

Safety of Medicines (Evaluation) Bill

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TO

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

BE 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— 5
 - (a) no fewer than two statisticians from the Office for National Statistics, and
 - (b) no fewer than eight members of the National Institute for Health Research.
- (3) The Secretary of State may nominate one of the members of the Panel to act as chairman. 10
- (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.
- (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.* 15
- (6) The Panel shall cease to exist after it has reported to the Secretary of State under section 2(7).

2 Duty of the Panel 20

- (1) The Panel must conduct a review of methods of testing the safety of medicines and drugs.

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- (2) The review must comprise a comparison of the effectiveness of –
- (a) human biology-based tests, and
 - (b) animal-based tests.
- (3) The medicines or drugs considered in the comparison of tests must include products – 5
- (a) designed to treat a wide range of disease types, and
 - (b) which have been licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) or Medicines Control Agency (MCA).
- (4) Some of the products considered in accordance with subsection (3) must have been withdrawn from sale or use on grounds of safety. 10
- (5) 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.
- (6) 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 – 15
- (a) computer simulations,
 - (b) tests involving human cells, tissues and DNA, and
 - (c) early clinical tests on volunteers.
- (7) The Panel must send the Secretary of State a report on its review within two years of the date of its appointment. 20
- (8) 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.
- (9) In this section – 25
- “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. 30
- 3 Duty of MHRA**
- The MHRA 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). 35
- 4 Expenses**
- There shall be paid out of money provided by Parliament any expenses of the Secretary of State under the Act.*
- 5 Short title and extent**
- (1) This Act may be cited as the Safety of Medicines (Evaluation) Act 2009. 40
- (2) This Act extends to England and Wales, Scotland and Northern Ireland.

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*Presented by Dr Ian Gibson
supported by
Mr Mike Hancock and Mr David Amess.*

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