FROM THE MINISTER OF HEALTH

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Dear Keith,

WESTMINSTER RARE CANCERS BILL – LEGISLATIVE CONSENT MOTION

I wish to advise you about a Legislative Consent Motion (LCM) asking the Assembly to agree to provisions that deal with the transferred matter of medicines within the Rare Cancers Bill. The aspects that will require a LCM relate to clause 1 of this Bill. A copy of the Bill as introduced in Parliament is available at: Rare Cancers Bill 2024-25

Background

On 16 October 2024, Dr Scott Arthur (Labour) presented his private member's bill (PMB), the Rare Cancers Bill 2024-25 to the House of Commons. The Bill passed its second reading on 14 March 2025, where the Government confirmed its support for the Bill. The overall 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

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

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.

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%).

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.

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.

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 Rare Cancers 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.

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.

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.

I can advise that Departmental officials were involved in initial discussions about the widening the scope of the duties introduced by this Bill in order to promote and facilitate research into rare cancers that would be inclusive of patients across the whole of the UK prior to the Bill being presented, as were colleagues in Wales and Scotland. However, following these discussions, and primarily due to the current legislative framework in Northern Ireland and the lack of Secondary Use of Data regulations, it was acknowledged that we would be unable to implement the UK wide contact Registry here in Northern Ireland which is a key part of the Bill.

The Department however remains supportive of the intention underpinning the Bill and with the proposal to legislate for a Rare Cancer Research lead but indicated a preference not to go down the legislative route for this (as did Scotland). In addition, and subject to funding being available, my Department would also aim to ensure that there is equitable access to research in relation to rare cancer trials.

Clause 1 of the Rare Cancers Bill however 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.

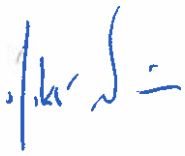
Such a review must also consider regulatory approaches in other countries compared to the UK's approach by assessing international regulatory approaches for orphan medicinal products, with a view to assessing whether the regulations in the UK are considered effective at encouraging research and development 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.

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 would fall under Schedule 3 of the Northern Ireland Act 1998 and the legislative competence of the Northern Ireland Assembly.

It is important to emphasise that any proposed amendments to the Human Medicines Regulations 2012 as a consequence of a review conducted by the Secretary of State for Health would still need to be taken forward jointly on a UK-wide basis and would still be subject to the draft affirmative procedure in both Houses of Parliament and the NI Assembly.

Colleagues in the Department of Health and Social Care in England have advised a provisional date of 9th July has been pencilled in for Committee stage consideration of the Bill. I will, of course, continue to keep you apprised of all developments with the Bill and I look forward to working with the Health Committee on this issue.

Yours sincerely



Mike Nesbitt MLA
Minister of Health