MEDICINES AND MEDICAL DEVICES BILL

Supplementary Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee

CONTENTS

A. SUMMARY OF THE ADDITIONAL DELEGATED POWER

The following power is contained in the amendments tabled by the Government on 16 June 2020.

POWER	JUSTIFICATION	SCRUTINY
Clause X[1]: Information Systems Power to make provision about the establishment and operation of information systems for purposes relating to medical devices.	This delegated power can be used to create and further develop information systems for the purposes of enabling information on medical devices to be analysed and tracked. Making provision for information systems in secondary legislation will enable those systems to be developed over time so that they can react to changes in technology and respond to any emerging safety concerns that the systems can help address.	Affirmative

[1] The clause would be inserted after clause 15. For the purposes of this document, it is referred to as "clause X".

B: ANALYSIS OF ADDITIONAL DELEGATED POWERS

Clause X: Information Systems

Power conferred on: Secretary of State

Power exercised by: Regulations made by statutory instrument

Parliamentary Procedure: Affirmative

Context and Purpose

1. Clause X provides for a delegated power to establish and operate one or more information systems. The power specifies that the Health and Social Care Information Centre (HSCIC) (a body established under section 252 of the Health and Social Care Act 2012) will establish and operate the system(s). The purpose of this power is to enable information on medical devices to be obtained, analysed, used and disseminated by the HSCIC. The information can include information about devices used to treat private patients.

2. The power (apart from one exception – see clause X(6)(a)) may only be exercised for one or more of three specified purposes: the safety and performance of medical devices, the safety of individuals treated with medical devices, and improving medical device safety and performance through advances in technology.

Justification for taking the power

3. The intention is that the information system or systems created under this power will be developed over time, perhaps initially starting to record information in relation to a small sub-set of medical devices (for example higher risk devices) and then expanding in scope to cover other types of devices in future stages. Any expansion will follow consultation with stakeholders and be guided by advances in technology and emerging safety risks where more effective monitoring of device safety and performance through an information system will mitigate risks to patient safety. Enabling provision to be made in secondary legislation means that any information system can be updated to reflect collaboration with existing and future clinical registries so that processes for data collection remain streamlined, avoid duplication and reduce the burden on organisations providing the data. Future amendments to the secondary legislation governing the operation of any information system will ensure that the system remains as effective as possible at monitoring the safety of medical devices. For these reasons it is appropriate for these provisions to be set out in secondary legislation.

Justification for the procedure

4. As with other powers in this Bill this power is subject to the affirmative procedure. We consider this to be the correct procedure for a provision of this sort where the subject matter is new, where there are a number of potential stakeholders with an interest and where any future changes could be of significant interest to Parliament.

Example of how the power could be used

5. This power can be used to establish an information system in relation to high-risk, implanted medical devices such as heart stents, pacemakers and breast implants. The system could record the unique identifier of a device, alongside information about the patient and the clinical procedure used.

6. Clause X(2) sets out four possible matters for which provision may be made under the power. Clause X(3)-(6) further elaborate, in relation to each of those matters, on the sort of specific provision the regulations could make.

7. In relation to the descriptions of information which may or must be entered into the information system (clause X(2)(a)) the sort of matters which might need to be set out and defined in regulations are:
    a. The type of data needed to identify the device: unique identifiers, serial numbers, batch numbers, lot numbers;
    b. The information needed about the patient treated with the device;
    c. The information needed about the operation or procedure carried out in relation to the device.

8. In relation to requirements to provide information for the purposes of the information system (clause X(2)(b)) the sort of matters which might be set out in the regulations are:
    a. The people or bodies who can be required to provide information: these may be NHS bodies but also private hospitals or clinics or third sector bodies operating in the health sphere;
    b. The timescale for providing information and the manner in which the information can or must be provided;
    c. The regulations could also make provision for ensuring that the HSCIC is required to consider that, where it has relevant information under its powers under the Health and Social Care Act 2012, the information is not collected again for purposes of the information system.

9. In relation to the use and disclosure of information (clause X(2)(c)) the sort of matters which might be set out in the regulations are:
    a. The nature of any analysis carried out on the information: what steps must be taken before analysis is carried out, what the outcome of that analysis should be e.g. descriptive, predictive or prescriptive models relevant to the three purposes governing the exercise of the power or for any relevant secondary purposes;
    b. The disclosure of the information contained in the information system;
    c. What other uses the information might be put to, such as linking with existing databases or future databases.