

EXPLANATORY NOTES

Rare Cancers Act 2026

Chapter 8

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RARE CANCERS ACT 2026

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Rare Cancers Act 2026 which received Royal Assent on 5 March 2026 (c. 8).

- These Explanatory Notes have been provided by the Department of Health and Social Care, with the consent of Dr Scott Arthur MP in order to assist the reader in understanding the Act. They do not form part of the Act and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Act will mean in practice; provide background information on the development of policy; and provide additional information on how the Act will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Act. They are not, and are not intended to be, a comprehensive description of the Act.

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Overview of the Act

1 This Act is intended to support research and investment for rare cancers. The Act uses the definition of a rare disease consistent with that specified in The UK Rare Diseases Framework[1]: a condition which affects less than 1 in 2,000 people.

2 The Act specifically achieves this by:

a. Ensuring the Government publishes a review of the law relating to marketing authorisations for orphan medicinal products that are for the diagnosis, treatment or prevention of cancer. The review must consider regulatory approaches in other countries compared to the UK's approach. These relevant regulations are in Part 5 of the Human Medicines Regulations 2012.

b. Placing a duty on the Secretary of State for Health and Social Care in England in order to facilitate or otherwise promote research in relation to rare cancers, to ensure that appropriate arrangements are in place for ensuring patients can be easily contacted about research and that there is adequate oversight of research delivery for rare cancers.

c. Amending the Health and Social Care Act 2012 to ensure that patients with rare cancers can be easily contacted about relevant research and clinical trials, by allowing patient data in NHS England information systems to be disclosed for the purpose of enabling potential participants in those trials to be identified and contacted.

Policy background

3 This Act was introduced by Dr Scott Arthur MP in the House of Commons and Baroness Julie Elliott in the House of Lords.

4 There are different definitions for what is defined as a rare cancer. Some charities define this as, less than 6 in 100,000. However, for the purposes of the Rare Cancers Act, a rare cancer is defined in line with a rare disease i.e. defined as a condition which affects less than 1 in 2,000 people, as per The UK Rare Diseases Framework[1].

5 Research into treatments for rare cancers can be less appealing for companies than research into common conditions because the smaller patient population can make it more challenging to develop a sufficiently robust evidence base to satisfy regulators, as well as a small market limiting the return on their investments.

6 A disease registry is a collection of data about individuals who have a specific disease or condition. In England, the National Disease Registration Service collects and manages data on individuals diagnosed with cancer which is shared with NHS England through an opt-out process via a Secretary of State Direction[2].

7 A contact registry is a database that collects and stores information about individuals who are interested in participating in research. Unlike a disease registry, a contact registry helps researchers connect with potential study participants. The Be Part of Research (BPoR) registry is provided by the National Institute for Health and Care Research (NIHR) in England. It

[1] The UK Rare Diseases Framework, Department of Health and Social Care, Published 9 January 2021. Last Accessed 11/02/2025. [https://www.gov.uk/government/publications/uk-rare-diseases-framework/the-uk-rare-diseases-framework]

[2] National Disease Registries Directions 2021, Last Accessed 11/02/2025. [https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/national-disease-register-service-directions]

allows individuals across the UK who are interested in taking part in research to find studies – including clinical trials - that are relevant to them and sign up. Research teams are also able to recruit to studies via BPoR who contact those individuals who have signed up.

DHSC/NIHR Research Funding

8 The Department of Health and Social Care invests over £1.7 billion per year in research through the National Institute for Health and Care Research (NIHR) and NIHR research expenditure for all cancers was £133 million in 2023/24.

9 DHSC also funds NIHR infrastructure, which provides world-class research expertise, specialist facilities, a research delivery workforce and support services, which all help to support and deliver research across the NHS and wider health and care system. The NIHR Research Delivery Network (RDN) launched in 2024. Building on the success of the NIHR Clinical Research Network (CRN), its mission is to enable the health and care system to attract, optimise and deliver research across England.

10 In England, the NIHR currently has National Specialty Leads for research delivery within the Research Delivery Network (RDN). Their role is primarily to support research delivery in their discipline within health and care settings, with knowledge and experience of the full scope of the NIHR and the wider health and care delivery infrastructure in England. Working with patients, public, health and care professionals (including research and development communities within the NHS and wider care system), academics and life sciences partners, the National Specialty Leads aim to ensure strategic oversight and a focus on continuous improvement of the research delivery portfolio.

