Dear Sir Bill,

UPDATE ON THE EUROPEAN COMMISSION’S PROPOSALS FOR A REGULATION ON MEDICAL DEVICES AND A REGULATION ON IN VITRO DIAGNOSTIC DEVICES (14493/12, 14499/12)

Further to my letter of 3 September, I am writing to update you on the progress of negotiations on the proposed new EU Regulations for medical devices and in vitro diagnostic (IVD) devices.

PROGRESS IN COUNCIL

In June 2015, the Latvian Presidency reached Council agreement on a ‘Partial General Approach’ for both Regulations. This important political milestone allowed the Luxembourgish Presidency to resolve outstanding ‘technical’ and ‘drafting’ issues with the Council texts over the summer, which included work on the Recitals. At the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council on 5 October, Council finalised its full ‘General Approach’¹. This provided the basis to start informal trilogue negotiations with the European Parliament and Commission. The Parliament’s position was adopted in April 2014 through its proposed amendments to the Commission’s proposal.

The Presidency represented the position of the Council in a series of technical and political trilogues with the Parliament and Commission. These trilogues were scheduled to run from October to December 2015. For this purpose, the two Regulations were split into four ‘blocks’, the detail of which is Annexed to this letter. However, it will not be possible to secure a full agreement to both

Regulations before the end of the Luxembourgish Presidency, which was formally confirmed at EPSCO on 7 December. The key difficulty appears to be the highly technical nature of these substantial Regulations.

Trilogue negotiations will therefore continue in 2016, and there is a collective will to reach a final agreement under the Dutch Presidency, whose forward planning and expertise in medical devices will prove important in securing sensible compromises with the Parliament and Commission.

**Agreed Text and Key Issues**

Despite not reaching agreement on the whole texts, there are relatively fixed agreements on several important aspects around the scope of the Regulations (Chapter I), obligations on economic operators (Chapter II) and the identification and traceability of devices (Chapter III). However, it should be noted that during these informal trilogues no specific agreements can be considered as final until every aspect of the texts have been discussed and agreed.

From the perspective of the UK, the most important agreement reached so far is our success in retaining an exemption for hospitals to manufacture and use their own devices ‘in-house’, without needing to meet the same regulatory requirements as a commercial manufacturer; this is particularly important for NHS pathology labs. As a result of engagement with MEPs, the agreement reached is actually an improvement on the Council text, as it narrows the scope of particular requirements to the highest class of IVDs only; the Council text required this for both Class C and Class D IVDs.

The other key UK priority for negotiations, pre-market scrutiny, has only been discussed in a preliminary way, but we remain optimistic of finding an appropriate compromise.

However, there was less progress on several other issues including the re-processing of single-use devices, genetic testing, the use of hazardous substances and mandatory liability insurance for manufacturers. These issues have emerged as important issues throughout negotiations that we continue to pay close attention to.

Re-processing is not a key concern for the UK, which currently advises against such practice but has not banned it. The Council text would allow Member States the choice of whether to allow re-processing on their territory or not. However, this has become a key point of contention for others and needs to be considered carefully during negotiations.
The European Parliament has proposed amendments that would severely hamper the use of all types of genetic testing across the EU. There is significant opposition in Council and among stakeholders for this proposal, which would mean all genetic tests could only be conducted with the approval of a qualified medical professional, and only once full consent had been provided, informed by ‘appropriate genetic counselling’ – again involving a medical professional – for any predictive or diagnostic test involving genetic material. This would be highly inappropriate for a broad range of tests that utilise some form of genetic material.

The European Parliament has also proposed amendments that would ban medical devices containing any trace of substances that can be considered carcinogenic, mutagenic or toxic to reproduction (CMRs) or have endocrine-disrupting properties in any form. We are concerned about this proposal, which would also affect devices where there is no risk of such materials having any effect on the patient or user in their particular form, and which have been safely used as such for many years. We hope to find a compromise that will maintain patients’ access while allowing for such substances to be phased out in favour of newer and safer alternatives as they become available.

