Northern Ireland Assembly

Committee for Health

Report on the Legislative Consent Memorandum on the Rare Cancers Bill

Ordered by the Committee for Health to be published on 19 June 2025.

Report: NIA 105/22-27 Committee for Health.

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Powers and Membership

Powers

1. The Committee for Health is a statutory departmental committee established in accordance with paragraphs 8 and 9 of Strand One of the Belfast Agreement and under Assembly Standing Order No 48. The Committee has a scrutiny, policy development and consultation role with respect to the Department of Health and has a role in the initiation of legislation.

2. The Committee has power to:
    - consider and advise on departmental budgets and Annual Plans in the context of the overall budget allocation;
    - approve relevant secondary legislation and take the Committee Stage of relevant primary legislation;
    - call for persons and papers;
    - initiate inquiries and make reports; and
    - consider and advise on matters brought to the Committee by the Health Minister.

Membership

The Committee has 9 members, including a Chairperson and Deputy Chairperson, and a quorum of five members. The membership of the Committee is:

- Philip McGuigan MLA (Chairperson)
- Danny Donnelly MLA (Deputy Chairperson)
- Alan Chambers MLA
- Linda Dillon MLA
- Diane Dodds MLA
- Órlaithí Flynn MLA

- Nuala McAllister MLA
- Colin McGrath MLA
- Alan Robinson MLA

Introduction

1. The Rare Cancers Bill ("the Bill") was introduced in the UK Parliament as a Private Members Bill by Dr Scott Arthur MP on 16 October 2024. A copy of the Bill as introduced and accompanying explanatory notes are included at Appendix 1. The Bill passed second reading in the House of Commons on 14 March 2025, where the UK Government confirmed its support for the Bill.

2. The Rare Cancers Bill will introduce three measures intended to encourage more research into rare cancers. It will:

    - Place a duty on the Secretary of State for Health and Social Care in England to promote and facilitate research into rare cancers;

    - Improve patient recruitment into clinical trials for rare cancers through greater data sharing; and

    - Requires the government to review UK-wide law on marketing authorisations (product licences) for "orphan medicinal products" that diagnose, prevent or treat cancer.

3. The Bill is currently at Committee Stage in the Bill process.

4. As Clause 1 of the Bill 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) for orphan medicinal products and that the Human Medicines Regulations 2012 apply on a UK-wide basis and is a fully transferred matter, it requires the approval of the Assembly through a Legislative Consent Motion.

5. The Department of Health have outlined that any proposed amendments to the Human Medicines Regulations 2012 as a consequence of a review by the Secretary of State would still be subject to the draft affirmative procedure in both Houses of Parliament and the Assembly.

6. The Minister laid a Legislative Consent Memorandum (LCM) in the Assembly on 3 June 2025 and it was referred to the Committee for Health for its

consideration. A copy of the LCM is included in Appendix 2. The Memorandum sets out the Minister's intention to seek the Assembly's endorsement of Northern Ireland's inclusion in the Rare Cancers Bill.

Policy Background

7. Rare cancers (defined as those affecting fewer than 1 in 2,000 people) account for 17–18% of UK cancer diagnoses. Despite this, research funding, clinical trials, and treatment development are disproportionately low for these cancers. Patients can therefore often face delayed diagnosis, limited treatment options, and poor survival rate**s** compared to those with more common cancers.

8. Pharmaceutical companies have little financial incentive to invest in rare cancer treatments due to:

    i. Small patient populations,

    ii. High costs of drug development,

    iii. Regulatory hurdles.

9. Orphan drug incentives do exist, but may be outdated or insufficient, requiring review and reform.

10. Rare cancer patients struggle to find and access appropriate trials. Trials are often scattered, or delayed due to a lack of coordination and patient data. A centralised registry and trial-matching system could significantly improve trial access and design.

11. There is no dedicated authority or specialty lead within the NHS or NIHR focusing on rare cancers. This results in fragmented research efforts, duplication, and missed opportunities for collaboration.

12. Some existing non-cancer drugs may be effective for rare cancers, but there's no clear pathway or funding structure to support their investigation and

approval. Repurposing can offer a faster and cheaper route to new treatments, if properly supported.

The Provisions of the Rare Cancers Bill

13. The Bill is six clauses. Clause 1 of the Bill places a legal duty on the Secretary of State to do the following: conduct a thorough review of UK law governing the marketing authorisations (i.e., product licences) for orphan medicinal products used in the diagnosis, prevention, or treatment of cancer; compare the UK's framework with regulatory systems in other countries, assessing whether the current rules effectively encourage research and development into rare cancer treatments; and prepare and publish a formal report detailing the conclusions of this review, and lay it before Parliament within three years of the Bill becoming law.

14. Clause 2 of the Bill focuses on significantly improving access to and coordination of clinical trials through two key measures. These are appointing a national speciality lead for rare cancer research and providing centralised registries for trials and patients.

15. Clause 3 aims to strengthen clinical trial enrolment and evidence-building for rare cancers through the establishment of a bespoke patient registry and by enabling data-sharing from national registries.

16. Clause 4 introduces reforms aimed at accelerating drug development and repurposing for rare cancer patients by reviewing MHRA’s role in licensing trials and expanding the NHS medicines repurposing programme.

17. Clauses 5 and 6 are the commencement and short title of the Bill.

Committee Consideration

18. The Committee was briefed by officials on the Rare Cancers Bill at its meeting on 12 June 2025. The Hansard of the briefing can be found at Appendix 3 and a copy of all the Department's papers are included at Appendix 2.

19. At the briefing officials confirmed that Legislative Consent is required for Clause 1 of the Bill and that the provisional date for the motion was 30 June 2025. At the briefing Members raised a number of issues including:

    i. The use of secondary data in cancer research. Officials advised that a separate amending Bill would be brought forward shortly in relation to the use of data.

    ii. Members sought clarity on the implications of this Bill on staffing and finance in the Department of Health and the Trusts. Officials advised that this will be taking forward by DHSC and there will be no additional cost. Officials advised that any amendments coming through this legislation will be taken forward by officials in the Department.

Conclusion

20. At its meeting on 12 June 2025, the Committee agreed to support the Minister's Legislative Consent Motion asking the Assembly to endorse the principle of Northern Ireland's inclusion in the Rare Cancers Bill.

Links to Appendices

Appendix 1: Bill Papers

View the Rare Cancers Bill as introduced

Appendix 2: Memoranda and Papers from the Department for Health

View memoranda and Papers supplied to Committee from the Department of Health

Appendix 3: Minutes of Evidence

View Minutes of Evidence from the Department of Health briefing on 12 June 2025

This Report can be made available in a range of formats including large print, Braille etc. For more information please contact:

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