

Opening Statement

Good morning, everyone and thank you for the opportunity to appear today and speak with you on this proposed legislation.

This legislation, when enacted, will achieve a number of aims. Firstly, it will provide for an exemption of Rent-a-Room income of up to €14,000 per annum to be disregarded from the medical card and GP visit card income assessment process.

Secondly, it amends current legislation to clarify regulatory powers concerning the supply and administration of medicinal products.

And thirdly, it will provide for the establishment of regulations to help deal with shortages of medicinal products by way of introduction of a Medicines Substitution Protocol (MSP). This will include a framework for therapeutic substitution by pharmacists in line with a clinically approved protocol. In other words, the supply of a specified therapeutic alternative medicinal product in limited circumstances, where there is a shortage of a prescribed medicine.

In addition to the amendments already proposed, we also wish to introduce a new amendment at this juncture that will further help us to prevent and manage shortages of medicinal products and improve

security of supply. The proposed amendment, which I will outline later in further detail, introduces reporting obligations for actors in the medicines supply chain and allows this information to be used as part of our national approach to prevent shortages and where they occur, mitigate their impact.

Finally, having taken on board the comments previously raised at past meetings in relation to this Bill, I wish to inform the Committee that the Government is in the process of finalising a further amendment to facilitate pharmacist prescribing - to be introduced at Report Stage - to be included within this Bill.

This will take the form of a further amendment of the IMB Act of 1995 to introduce a regulation making provision that will enable the Minister for Health to make regulations that will enable pharmacists to prescribe. As the Committee are aware, in July 2023, Minister Donnelly established the Expert Taskforce to support the expansion of the role of pharmacists in Ireland, whose first recommendation to extend prescriptions is now in operation. The Taskforce are now addressing the introduction of pharmacy prescribing, of which part will encompass the capacity of pharmacists to assess a framework of agreed minor ailments, with underpinning protocols.

By enabling pharmacist prescribing, we open doors for the healthcare service. We empower pharmacists to leverage their unique expertise, to take on expanded roles in patient care, and to play a more integral role in our healthcare teams. We enhance patient access to vital medications, reduce healthcare costs, and improve health outcomes for individuals and communities.

It is crucial to emphasize that the implementation of this amendment to introduce prescribing hinges on several key enablers, including education, training, guidance from our regulators, and any additional necessary support systems. These foundational elements will be put firmly in place as part of the introduction of pharmacist prescribing. Behind every prescription, every medication, and every healthcare decision, lies a patient, a person in need of care, compassion, and support. It is our duty to ensure that they receive the highest standard of care possible.

This authority will be subject to the appropriate framework being in place and operate in tandem with the safeguards provided for in other legislation including;

- conferring authority for accreditation and quality assessment of the training,
- operate in conformance with applicable standards of care expected, the current Fitness to Practice and Code of Conduct

requirements as set out by the Pharmaceutical Society of Ireland
and,

- provide for a defined regulatory governance structure to be applied to the settings within which the prescribing activity occurs.

Health (Miscellaneous Provisions) Bill 2024

Committee Stage Amendments - Thursday 21st March 2024

Amendment Number 1:

SECTION 9

1. In page 10, between lines 5 and 6, to insert the following:

“Report on prescription-free oral contraceptives

9. *The Minister shall, within six months of the passing of this Act, prepare and lay before Dáil Éireann a report on allowing pharmacists to dispense prescription-free oral contraceptives.”.*

—Róisín Shortall.

Response from Minister Butler:

I wish to thank Deputy Shortall for her proposed amendment but at this time the Government does not propose to proceed with its inclusion. On a technical note, the purpose of the Bill is not to change the status of Oral Contraceptive Pills from prescription only to non-prescription products. Rather the Bill will provide that pharmacists may sell and supply certain prescription products in line with a protocol, subject to appropriate regulation and controls to be set out in secondary legislation. It is intended that regulations would be put in place to facilitate the sale and supply of Oral Contraceptive Pills on that basis, but this will be done on the basis of further clarity as to the appropriate framework and consultation with stakeholders.

We welcome the Deputy's support to for enhanced access to contraception however, six months is not a feasible time-frame to introduce the necessary changes and report back on impacts. While we share her ambitions in this area, our focus will be on introducing expanded options for women and embedding awareness of these changes.

Amendment Number 2:

In page 10, between lines 5 and 6, to insert the following:

“Report on the role of pharmacists in chronic disease management

- 9.** *The Minister shall, within six months of the passing of this Act, prepare and lay before Dáil Éireann a report on expanding the role of pharmacists in chronic disease management.”.*

Response from Minister Butler:

I wish to thank Deputy Shortall for her proposed amendment but at this time the Government does not propose to proceed with its inclusion.

