FROM THE MINISTER OF HEALTH

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Business Office
Northern Ireland Assembly
Parliament Buildings
Ballymiscaw
Stormont
Belfast
BT4 3XX

Castle Buildings
Stormont Estate
BELFAST, BT4 3SQ
Tel: 028 9052 2556
Email: private.office@health-ni.gov.uk

Our Ref: SUB-0318-2025

Date: 2 June 2025

Dear Business Office,

Notice of laying of Legislative Consent Memorandum: Rare Cancers Bill

In accordance with standing Order 42A(4)(a), I attach a copy of a legislative consent memorandum for laying before the Assembly. The draft motion to be tabled is:
"That this Assembly endorses the principle of the extension to Northern Ireland of Clause 1 to the Rare Cancers Bill, as introduced, to provide for a mandated requirement on the Secretary of State for Health to conduct a review of the law on marketing authorisations for orphan medicinal products and how regulations incentivise research and development into medicinal products for the diagnosis, prevention and treatment of rare cancers in the UK".

Further information can be obtained from Karen Simpson, Head of Medicines Legislation Unit on Extension 22799 if required.

Yours sincerely

Mike Nesbitt MLA
Minister of Health

LEGISLATIVE CONSENT MEMORANDUM

Rare Cancers Bill

Legislative Consent Motion

1. The draft motion, which will be tabled by the Health Minister, is:

"That this Assembly endorses the principle of the extension to Northern Ireland of Clause 1 to the Rare Cancers Bill, as introduced, to provide for a mandated requirement on the Secretary of State for Health to conduct a review of the law on marketing authorisations for orphan medicinal products and how regulations incentivise research and development into medicinal products for the diagnosis, prevention and treatment of rare cancers in the UK".

Background

2. This memorandum has been laid before the Assembly by the Health Minister under Standing Order 42A(2). The Rare Cancers Bill was introduced in the House of Commons on 16th October 2024. The latest version of the Bill can be found at Rare Cancers Bill publications - Parliamentary Bills - UK Parliament.

3. The Bill passed its second reading[1] in the House of Commons on 14 March 2025, where the Government confirmed its support for the Bill.

Summary of the Bill and its policy objectives

4. The aim of this Bill is to "make provision to incentivise research and investment into the treatment of rare types of cancer; and for connected purposes". If passed, the bill would introduce three measures intended to encourage more research. It would do this by:

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

    b) improving patient recruitment into clinical trials for rare cancers through greater data sharing in England; and

[1] Rare Cancers Bill - Hansard - UK Parliament

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

5. Rare cancers are types of cancer that affect relatively small numbers of people. The definition of a rare cancer can vary. The Rare Cancers Bill follows the UK Rare Diseases Framework and defines a rare cancer as a type of cancer that affects fewer than 1 in 2,000 people. Rare cancers are more commonly defined as cancers where fewer than six in 100,000 people are diagnosed each year. Although they are less frequently diagnosed, they collectively account for almost one in every five of all cancer diagnoses each year.

6. There are many different types of rare cancer. They include blood cancers, cancers affecting the female reproductive organs or digestive system, head and neck cancers, and cancers that affect soft tissues, known as sarcoma. Analysis from the rare cancers charity Cancer 52 and the National Cancer Research Institute has shown that in the financial year 2020-2021, £179 million of UK non-commercial research funding focused on less common or rare cancers, representing 54% of overall cancer research expenditure. Within this, most funding was dedicated to blood cancer research (30%), followed by research on gastrointestinal cancer (cancers of the digestive system) (25%) and brain and nervous system cancers (16%).

7. Charities and researchers have drawn attention to the difficulties of recruiting participants for research studies on rare cancers that affect relatively small numbers of people. In a 2024 patient survey, the charity Cancer 52 found that 82% of respondents with a less common or rare cancer were not offered an opportunity to be part of a clinical trial. The Rare Cancers Bill proposes appointing a National Speciality Lead for Rare Cancers, to advise on research design and facilitate collaboration in rare cancer research.

8. The Be Part of Research database is the most comprehensive listing of clinical trials and other health research studies being conducted in the UK. It is maintained by the National Institute for Health and Care Research (NIHR). Patients and healthcare professionals can search and browse the Be Part of Research listings to find research studies that are relevant to them. Patients can also register with the service to be matched to studies that may be suitable for them.

