Off-patent Drugs Bill

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Require the Secretary of State to take steps to secure licences for off-patent drugs in new indications; to require the National Institute for Health and Care Excellence to conduct technology appraisals for off-patent drugs in new indications; 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:—

PART 1

LICENSING OF EXISTING OFF-PATENT DRUGS

1 Duty of the Secretary of State to take steps to secure a licence for off-patent drugs in new indications

(1) The Secretary of State shall make an application for a licence where—

(a) an off-patent drug is licensed for a particular therapeutic indication; and

(b) there is a new indication for the same off-patent drug; and

(c) that indication is not permitted under the licence; and

(d) no other organisation has already undertaken to seek a licence for the new indication; and

(e) such requirements as may be set out in regulations made under section 3 of this Act have been met.

(2) In this section "an application" means an application for the appropriate licence under the Human Medicines Regulations 2012, and all reasonable steps preparatory to making such an application.

(3) An application under this section must be made within six months of the Secretary of State becoming aware of, or being notified of, the existence of the criteria in subsection (1) above.

2 Exercise of Secretary of State's duty to take steps to secure a licence for off-patent drugs in new indications

(1) The Secretary of State may require a body specified in section 2(2) to exercise those of the Secretary of State's functions under section 1 of this Act as the Secretary of State may direct.

(2) Those bodies are—

(a) the Health Research Authority; or

(b) such other public body as may be prescribed by regulations made under this Act.

(3) Powers under this section may be exercised on such terms as may be agreed by the Secretary of State, including terms as to payment.

3 Regulations as to the exercise by the Secretary of State of the duty to take steps to secure licences for off-patent drugs

(1) The Secretary of State shall make regulations imposing requirements in accordance with this section on the Secretary of State and/or any body to whom the Secretary of State has delegated the Secretary of State's functions under section 2 of this Act.

(2) Regulations made under this section may specify further requirements that would need to be met before a licence is sought for off-patent drugs in new indications.

PART 2

PROVISIONS RELATING TO CONDUCTING NICE TECHNOLOGY APPRAISALS FOR OFF-PATENT DRUGS

4 Duty of the Secretary of State to direct NICE technology appraisals for off-patent drugs

(1) Where there is a new indication for an off-patent drug that meets such minimum requirements as shall be identified in regulations made under section 5 of this Act, the Secretary of State shall direct NICE to conduct a technology appraisal in relation to that drug for that indication.

(2) The Secretary of State's duty under subsection (1) shall apply notwithstanding whether the off-patent drug is licensed or unlicensed.

(3) Sections 4 to 6 of this Act apply only in circumstances where the Secretary of State's duty under section 1 of this Act does not apply.

5 Regulations relating to NICE technology appraisals

(1) Regulations shall establish the circumstances under which the Secretary of State shall require NICE to conduct a technology appraisal for off-patent drugs in new indications.

(2) Before making regulations under subsection (1), the Secretary of State shall consult such persons or organisations as appear to the Secretary of State to be representative of interests likely to be substantially affected by the regulations.

6 NICE technology appraisal recommendations

(1) Where a NICE technology appraisal recommendation is made following a direction under section 4 of this Act, NICE shall recommend that relevant health bodies provide funding within a specified period to ensure that the drug be made available for the purposes of treatment of patients.

(2) NICE shall specify in a technology appraisal recommendation the period within which subsection (1) must be complied with by relevant health bodies.

(3) The period in subsection (2) must be a period that begins on the date the recommendation is published by NICE and ends on the date 3 months from that date, unless NICE specifies otherwise.

(4) A relevant health body must comply with a technology appraisal recommendation.

PART 3

GENERAL PROVISIONS

7 Annual report

(1) As soon as practicable after the end of each financial year, the Secretary of State shall publish an annual report on the steps taken in the exercise of the Secretary of State's duties under this Act.

(2) The Secretary of State shall lay the annual report before Parliament.

8 Regulations

(1) Any power to make regulations under this Act is exercisable by statutory instrument.

(2) No instrument containing regulations under this Act is to be made unless a draft has been laid before Parliament and approved by a resolution of each House.

(3) The first regulations under this Act are to be laid no later than the end of the period of four months beginning with the date specified in section 10(2) of this Act.

9 Interpretation

In this Act—

"drug" shall be interpreted to include any "medicinal product" within the meaning of the Human Medicines Regulations 2012 and any "health technology" within the meaning of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013;

"Health Research Authority" has the same meaning as in Part 3 of the Care Act 2014;

"indication" is the clinical use to which a drug is put. It denotes the appropriate therapeutic treatment for a given condition, the route of administration and the dose in relation to a specific patient population;

"licence" has the meaning given to "marketing authorisation" in regulation 8(1) of the Human Medicines Regulations 2012;

"NICE" means the National Institute for Health and Care Excellence, established under section 232 of the Health and Social Care Act 2012;

"off-patent drug" means a drug whose patent has expired or is not subject to an extended marketing protection period;

"relevant health body" has the same meaning as in regulation 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

10 Extent, commencement and short title

(1) This Act extends to England and Wales, Scotland and Northern Ireland, save for sections 4 to 6 which apply to England and Wales only.

(2) This Act comes into force on the day following Royal Assent.

(3) This Act may be cited as the Off-patent Drugs Act 2014.

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