It is expected that an expanding the role of the pharmacist in chronic disease management will be part of the overall development of that profession and encompassed by the recommendations from the Expert Taskforce on Pharmacy on pharmacist prescribing. We agree that pharmacists have a greater role to play here and are committed to further expanding the potential of pharmacists. I will note that the recent introduction to changes to prescriptions, whereby pharmacists can extend prescriptions for patients where appropriate, is an important step in the involvement of pharmacists in chronic disease management and allows them to be more impactful for patients in this area.

Amendment Number 3:

I move amendment No. 3.

In page 11, line 27, to delete “supply.” and substitute “supply.”.

—An tAire Sláinte.

Speaking Points for Minister Butler:

This is a technical amendment concerning the correct legislative wording of the amendment.

Amendment Number 4:

I move amendment No. 4.

In page 11, after line 27, to insert the following:

“Reporting of information to support the security of supply of medicines

32I. (1) *The Health Products Regulatory Authority may require a relevant person to provide to the Authority, in such form and manner and within such period as may be prescribed by regulations made by the Minister, such information in relation to medicinal products within the possession or control of the relevant person as the Authority considers necessary for the purpose of the management of the availability of medicinal products in the State, including—*

(a) the monitoring of the current and future supply of medicinal products, and

(b) the identification and management of medicinal product shortages.

(2) *A relevant person shall comply with a requirement set out in regulations made under subsection (1).*

(3) *In this section, ‘relevant person’ means the following persons involved in the manufacture or supply of a medicinal product:*

(a) the holder of a manufacturer’s authorisation granted under Regulation 8 of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

(b) the holder of a marketing authorisation granted in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007;

(c) the holder of a community marketing authorisation within the meaning of the Medicinal Products (Control of Placing on the Market) Regulations 2007;

(d) the holder of a wholesaler’s authorisation granted under Regulation 9 of the Medicinal Products (Control of Wholesale Distribution)

Regulations 2007 (S.I. No. 538 of 2007);

(e) a retail pharmacy business within the meaning of the [Pharmacy Act 2007](#);

(f) a hospital;

(g) such other persons or legal entities, being persons or entities authorised or entitled to supply medicinal products, as may be prescribed in regulations made by the Minister.”.”.

—An tAire Sláinte.

Speaking Points for Minister Butler:

As the Committee members will be aware, issues surrounding security of medicines supply have been increasingly well characterised, both nationally and internationally, in recent years. The causes of such supply issues are multifaceted, ranging from pandemics to geopolitical events and potential shortages of raw materials. Medicine availability is complex and involves the interface of the medicine regulatory system, clinical policies, national policies, pricing, and reimbursement policies. Whilst the temporary unavailability of a medicine (i.e., a shortage) is one potential consequence, supply chain security and sustainability are broader issues.

Because of the interlocking challenges facing the world, medicine shortage management requires constant iterative development to achieve the best outcomes for patients. For this important and complicated work Ireland needs to implement policy focusing on what feasible solutions can be achieved.

Now is the time to implement an update to Ireland's medicine shortages framework to utilise how it can be more effective prior to and when a shortage occurs and to accelerate learning and improvement cycles. Improved information and early notification will be vital in the management of our medicines shortages.

This takes the form of a further amendment of section 32 of the IMB Act of 1995 to introduce reporting obligations for actors in the medicines supply chain and allow for this information to be used in national medicinal planning systems. These reporting requirements, in line with European obligations, seek to improve visibility of the medicines supply chain to Ireland and help the management of medicines availability in Ireland.

This amendment will mandate “relevant persons” to provide information in relation to medicinal products within their possession or control to the Health Products Regulatory Authority, as requested by them as the Medicines Regulator.

It is envisaged that this information, while simple in theory, will yield multiple benefits for our national management of medicines availability. This reporting obligation will allow for additional visibility of the presence of medicines in Ireland, increase our ability to mitigate the impact of shortages, and increase our capacity to prevent them

occurring at all, while allowing us to feed into European Shortages mitigation measures, such as the European Shortages Monitoring Platform, to be functional in February 2025.

These measures will support the national system for the management and security of medicines supplies and will facilitate a more proactive system for the management of medicines shortages.

Closing Statement:

I look forward to listening to Deputies' views and working with you to progress this important legislation through the Dáil as quickly as possible. Given that the core objectives represent positive actions to benefit students, renters, patients, and families, especially in the context of the current cost of living crisis and accommodation challenges in Ireland, I hope to enact the legislation as soon as possible to ensure early and timely implementation.

In addition, the proposed amendment around Pharmacy prescribing to be introduced at report stage aims to reduce pressure on GP practices and utilise the skills of pharmacists for the benefits of patients across the country.

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Assistant Secretary: Niall Redmond - 087 1128576.

Pharmacy amendments, Medicines Supply & shortages

amendments, Pharmacy Prescribing (report stage) amendment

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