11 In September 2024, DHSC, through the NIHR, announced new investment in brain cancer research through a series of targeted calls designed specifically to help stimulate the research community, working with partners such as the Tessa Jowell Brain Cancer Mission to reach the broader community. The most significant element in this approach is the Brain Tumour Research Consortium[3] launched December 2025, a transformative new approach to bring together the research community to evaluate novel therapies and treatments.

12 DHSC published a National Cancer Plan on 4 February 2026 that includes a chapter on 'Rare and less common cancers' which references the Government implementing this Act.

Orphan Drugs and Designation

13 An Orphan Drug is a pharmaceutical developed for a rare disease. The MHRA published guidance on orphan medicinal products on 31 December 2020.

14 The MHRA is responsible for reviewing applications from companies for orphan designation at the time of a marketing authorisation application (MAA). There is no orphan designation step prior to application for a marketing authorisation in the UK.

15 To qualify for orphan designation, a medicine must meet the following criteria:

a. it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating.

b. the prevalence of the condition in UK must not be more than 5 in 10,000, or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development.

[3] https://www.nihr.ac.uk/news/nihr-launches-ps137m-investment-brain-tumour-research

c. no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists in UK or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

16 Satisfactory methods may include authorised medicinal products, medical devices or other methods of diagnosis, prevention or treatment which are used in UK.

Legal background

17 The legal background of the Act is set out in the *Commentary on Provisions of the Act* section of this document.

Territorial extent and application

18 Section 4, subsection (1) and (2) set out the territorial extent of the Act, which describes the jurisdictions in which the Act forms part of the law.

19 Section 1 extends and applies across the UK. Section 2 and 3 extend to England and Wales and apply in England.

20 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.

Commentary on provisions of Act

Section 1: Review of law on marketing authorisations

21 Subsection (1)(a) places a duty on the Secretary of State for Health and Social Care, to carry out a review of the law related to marketing authorisations (in Part 5 of the Human Medicines Regulations 2012 (S.I. 2012/1916)) for orphan medicinal products for the diagnosis, prevention or treatment of cancer. These regulations apply UK-wide.

22 Subsection (1)(b) requires that the conclusions of the review must be prepared and published in a report.

23 Subsection (2) provides that the review referenced in subsection (1) must consider regulatory approaches in other countries compared to the UK's approach. This ensures the review must assess international regulatory approaches for orphan medicinal products, with a view to assessing whether the regulations in the UK are considered effective at encouraging research and development for treatments of rare cancers.

24 Subsection (3) requires the report referenced in subsection (1) to be published before the end of the period of three years beginning with the day on which the Act was passed.

25 Subsection (4) requires that the Secretary of State must lay a copy of the report referenced in subsection (1) before Parliament.

26 Subsection (5) contains a list of relevant definitions of terms which appear in Section 1 of the Act.

Section 2: The Secretary of State's duties as to research

27 Section 2 amends section 1E of the National Health Service Act 2006, which outlines the Secretary of State for Health and Social Care's duty to facilitate research. The Rare Cancers Act amends section 1E to require that the research the Secretary of State for Health and Social Care is required to facilitate includes research into rare cancers, as below.

28 In discharging that duty, the Secretary of State must ensure appropriate arrangements are in place to facilitate or promote research in relation to rare cancers.

29 Such arrangements are to:

a. enable potential participants in clinical trials to be identified and contacted. This is intended to ensure patients with rare cancers can be easily contacted about relevant research, including clinical trials, by creating a bespoke contact registry service for patients with rare cancers. For example, DHSC funds a contact registry service called Be Part of Research which could undergo further development to deliver a bespoke offering for rare cancer patients.

b. ensure that a person (known as "the National Specialty Lead for rare cancers") is appointed, with a job description including promoting and facilitating research into rare cancers by providing advice in relation to the design and planning of research and facilitating collaboration between interested persons. This is intended to ensure there is adequate oversight of research delivery for rare cancers by providing leadership and advice with a view to improve rare cancer research. There are already National Specialty leads in the NIHR Research Delivery Network (RDN) that serve this purpose for specific disease areas. This Act mandates the appointment of a specialty lead for rare cancers, which could be delivered through an extension to existing cancer specialty lead roles in the NIHR RDN.

