A Bill [as amended in Standing Committee C] to provide for the compilation and disclosure of information about medicinal products and related matters, subject to certain restrictions, to amend the Medicines Act 1968, and for connected purposes.

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Medicines Information Bill

[AS AMENDED IN STANDING COMMITTEE C]

ARRANGEMENT OF CLAUSES

Clause

A

BILL

[AS AMENDED IN STANDING COMMITTEE C]

TO

Provide for the compilation and disclosure of information about medicinal products and related matters, subject to certain restrictions; to amend the Medicines Act 1968; and for connected purposes. A.D. 1993.

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. In this Act— Interpretation.

"the 1968 Act" means the Medicines Act 1968; 1968 c. 67.

"animal test certificate" has the same meaning as in section 32(2)(b) of the 1968 Act;

"applicant" means a person making an application under sections 3 or 4 below;

"application" means an application in writing;

"clinical trial" has the same meaning as in section 31 of the 1968 Act;

"clinical trial certificate" has the same meaning as in section 31(3)(b) of the 1968 Act;

"commercial interest" has the meaning assigned to it by section 5(6) of this Act;

"Commission" means the Medicines Commission established under section 2 of the 1968 Act;

"committee" means a committee established under section 4 of the 1968 Act;

"the index" means the index referred to in section 2 below;

"licence of right" has the same meaning as in section 25(4) of the 1968 Act;

"the licensing authority" has the same meaning as in section 6(3) of the 1968 Act;

"medicinal product" has the same meaning as in section 130(1) of the 1968 Act and includes any substance to which, by virtue of an order under section 105(1) of the 1968 Act, any requirement of that Act applies;

"the Ministers" has the same meaning as in section 1(1) of the 1968 Act;

"product licence" has the same meaning as in section 7(2) of the 1968 Act;

"record" includes information recorded in written, printed, electronic or machine readable form or in the form of a film, photograph, videotape or sound recording;

"the relevant authorities" are the licensing authority, any committee established under section 4 of the 1968 Act, the Commission and any person acting as an agent for any of those authorities; and

"relevant person" has the meaning assigned to it by section 3(7) of this Act.

Duty to maintain an index.

2.—(1) Each of the Ministers shall maintain an index identifying—

(a) any product licence, licence of right, clinical trial certificate, clinical trial exemption certificate or animal test certificate which is in force or which has been in force since the date of commencement of this Act;

(b) any information of a kind referred to in paragraphs (b) to (f) of section 3(1) below which refers to a product which is the subject of a product licence or licence of right which is, or which since the date of commencement of this Act has been, in force;

(c) any other information of a kind referred to sections 3(1) or 3(5) below which is available in accordance with the requirements of those sections;

(d) in respect of any conviction for an offence under Part II of the 1968 Act, the name of the person convicted, the provision of the Act which was contravened, particulars of the offence and the penalty imposed by the court;

(e) the classes of information to which access may be given under section 4(1) of this Act.

(2) Each of the Ministers shall make the index required by this section available at all reasonable times for inspection by the public.

(3) The index required by this section may be held in any form.

Access to information.

3.—(1) Subject to the provisions of section 4 below the Ministers shall make available to any person on request a copy of—

(a) any product licence or licence of right which is, or since the date of commencement of this Act has been, in force;

(b) in the case of a product licence which was granted after the date of commencement of this Act, a summary and evaluation of the information relating to the safety, quality and efficacy of the product which was considered by the relevant authorities (whether or not it was relied on by them) before the granting of that licence;

(c) in the case of a product licence which has been suspended, varied or revoked after the date of commencement of this Act, a summary and evaluation of the information which led the relevant authorities to take such action;

(d) in the case of a product licence which the licensing authority has, after the date of commencement of this Act, proposed to suspend, vary or revoke, a copy of any notice given to, together with any representations made by, the holder of a licence in relation to such a proposal in accordance with Schedule 2 to the 1968 Act and any report of the Commission or of a committee referred to in that Schedule;

(e) any advice given by, or the recommendation of, the Commission under section 3 of the 1968 Act;

(f) any advice given by a committee established under section 4 of the 1968 Act;

(g) any order made under section 62(1) of the 1968 Act;

(h) any proposals which are or have been the subject of consultation under section 129(6) of the 1968 Act and any response received from any organisation consulted under that section;

(i) any report of an inspection carried out under section 112 of the 1968 Act, the results of the analysis of any sample taken under that section and any representations made to the licensing authority in writing in relation to the report or results by the person at whose premises the inspection was carried out or the sample was taken;

(j) any reports of suspected adverse reactions experienced by persons to whom a licensed product has been administered.

(2) Where representations of the kind referred to in paragraph (i) of subsection (1) above have been received by the relevant authorities, in relation to any report of results of the kind referred to in that paragraph, a copy of those representations shall be made available when supplying a copy of the report or results to any person under that section.

(3) No information of a kind referred to in paragraph (d) of subsection (1) above shall be made available under that subsection until the licensing authority has determined whether it will suspend, vary or revoke the licence in question.

(4) The provisions of paragraphs (e) to (i) of subsection (1) above shall not apply in respect of any advice, recommendation, order, proposal, inspection or sample which was (as the case may be) given, made, issued or taken before the date of commencement of this Act.