In an effort to guarantee appropriate recourse for victims of defective medical devices, the Parliament has called for compulsory liability insurance for all manufacturers. The problem with this is practical, in that insurance companies may not want to offer this protection in all cases. Even if available, the premiums would be very expensive and potentially unaffordable for SMEs. The core of the Parliament’s concern is long-term implants, where problems may emerge years after a manufacture has ceased to trade and cannot be held to account. However, in such a case the defunct manufacturer would have also ceased paying insurance premiums. We are not aware of an insurer that would offer an ongoing coverage following the cessation of premium payments, and if they did it would have to be prohibitively expensive to cover the ongoing risk. Again, we are working to find an acceptable solution.

**Next Steps**

Trilogue negotiations will continue under the Dutch Presidency, with a view to securing informal agreement to all key issues with the Commission and European Parliament. We would not expect this to be achieved much before June 2016, when Council could then formally adopt a First Reading Position, which would be sent to the Parliament for an accelerated Second Reading. The Regulations could be adopted and enter into force around Autumn 2016, and would then apply in the UK from 2019 and 2021 for medical devices and IVDs respectively.
We have offered our full support to the Dutch Presidency, and will work with them to secure appropriate compromises with the Parliament and Commission. We also continue to engage closely with key stakeholders, particularly industry, as we look forward to implementation of the new Regulations.

Parliamentary Scrutiny
As you are aware, these regulations have cleared scrutiny in the Lords, but remain under scrutiny in the Commons. In September, your Committee acknowledged the partial ‘General Approach’ and our intention to support the Presidency to enter the trilogue process. You requested a further update once trilogues near their conclusion, so that you could review any significant changes to the text and consider lifting scrutiny. However, as trilogues will continue longer than anticipated, I wanted to formally update you with progress at this point.

Around Spring 2016, when we expect the content of the final compromise package to become clearer, I expect to write again to seek a scrutiny waiver, which would allow us to vote on the final Council position in line with the conditions specified in that waiver. My officials have agreed with the Committee Clerk that this will be necessary because there is unlikely to be time to present the final compromise to the Committee for a decision before we would be asked to vote on it in Council. Following a vote, I would then write again to set out the final details of the Council First Reading Position, and ask the Committee to formally lift scrutiny, which would be based on our having voted on a package within the conditions set out in any such waiver and being a positive outcome for the UK.

Implementation
Finally, we are looking ahead to the implementation of the new Regulations, which must be completed during the transition periods. It is important that stakeholders are engaged in this planning process, and we have already had initial discussions with many of them, with a view to producing a detailed implementation plan, although it cannot be finalised until the requirements of the Regulations are agreed and the timescale is clear. My officials continue to engage closely with yours, and other key stakeholders, as we look forward to finalising and implementing the new Regulations.
I am copying this letter to the Clerk of the Commons Scrutiny Committee, to Les Saunders, Cabinet Office European & Global Issues Secretariat and David Winks, the Department of Health’s Scrutiny Co-ordinator at. I am also writing in similar terms to the Devolved Administrations and Lord Boswell.

Yours sincerely,

George Freeman MP
Minister for Life Sciences
ANNEX – FOUR ‘BLOCKS’ FOR TRILOGUE NEGOTIATIONS

Block 1 consists of Chapter I (Scope), Chapter II (Obligations of economic operators) except Article 15 of the draft Regulation on Medical Devices (Re-processing), Chapter V, section I (Classification), and the related annexes.

Block 2 consists of Chapter III (Identification and traceability), Chapter VI (Clinical evaluation for medical devices and performance evaluation for IVDs), Chapter IX (Confidentiality and data protection), Chapter X (Final provisions, including transitional measures), and the related annexes.

Block 3 consists of IVD-specific issues, notably rules on IVDs for self-testing and genetic testing, as well as classification rules and parts of the provisions on performance evaluation.

Block 4 consists of Chapter IV (Notified bodies), Chapter V, section II (Conformity assessment), Chapter VII (Surveillance of the market), Chapter VIII (Cooperation between Member States, notably the Medical Device Coordination Group), and the related annexes.

The definitions and recitals relating to a specific block were examined together with the enacting terms of that block.