30 Subsection (4) provides a definition of the term "rare cancer". This has been defined as a cancer that affects not more than 1 in 2000 persons in the UK which is consistent with the UK Rare Diseases Framework. The wording allows for either 'incidence' or 'prevalence' approaches to be used to define a rare cancer.

Section 3: Disclosure of information for research purposes

31 Section 3 amends Section 261 of the Health and Social Care Act 2012 ('the 2012 Act') which confers on NHS England a power to disclose information obtained in connection with information systems. The amendments ensure that NHS England has a power to disclose such information for the purpose of facilitating clinical trials in relation to rare cancers. The intention is that the Secretary of State for Health and Social Care could direct NHS England to exercise this power in order to share information from the National Disease Registration Service with the NIHR 'Be Part of Research' Registry, so that patients may be identified and contacted.

32 Subsection (2) inserts new paragraph (da) into section 261(5) of the 2012 Act. The amendment ensures that NHS England may disclose information which it obtains by complying with a direction under section 254 or a request under section 255 of the 2012 Act for the purpose of facilitating the carrying out of relevant clinical trials by enabling potential participants to be identified and contacted.

33 Subsection (3) inserts into section 261 new subsection (5A) which defines "relevant clinical trials" (and terms used within that definition) for the purpose of new section 261(5)(da).

34 Subsection (4) inserts new subsections (6A) and (6B) into section 261 of the 2012 Act. These provide that where section 261 confers a power to disclose information, that power does not override the data protection legislation. This ensures compatibility of the processing of data under section 261 with the data protection legislation.

35 Insofar as subsection (4) is not limited to rare cancers (i.e. new subsections (6A) and (6B) are not limited to new subsection (5)(da) inserted into section 261 but instead apply to section 261 in its entirety), the provision made by subsection (4) is consequential in nature i.e. its purpose is to avoid doubt as to whether the rest of section 261 otherwise allows for the processing of information in contravention of the data protection legislation. Since section 261 is already considered to be subject to the data protection legislation, new subsections (6A) and (6B) do no more than restate that position. The amendment made by subsection (4) thus spells out the position rather than amends the current position under section 261 and, accordingly, subsection (4) does not change the law other than for rare cancers.

Section 4: Extent

36 Subsection (1) indicates that the territorial extent of Sections 2 and 3 in the Act is England and Wales. The relevant legislation applies in England only.

37 Subsection (2) provides that the territorial extent of Section 1 in the Act is England and Wales, Scotland and Northern Ireland. The aim of Section 1 is to mandate a review of the Human Medicines Regulations 2012, which are UK wide in extent and application, and the review required under this section will look at the operation of those Regulations. Medicines are reserved in respect of Scotland and Wales, but fully transferred in respect of Northern Ireland.

Section 5: Commencement

38 Section 5 make provision for the commencement of the Act.

Section 6: Short title

39 Section 6 sets out the short title.

Commencement

40 Section 5 provides for all sections to come into force at the end of the period of two months beginning with the day on which this Act is passed.

Related documents

41 The following documents are relevant to the Rare Cancers Act and can be read at the stated locations:

- **The UK Rare Diseases Framework**, Published 9 January 2021 [https://www.gov.uk/government/publications/uk-rare-diseases-framework/the-uk-rare-diseases-framework]
- **National Disease Registries Directions 2021**, Published 30 September 2021 [https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/national-disease-register-service-directions]

Annex A – Hansard References

42 The following table sets out the dates and Hansard references for each stage of this Act's passage through Parliament.

Stage	Date	Hansard Reference
House of Commons		
Introduction	16 October 2024	1st reading
Second Reading	14 March 2025	Vol. 763 Col. 1388
Money Resolution	30 June 2025	Vol. 770 Col. 97
Committee Stage	2 July 2025	First sitting: Col. 1
Report Stage	11 July 2025	Vol. 770 Col. 1257
Third Reading	11 July 2025	Vol. 770 Col. 1257
House of Lords		
Introduction	14 July 2025	Vol. 847
Second Reading	16 January 2026	Vol. 851 Col. 1958
Order of Commitment discharged	11 February 2026	Vol. 853
Third Reading	27 February 2026	Vol. 853. Col. 854
Royal Assent	5 March 2026	Vol. 853

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