(5) The information specified in subsection (1) above shall be required to be made available only in relation to a product which is, or which at any time since the date of commencement of this Act was, offered for sale, supply or export by a relevant person.

(6) Where information specified in paragraphs (e) and (f) of subsection (1) above refers to a product for which an application for a licence has been made the information shall not be required to be made available until a licence for that product has been granted and the product has been made available for sale, supply or export by a relevant person.

(7) For the purposes of subsections (5) and (6) above, "relevant person" means a person who holds or has held or who is or was required to hold a product licence, a manufacturer's licence or wholesale dealer's licence within the meanings of sections 7(2), 8(2) and 8(3) respectively of the 1968 Act.

Restrictions on the provision of information.

4.—(1) No information shall be made available under this Act which would identify or lead to the identification of—

(a) any individual to whom a medicinal product has been administered; or

(b) any person who has made a report to the relevant authorities concerning any such individual; or

(c) any individual who has carried out any test involving the administration of a product, substance or article to animals;

unless that individual or person is the applicant or has consented to the information being made available to the applicant.

(2) No information about—

(a) a manufacturing process, or any equipment, raw material or component used in that process (including the specifications for any such equipment, material or component or the methods of determining whether those specifications have been achieved);

(b) the identity of, or any information concerning, a product under development;

shall be made available under this Act if the acquisition of that information by a person having a commercial interest would prejudice to an unreasonable degree the commercial interest of the person from whom the information was obtained or to whom it relates.

(3) For the purposes of subsection (2) above a "product under development" means a product in a form which is not and has not been the subject of a product licence or a licence of right but does not mean a product, substance or article to which the provisions of section 3(5) above apply.

(4) The Ministers shall determine whether information is of a description to which the provisions of this section apply and, for the purposes of a determination under subsection (2) above, the burden of proving that the information is of the description mentioned in that subsection shall be on the person from whom the information was obtained or to whom it relates.

Giving of access.

5.—(1) The index which is required to be maintained under section 2 above and any information which is required to be made available under section 3 above shall, at the request of the applicant, be made available in either or both of the following ways—

(a) by making it available for inspection by the applicant without charge;

(b) by supplying a copy of it (or, in the case of the index, a copy of entries from it) to the applicant, for which a reasonable charge which shall not exceed the cost of making and, where applicable, posting it to the applicant may be made.

(2) Information which is made available under section 4(1)(a) above shall be so made available without charge.

(3) Where an extract of information is supplied under section 4(1)(b) above a reasonable charge, which shall not exceed the cost of making and, where appropriate, posting the extract to the applicant may be made.

(4) Any information which is required to be made available to any person under this Act shall be made available as soon as practicable and in any case within the specified period.

(5) For the purpose of subsection (4) above the specified period—

(a) in any case to which the provisions of section 4(3) above apply is six weeks from the date on which the application was made;

(b) in any other case is four weeks from the date on which the application was made.

Amendment of 1968 Act.

6.—The following section shall be substituted for section 118(1) of the 1968 Act—

"118—(1) If any person discloses to any other person any trade secret which has been obtained by him in premises which he has entered by virtue of section 111 of this Act or which has been obtained by or furnished to him in pursuance of this Act he shall be guilty of an offence unless—

(a) the information was disclosed in accordance with the provisions of the Medicines Information Act 1993, or

(b) the disclosure was made in the performance of his duty, or

(c) the disclosure was made or authorised by a Minister in the public interest.

(1A) For the purposes of this section a "trade secret" means information about—

(a) a manufacturing process, or

(b) the results of any investigation into the properties of a product under development, or

(c) the specifications and composition of any product under development,

if the acquisition of that information by a person having a commercial interest would prejudice to an unreasonable degree the commercial interest of the person from whom the information was obtained or to whom it relates.

(1B) In this section "commercial interest" has the same meaning as in section 5(6) of the Medicines Information Act 1993 and "product under development" has the same meaning as in section 4(3) of that Act.".

Financial provisions.

7.—(1) The Ministers, when determining the amount of fees to be prescribed by regulations under section 1(1) of the Medicines Act 1971 (fees for applications for or in respect of licences etc. under Part II of the Medicines Act 1968), may take into account, in addition to any other matters that they are authorised to take into account, the costs of the performance of their functions under this Act.

(2) Any sums received by a Minister of the Crown under this Act shall be paid into the Consolidated Fund.

Short title, commencement, and extent.

8.—(1) This Act may be cited as the Medicines Information Act 1993.

(2) This Act shall come into force on 1 September 1993.

(3) This Act extends to Northern Ireland.

Medicines Information

A BILL

[AS AMENDED IN STANDING COMMITTEE C]

To provide for the compilation and disclosure of information about medicinal products and related matters, subject to certain restrictions; to amend the Medicines Act 1968; and for connected purposes.

Presented by Mr Giles Radice,
supported by
Hilary Armstrong, Mr Alistair Darling, Mr Nick Raynsford, Mr Chris Smith, Mr Archy Kirkwood, Mr Jeff Rooker, Sir Richard Body, Mr Jack Thompson and Tessa Jowell

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