To: stakeholder representative bodies (medicines and pharmacy)

Dear all,

Informal consultation on urgent changes to the Human Medicines Regulation 2012 to ensure the continuity of supply of medicines (including in a 'no deal' Brexit)

Prompted by the preparations for the UK's exit from the EU, the Department of Health and Social Care is proposing some changes the Human Medicines Regulations 2012 to ensure the continuity of supply of medicines when the UK leaves the EU, including in a 'no deal' scenario. We have spoken to a number of representative bodies about the changes and would be happy to speak to others as well.

Normally, we would consult publicly for 12 weeks before making any changes to the Human Medicines Regulations 2012. However, you will understand that any legislative changes in relation to the UK's exit from the EU need to be progressed quickly so that they are in force before the day that the UK leaves the EU. Therefore, we are seeking views of the relevant stakeholder representative bodies on the proposed changes **by close on 12 December 2018**.

Background

The Government is preparing for the UK's exit from the EU, including for a scenario in which the UK leaves the EU without agreement (a 'no deal' scenario). We have asked pharmaceutical companies that supply the UK with medicines from, or via, the EEA, to ensure they have a minimum of six weeks' additional supply in the UK. And in light of this, we have advised healthcare providers (hospitals, pharmacies etc.) and prescribers that they do not need to take any steps to stockpile additional medicines or write longer prescriptions.

In addition, we have now also undertaken an exercise to identify any further actions that could support the continuity of supply of medicines in a 'no deal' scenario. The actions range from trying to increase the manufacture or packaging of products in the UK to controlling distribution and dispensing flexibilities and stopping exports. We believe that most of the actions identified can be taken within the existing legislative framework, the Human Medicines Regulations 2012, but may require, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) to fast track applications or the Department to make changes to the Drug Tariff.

There are however two areas that require changes to the legislation. We are seeking your views on the proposed changes to the Human Medicines Regulations 2012 in these areas.

Amendment 1: provision for a 'serious shortage protocol' for serious national shortages of medicines

This amendment introduces a new regulation into the Human Medicines Regulation 2012 enabling Ministers to issue a 'serious shortage protocol'. Such a protocol could be issued in case of a serious national shortage and would enable community pharmacists and other dispensers, to dispense in accordance with the protocol rather than the prescription without contacting the GP. The pharmacist would still use their professional judgment to decide on what medicine to dispense. The protocol would be developed with clinicians and would clearly indicate what alternative can dispensed and to which patients it applies. The protocol covers four possibilities:

- Dispensing a reduced quantity
- Dispensing an alternative dosage form

- Dispensing a therapeutic equivalent
- Dispensing a generic equivalent

A '. In particular in a scenario with multiple large shortages, protocols will support pharmacists and GPs by reducing the time needed for pharmacists and GPs to liaise with each other and with patients. It has been drafted as a reserve power that would allow Ministers to issue serious shortage protocols during any serious national shortage, not just for potential supply shortages in a 'no deal' scenario.

This amendment will be progressed as part of the 'Human Medicines (FMD) (Amendment) Regulations 2019' which we expect to be lay in Parliament in January 2019.

Question 1: Do you agree with the introduction of the provision for a 'serious shortage protocol' to deal with serious national shortages of medicines?

Amendment 2: provision for a regulation making power in relation to serious shortages in case of a 'no deal' Brexit

This amendment introduces a new regulation into the Human Medicines Regulation 2012 enabling Ministers to continue to make changes to the Human Medicines Regulation 2012 in relation to serious shortages caused by the UK's exit from the EU.

The Human Medicines Regulation are made under the European Communities Act. If the UK leaves the EU without a deal we can no longer make regulations under the European Communities Act which mean that we cannot amend the Human Medicines Regulations in the way that we have to date. We are therefore proposing a new regulation making power in the Human Medicines Regulations themselves, using powers under the EU Withdrawal Act 2018. That power will enable us to continue to amend the Human Medicines Regulations but only in relation to serious shortages as a consequence of Brexit and can be considered a safety valve. If we have to make changes to the legislation to support the supply chain in a 'no deal' scenario then we can do that.

This amendment will be progressed as part of the 'no deal' legislation which we expect to lay in Parliament in January 2019. Unlike the amendment to introduce the 'serious shortage protocol', this amendment will only be progressed in case the UK leaves the EU without a deal.

Question 2: Do you agree with the introduction of a regulation making power in relation to serious shortages in case of a 'no deal' Brexit?

Impact assessment

We expect that a 'serious shortage protocol' would have an impact on pharmacists and GP and on patients:

- There will be a positive impact on pharmacists and GPs who will save time and resource by not having to liaise with each other for each individual patient that has been prescribed a medicine for which a protocol is available.
- There will be a positive impact on patients who continue to have (quick) access to treatment.

We have not yet quantified the impact.

Equality impact assessment

We expect that both proposals will help secure the continuity of supply of medicines and allow patients, including those with protected characteristics, continued access to medicines.

Question 3: Do you have views on the principles outlined above, which are informing our assessment of impacts?

Draft regulations

The draft regulations have been attached to this email. New regulation 226A covers the 'national shortage protocol' and new regulation 344B covers the regulation making power in a 'no deal' situation.

Please note that whilst the two amendments have been included in the same draft Statutory Instrument, they will be taken forward in separate Statutory Instruments. New Regulation 344B will only be progressed in case of a 'no deal' whereas regulation 226A will be progressed anyway.

Question 4: Do you have comments on the draft provisions?

Please send your responses to the questions or any other comments to me **by close on 12 December 2018**.

If you have any questions, please do not hesitate to contact me.

Kind regards,
Sandor

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