

# Safety of Medicines Bill

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**B I L L**

TO

Make provision about methods of testing the safety of medicines; and for connected purposes.

**B**E IT ENACTED by the Queen’s most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

**1 Medicines Safety Evaluation Panel**

- (1) The Secretary of State must, within six months of the date on which this Act is passed, appoint a Medicines Safety Evaluation Panel (“the Panel”).
- (2) The members of the Panel are to be appointed by the Secretary of State and must include no fewer than six members of the National Institute for Health Research. 5
- (3) The Secretary of State may nominate one of the members of the Panel to act as chairman.
- (4) The Secretary of State must, in appointing members to the Panel, take steps to ensure that no members appointed have any commercial or other interests which may conflict with their duties on the Panel. 10
- (5) *The Secretary of State may make payments to the chairman of the Panel by way of remuneration and make payments to him and other members of the Panel in respect of expenses incurred by them in the performance of their duties.*
- (6) The Panel shall cease to exist after it has reported to the Secretary of State under section 2(6). 15

**2 Duty of the Panel**

- (1) The Panel must conduct a review of methods of testing the safety of medicines.
- (2) The review must comprise a comparison of the effectiveness of—
  - (a) human biology-based tests, and 20
  - (b) animal-based tests.

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- (3) The medicines to be tested in accordance with section 2(2) must have –
- (a) been licensed for marketing by the appropriate regulatory authority or have been authorised to enter clinical trials,
  - (b) been withdrawn from sale or never marketed on grounds of safety, and
  - (c) collectively caused a range of adverse reactions. 5
- (4) The Panel must commission bodies which it considers appropriate to conduct those human biology-based tests it regards necessary for the purposes of conducting the review.
- (5) In determining the types of test to be conducted for the purposes of subsection (2)(a), the Panel shall have regard to the desirability of using all available technologies, including – 10
- (a) computer simulations,
  - (b) tests involving human cells, tissues and DNA, and
  - (c) early clinical tests on volunteers.
- (6) The Panel must send the Secretary of State a report on its review within two years of the date of its appointment. 15
- (7) The Secretary of State must publish the report, save that in doing so he may take such steps as he considers necessary to protect commercially confidential information.
- (8) In this section – 20
- “animal-based tests” means those tests required by Directives 2004/27/EC and 2003/63/EC;
  - “early clinical tests” means tests involving minuscule levels of exposure to the product;
  - “human biology-based tests” means tests dependent on human biological material and data. 25
- 3 Duty of Medicines and Healthcare products Regulatory Agency**
- The Medicines and Healthcare products Regulatory Agency must provide, on request, all information it holds relating to the testing of products which the Panel requires in pursuance of its duty to conduct a comparison of tests under section 2(2). 30
- 4 Financial provisions**
- There shall be paid out of money provided by Parliament any expenses of the Secretary of State under this Act.*
- 5 Short title and extent** 35
- (1) This Act may be cited as the Safety of Medicines Act 2011.
  - (2) This Act extends to England and Wales, Scotland and Northern Ireland.

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## B I L L

To make provision about methods of testing the safety of medicines; and for connected purposes.

*Ordered to be brought in by Mr David Amess,  
Mr Peter Bone, Peter Bottomley,  
Karen Bradley, Jackie Doyle-Price,  
Paul Flynn, Mr Mike Hancock,  
Dr Julian Huppert, Caroline Lucas,  
Grahame M. Morris, Mark Pawsey  
and Bob Russell.*

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*Ordered, by The House of Commons,  
to be Printed, 20 July 2010.*

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