Medicines and Medical Devices Bill

AMENDMENTS

TO BE MOVED

IN GRAND COMMITTEE

Clause 1

BARONESS CUMBERLEGE
LORD PATEL

Page 1, line 9, at end insert "as the overriding consideration"

Member's explanatory statement
The purpose of this amendment is to ensure that patient safety is the overriding purpose of the Bill.

Clause 3

LORD CLEMENT-JONES

Page 2, line 41, at end insert "subject to subsection (1A)"

Member's explanatory statement
This amendment is a paving amendment for the amendment also in the name of Lord Clement-Jones to page 2, line 41.

Page 2, line 41, at end insert—

"(1A) Within 6 months of this Act coming into force, the Secretary of State must—

(a) consult with the pharmaceutical and pharmacy community on an agreed framework outlining the use, retention and disclosure of information collected for the purpose of preventing the supply of falsified human medicines; and

(b) lay a copy of the agreed framework before Parliament."

Member's explanatory statement
This amendment seeks to avoid unintended consequences as a result of data being used for purposes other than to ensure that medicines are safe, and therefore would require a framework for data use to be agreed in consultation with the pharmaceutical industry.

Clause 13

BARONESS FINLAY OF LLANDAFF

Page 7, line 37, at end insert—

"(iii) requirements about notification and reporting requirements in relation to clinical investigations undertaken to assess the safety or performance of a device,"

Member's explanatory statement
This amendment creates a power for the Secretary of State to make regulations about clinical investigations, using the definition presently operating in EU Regulation on Medical Devices 2017/745. The amendment allows discussion of medical device trials being registered on a publicly accessible database within six weeks, as is present practice for medicine trials.

Page 8, line 11, after "and" insert "unique device identification,"

Member's explanatory statement
This amendment seeks to raise the issue of tracking of medical devices. Coupled with amendments by Baroness Finlay to page 8, line 17 and page 10, line 20, it would allow regulations to provide for the tracking of all devices via a Unique Device Identifier, as they are used, with the information recorded either in registries or through hospital episode statistics data.

Page 8, line 15, after "maintaining" insert ", and ensuring expert oversight of,"

Member's explanatory statement
This amendment would raise the issue of expert panels overseeing registries, able to identify the right data points and to monitor both outlier performance and broad trends from the information a registry comes to contain.

Page 8, line 17, leave out from first "to" to end of line 18 and insert "the use of medical devices in individual procedures to be tracked and entered in a register, or within hospital episode statistics data, and"

Member's explanatory statement
This amendment seeks to raise the issue of tracking of medical devices. Coupled with amendments by Baroness Finlay to page 8, line 11 and page 10, line 20, it would allow regulations to provide for the tracking of all devices via a unique device identifier, as they are used, with the information recorded either in registries or through hospital episode statistics data.

BARONESS FINLAY OF LLANDAFF
LORD HUNT OF KINGS HEATH

Page 8, line 27, at end insert—

"( ) The provision mentioned in subsection (1)(b) may include provision for the development of a rapid provisional 2-year licensing procedure."

Clause 16

BARONESS FINLAY OF LLANDAFF

Page 9, line 18, leave out "may" and insert "must"

Member's explanatory statement
This amendment is designed to seek assurances from the Minister that the Government will proceed to make regulations under the Bill, setting up the new information system envisaged by Clause 16.

Page 9, line 28, leave out "may" and insert "must"

Member's explanatory statement
This amendment seeks to make the list of specified issues for the regulations to cover mandatory.

Page 9, line 37, at end insert—

"( ) requiring that information about every medical device implanted in the human body is entered and retained in an information system established under subsection (1);

( ) requiring that information about the use of other medical devices as may be necessary for the protection of patient safety is entered and retained in an information system established under subsection (1);

( ) establishing a mechanism for patients to enter reports of their experience following the use of any medical device in their treatment, requiring that this information be retained in any relevant information system established under subsection (1)."

Member's explanatory statement
This amendment mandates inclusion in the information system all medical devices implanted in the human body and the use of other medical devices as necessary for the protection of patient safety. The amendment additionally requires that patients should have a direct route to report their experience into any information system established under this section

Page 9, line 37, at end insert—

"( ) establishing a mechanism for patients to enter reports of their experience following the use of any medical device in their treatment, to be retained in any relevant information system established under subsection (1),"

Member's explanatory statement
The amendment requires that patients should have a direct route to report their experience into any information system established under this section.

Page 10, line 20, leave out "may" and insert "must"

Member's explanatory statement
This amendment seeks to strengthen the provisions of this Clause in relation to unique identifiers on medical devices, mandating, rather than permitting, their inclusion in the registration system set up by Clause 16.

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8 September 2020
