Rare Cancers Bill

[AS BROUGHT FROM THE COMMONS]

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[AS BROUGHT FROM THE COMMONS]

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B I L L

TO

Make provision to incentivise research and investment into the treatment of rare types of cancer; and for connected purposes.

BE IT ENACTED by the King'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 Review of law on marketing authorisations

(1) The Secretary of State must—

(a) carry out a review of the law relating to marketing authorisations for orphan medicinal products that are for the diagnosis, prevention or treatment of cancer, and

(b) prepare and publish a report setting out the conclusions of the review.

(2) In carrying out the review the Secretary of State must, in particular, consider regulatory approaches in other countries.

(3) The report must be published before the end of the period of three years beginning with the day on which this Act is passed.

(4) The Secretary of State must lay a copy of the report before Parliament.

(5) In this section—

"Human Medicines Regulations" means the Human Medicines Regulations 2012 (S.I. 2012/1916);

"marketing authorisation" has the meaning given by section 9 of the Medicines and Medical Devices Act 2021;

"medicinal product" has the meaning given by regulation 2 of the Human Medicines Regulations;

"orphan medicinal product" means a medicinal product in relation to which the orphan criteria set out in regulation 50G(2) of the Human Medicines Regulations are met.

2 Secretary of State's duties as to research

In section 1E of the National Health Service Act 2006 (Secretary of State's duty to facilitate research etc)—

(a) the existing text becomes subsection (1);

(b) after that subsection insert—

"(2) The research that the Secretary must facilitate or otherwise promote under subsection (1)(a) includes research into cancers that in the opinion of the Secretary of State are rare cancers.

(3) In discharging the duty under subsection (1)(a) in relation to those cancers, the Secretary of State must, in particular, ensure that there are such arrangements in place as the Secretary of State considers appropriate to—

(a) enable potential participants in clinical trials to be identified and contacted, and

(b) ensure that a person (to be known as "the National Specialty Lead for Rare Cancers") is appointed with a job description that includes promoting and facilitating research into rare cancers by—

(i) providing advice in relation to the design and planning of research, and

(ii) facilitating collaboration between interested persons.

(4) In this section "rare cancer" means a cancer that affects not more than 1 in 2000 people in the United Kingdom."

3 Disclosure of information for research purposes

(1) Section 261 of the Health and Social Care Act 2012 (power of NHS England to disclose information obtained in connection with information systems) is amended as follows.

(2) In subsection (5), after paragraph (d) insert—

"(da) the disclosure is made for the purpose of facilitating the carrying out of relevant clinical trials (whether or not in the United Kingdom) by enabling potential participants in those trials to be identified and contacted,".

(3) After subsection (5) insert—

"(5A) In subsection (5)(da) "relevant clinical trials" means clinical trials in connection with the research and development of orphan medicinal products for the diagnosis, prevention or treatment of cancers that in the opinion of NHS England are rare cancers; and for this purpose—

"orphan medicinal product" means a medicinal product in relation to which the orphan criteria set out in regulation 50G(2) of the Human Medicines Regulations 2012 (S.I. 2012/1916) are met;

"rare cancer" means a cancer that affects not more than 1 in 2000 people in the United Kingdom."

(4) After subsection (6) insert—

"(6A) A power conferred by this section to process information does not authorise the processing of information which would contravene the

data protection legislation (but the power is to be taken into account in determining whether the processing would contravene that legislation).

(6B) In subsection (6A) "the data protection legislation" and "processing" have the same meanings as in the Data Protection Act 2018 (see section 3 of that Act)."

4 Extent

(1) Sections 2 and 3 extend to England and Wales only.

(2) The remainder of this Act extends to England and Wales, Scotland and Northern Ireland.

5 Commencement

This Act comes into force at the end of the period of two months beginning with the day on which it is passed.

6 Short title

This Act may be cited as the Rare Cancers Act 2025.

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