



Ein cyf/Our ref VG/0340/20

Dr Dai Lloyd MS  
Chair, Health, Social Care and Sport Committee  
Welsh Parliament  
Cardiff Bay  
Cardiff  
CF99 1SN

12 October 2020

Dear Dai,

Thank you for your letter of 6 October seeking further clarification of progress in relation to my concerns about the provisions on the medical device information system in the Medicines and Medical Devices Bill.

As I mentioned in the Health, Social Care and Sport Committee last week the Bill is an enabling measure the implementation of which will be determined by regulations which have not yet been drafted. Although there is no timeline for the regulations I understand it is unlikely that there will be a draft available to comment on until well after the Bill receives Royal Assent, which is likely to be, at the earliest, towards the end of this year.

In the absence of the draft regulations and in order not to have to rely alone on the assurance in Lord Bethell's letter of 14 September that the Devolved Governments "particular considerations" will be taken into account when drafting the regulations, I have asked my officials to identify a series of broad principles which would shape the regulations in a way that would be acceptable to the devolved administrations collectively and form the basis of our negotiations with the Department. I attach the list which is currently being considered by Scottish and Northern Irish officials.

If these principles were to be agreed by the other Devolved Governments, DHSC and reflected in the regulations I believe that they would largely address my concerns. But the discussions on the principles with the Devolved Governments are at an early stage and they have not yet been shared with the Department.

I am optimistic that we may be able to make some progress with DHSC as my officials consider that they have shown a willingness to work collaboratively with us and the other Devolved Governments on the regulations.

When it is clear that the Devolved Governments can agree on a common line I will write again to Lord Bethell to ask him to give urgent consideration to accepting the principles and

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:  
0300 0604400

Bae Caerdydd • Cardiff Bay  
Caerdydd • Cardiff  
CF99 1SN

[Gohebiaeth.Vaughan.Gething@llyw.cymru](mailto:Gohebiaeth.Vaughan.Gething@llyw.cymru)  
[Correspondence.Vaughan.Gething@gov.wales](mailto:Correspondence.Vaughan.Gething@gov.wales)

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

to incorporate them in the regulations, hopefully before the Health, Social Care and Sport Committee finalises its report on 22 October.

I also attach Lord Bethell's letter of 14 September which you requested.

Yours sincerely,

A handwritten signature in black ink that reads "Vaughan Gething". The signature is written in a cursive, slightly slanted style.

**Vaughan Gething AS/MS**

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol  
Minister for Health and Social Services