of the group were discussed during the meeting and will be finalised shortly. It is planned for the group to be convened early next year and to submit its recommendations to the CHM in due course. The CHM in turn will advise the MHRA and their recommendation will be considered and contribute to the MHRA's final response to the Select Committee.

Depending on the complexity of issues to be considered and the number of Ad hoc group meetings to be held, we are hoping that the recommendation from the CHM will be received by July 2019 and after that the MHRA response incorporated in the Government response to the select committee.

As you are aware, we have been in discussions with Mrs Deborah Arnott and we will continue to do so to keep her aware of progress of the work.

In the meantime, the MHRA continues to support and engage with companies that express an interest in applying for a medicines licence.

I hope that you are reassured that actions are being progressed to address the recommendations set out in the Select Committee's report.

Yours sincerely

A handwritten signature in black ink, appearing to read 'I Hudson'. The signature is written in a cursive style with a large initial 'I' and a long horizontal stroke at the end.

Dr Ian Hudson  
Chief Executive