

# Medicines and Medical Devices Bill

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AMENDMENT  
TO BE MOVED  
ON REPORT

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**After Clause 40**

BARONESS CUMBERLEGE

Insert the following new Clause—

**“Independent Patient Safety Commissioner**

- (1) An independent Patient Safety Commissioner is established.
- (2) The Office of Patient Safety is to be hosted and funded by the Cabinet Office.
- (3) The Patient Safety Commissioner must publish a business plan, reviewed annually, which sets out, in relation to the discharge of the Commissioner’s functions—
  - (a) the Commissioner’s proposed main activities for the period covered by the plan (including the matters he or she intends to consider or investigate), and
  - (b) the Commissioner’s proposed strategic priorities for that period.
- (4) The Patient Safety Commissioner must appoint an advisory board to provide the Commissioner with advice and assistance relating to the discharge of his or her functions, consisting of persons who (taken together) represent a broad range of interests which are relevant to the Patient Safety Commissioner’s functions, and must from time to time publish a report on the procedure followed and the criteria used when making appointments to the advisory board.
- (5) The Commissioner’s functions are to—
  - (a) promote and improve patient safety with respect to the use of medicines and medical devices;
  - (b) promote the views and interests of patients and other members of the public in relation to the safety of medicines and medical devices;
  - (c) make recommendations to the Secretary of State;
  - (d) establish and, when deemed appropriate, revise Principles of Better Patient Safety;

**After Clause 40 - continued**

- (e) receive direct reports from patients and other members of the public, any other persons (whether natural or corporate), and the Secretary of State and, when the Commissioner deems appropriate, share those reports with relevant organisations and the Secretary of State;
  - (f) produce and lay before Parliament for the attention of any committees of either House whose remit covers medicines and medical devices—
    - (i) an Annual Report and Accounts, and
    - (ii) any other reports regarding patient safety, which may include recommendations to improve patient safety with respect to the use of medicines and medical devices.
- (6) For the purposes of subsection (5)(d), the Principles of Better Patient Safety must—
- (a) describe expected patient safety outcomes relating to the safety of medicines and medical devices; and
  - (b) be drafted in consultation with the public.
- (7) For the purposes of subsection (5)(f), the Commissioner may require a public body and other persons (whether natural or corporate) to provide such information as is reasonable in order to fulfil that function relating to the safety of medicines and medical devices.
- (8) In fulfilling his or her functions, the Commissioner may do anything which appears to be necessary or expedient for the purpose of, or in connection with, the performance of his or her functions.
- (9) The Commissioner has the duty to involve and inform patients and other members of the public in carrying out his or her functions.
- (10) The Commissioner may make recommendations to the Minister for the Cabinet Office for any additional powers which the Commissioner considers may be necessary to fulfil the duties and functions under this section.
- (11) The Minister for the Cabinet Office may by regulations make any other provision relating to the establishment of the Commissioner, including—
- (a) the appointment of a Commissioner,
  - (b) the terms of office,
  - (c) remuneration and financial and other assistance,
  - (d) staff, and
  - (e) any other matters the Minister for the Cabinet Office considers appropriate.
- (12) A statutory instrument containing regulations under this section may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.”

***Member’s explanatory statement***

*This new Clause would establish the Patient Safety Commissioner on a statutory basis, as recommended in the report of the Independent Medicines and Medical Devices Safety Review.*

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*25 November 2020*

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