9. When someone is diagnosed with cancer in the UK, their data is collected by the cancer registry service in their part of the UK. These national cancer registries collect information about patients and the cancer they have been diagnosed with, and about their treatment and how well it has worked. The data collected in these registries is used for service planning. Anonymised data can also be accessed and used by researchers. The Bill would place a duty on the Secretary of State to facilitate and promote research on rare cancers. This

would include taking steps to enable potential participants in clinical trials to be identified and contacted more easily. The explanatory notes to the bill say that this could be achieved by developing a tailored Be Part of Research service for patients with rare cancers, to help meet their specific needs. In addition, the bill would provide NHS England with the power to share information for the purpose of facilitating clinical trials for rare cancers. It would do this by amending section 261 of the Health and Social Care Act 2012, which sets out the circumstances in which NHS England can share data that it has collected about the health and social are system.

10. Orphan drugs are medicines that are used to treat rare conditions. They are known as orphan because pharmaceutical companies may be unwilling to invest in research and development for new treatments for diseases that only affect very small numbers of people. To help encourage more research and development, governments offer incentives for the development of orphan medicines.

11. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) decides which medicines are given an orphan designation, based on criteria set out in the Human Medicines Regulations 2012. The MHRA provides market exclusivity rights for these medicines, preventing any similar medicine being licenced for ten years. It also offers reduced fees for marketing authorisation applications for orphan medicines, and refunds all or part of these fees if an orphan marketing authorisation is granted.

Provisions which deal with a Devolution Matter

12. Clause 1 of the Rare Cancers Bill, as introduced[2], 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 for the diagnosis, prevention or treatment of cancer. Such a review must also consider regulatory approaches in other countries compared to the UK's approach by assessing 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. It also requires that the conclusions of such a review must then be prepared and published in a report and this report has to be published before the end of the period of three years beginning with the day on which the Act is passed, should the bill become law.

13. Given the fact that the Human Medicines Regulations 2012 apply on a UK-wide basis and Clause 1 of the Bill also relates to the fully transferred matter of medicines in respect of Northern Ireland, the provisions of this Clause

[2] Rare Cancers Bill (as introduced)

would fall under the legislative competence of the Northern Ireland Assembly.

Reasons for making the Provisions

14. The aim to mandate a review of the law related to marketing authorisations for orphan medicinal products for the diagnosis, prevention or treatment of cancer is to define a specific evidence base regarding rare cancers research and incentivisation in order to encourage further research and development for treatments of rare cancers.

Reasons for utilizing the Bill rather than an Act of the Assembly

15. Mandating a UK wide review of the law by the Secretary of State for Health and Social Care related to marketing authorisations for orphan medicinal products for the diagnosis, prevention or treatment of cancer to encourage research and development for treatments of rare cancers will be in the best interests of UK patients and their families as well as the wider UK population as a whole.

16. Any proposed amendments to the Human Medicines Regulations 2012, as a consequence of a review conducted by the Secretary of State for Health, will remain, as provided under the powers of the Medicines and Medical Devices Act 2021, to be consulted upon and made jointly on a UK-wide basis and subject to the draft affirmative procedure in both Houses of Parliament and in the Northern Ireland Assembly.

Consultation

17. Cancer charities that focus on rare cancers have been consulted with and expressed support for the bill and encouraged people to write to their MP to express their support for it in Parliament. These include The Brain Tumour charity, Brain Tumour Research, Pancreatic Cancer UK, and Neuroendocrine Cancer UK.

Human Rights and Equality

18. No significant equality implications are anticipated in relation to protected characteristics nor any rural needs implications with no detrimental impact on health inequalities. The Government's view is that the Rare Cancers Bill is compatible with the European Convention on Human Rights

Financial Implications

19. The Bill's explanatory notes give an indication of financial implications associated with the Bill, should it become law. There are however no

anticipated additional financial requirements locally associated with the proposed new provisions.

Summary of Regulatory Impact

20. No specific impact in Northern Ireland is anticipated on employment, charities, social economy enterprises and the voluntary sector

Engagement to date with the Committee for Health

21. The Minister of Health wrote to the Health Committee on 6 May 2025 advising them of his plans to progress with a Legislative Consent Motion (LCM) seeking the Northern Ireland Assembly's agreement to provisions that deal with the transferred matter of medicines within the Rare Cancers Bill.

Conclusion

22. The Minister of Health is supportive of the intention underpinning the Bill and is committed to ensuring that there is equitable access to research in relation to rare cancer trials. In addition, the Minister of Health considers that, in the interests of good government and consistency across the UK, in so far as the provisions set out in Clause 1 of the Rare Cancers Bill, dealing with the transferred matter of medicines, should extend to Northern Ireland.

Department of Health
02 June 2025