THE STATES OF DELIBERATION Of the ISLAND OF GUERNSEY

COMMITTEE FOR HEALTH & SOCIAL CARE

PROPOSED AMENDMENT TO THE MEDICINES (HUMAN AND VETERINARY) (BAILIWICK OF GUERNSEY) LAW, 2008

The States are asked to decide:-

Whether, after consideration of the Policy Letter entitled "Proposed amendment to the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008, relating to prescription-only medicines" dated 17th February 2025, they are of the opinion:-

- To replace the power in section 35 of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 for the States to make Ordinances to regulate the retail sale, supply in circumstances corresponding to retail sale, and administration of prescription-only medicines, with a power for the Committee for Health & Social Care to make Regulations for these purposes.
- To agree that all future Regulations and Orders made under the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 be laid before the States of Deliberation and that the Regulations may be annulled by the States if they see fit.
- 3. To continue to give effect to the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009 and give the Committee *for* Health & Social Care power to amend that Ordinance by Regulations; and
- 4. To direct the preparation of such legislation as may be necessary to give effect to the above decision.

The above Propositions have been submitted to His Majesty's Procureur for advice on any legal or constitutional implications in accordance with Rule 4(1) of the Rules of Procedure of the States of Deliberation and their Committees.

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COMMITTEE FOR HEALTH & SOCIAL CARE

PROPOSED AMENDMENT TO THE MEDICINES (HUMAN AND VETERINARY) (BAILIWICK OF GUERNSEY) LAW, 2008, RELATING TO PRESCRIPTION-ONLY MEDICINES

The Presiding Officer States of Guernsey Royal Court House St Peter Port

17th February, 2025

Dear Sir

1 Executive Summary

- 1.1 This Policy Letter seeks to make legislative changes to the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 ('the Medicines Law') so that the Committee for Health & Social Care ('the Committee') can respond quickly and flexibly to developments in the provision of prescription-only medicines ('POMs'). POMs are medicines which are not available to buy over the counter but instead require a prescription from a health practitioner, most commonly a doctor. They include treatments prescribed in the community and the Princess Elizabeth Hospital for acute illness, such as antibiotics for an infection, and chronic disease, such as an inhaler for asthma or insulin for diabetes.
- 1.2 The legislation governing medicines is outdated, and while an extensive review has been highlighted as a potential workstream for the next political term, the Committee would like to be able to make changes around POM provision more easily because the current process to do so is adversely impacting HSC's services, including the ability to provide patient-centred care. The Committee is currently required to make any changes by Ordinance of the States of Deliberation ('the States') and, in light of the fast-paced developments in health care, has not been able to allocate its policy resource to the development of multiple Policy Letters to respond to frequent changes.
- 1.3 It has become increasingly common for other health professionals, such as paramedics and physiotherapists, to prescribe to their patients POMs which are related to and within their scope of practice. Not only are these professionals sometimes better placed than doctors to prescribe directly for their patients, but

their ability to do so can reduce for service users their number of appointments and re-telling of their circumstances. Patient-centred care is at the heart of Partnership of Purpose¹ and underpins the Committee's recommendation for the legislative change in this Policy Letter. Further examples of expected improvements from the recommended change, including to service user experience, can be seen in paragraphs 3.4 - 3.16.

- To facilitate this change, and those set out in section 3 of this Policy Letter, the Committee seeks approval to replace the power in section 35 of the Medicines Law for the States to make Ordinances to regulate the retail sale, supply in circumstances corresponding to retail sale, and administration of POMs, with a power for the Committee to make Regulations for these purposes (proposition 1). In addition, the States is asked to give the Committee the power to amend the Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009² ('the POM Ordinance') by Regulations (proposition 3).
- 1.5 There is currently no requirement under the Medicines Law to lay Regulations or Orders before the States, other than Orders made under section 5. The Committee therefore recommends that legislative changes are made so that all future Regulations and Orders are laid before the States (**Proposition 2**).
- 1.6 The Medicines Law, 2008³ and its subordinate legislation (in its entirety, 'the Medicines Legislation') provides the legal framework for the regulation of medicines in the Bailiwick of Guernsey, and the governance arrangements that exist at a clinical level to regulate their safe use. This includes the regulation of their manufacture, sale and supply, import and export, labelling, advertising, and licensing and prescribing. The changes sought by the Committee will not affect these arrangements, which are summarised below and set out more fully in section 2 of this Policy Letter.
- 1.7 In common with the United Kingdom ('UK'), medicines are subject to classification from the medicines regulator the Medicines and Healthcare products Regulatory Agency ('MHRA') with the regulatory requirements for that classification subsequently set out in the Medicines Legislation. Prescription-only medicines are classified so by the MHRA because they are used for conditions that are best diagnosed and managed by health professionals, and their effects need closer supervision and monitoring than medications purchased over the counter.
- 1.8 Under the Medicines Law, statutory provisions relating to POMs, and any

¹ <u>Transforming Health & Social Care: A Partnership of Purpose - Billet d'État XXIV of</u> 2017

² Prescription Only Medicines (Human) (Bailiwick of Guernsey) Ordinance, 2009

³ Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008

amendments thereafter, can only be made by Ordinance of the States. Given the clinical focus of these provisions, of which the Assembly has limited knowledge, it is considered appropriate and proportionate for the Committee to have the power to make any necessary changes by Regulations. Doing so will enable the Committee to more readily reflect up to date professional practice on the advice of its senior clinical officers. The additional flexibility would be commensurate with the process to amend other sections of the Medicines Law, such as section 51 (business carried on by body corporate), is similar to the provisions of the Misuse of Drugs (Bailiwick of Guernsey) Law, 1974⁴ ('the Misuse of Drugs Law') and would align with the arrangements in place in the UK, without compromising the regulatory measures in place.

- 1.9 The POM Ordinance currently offers an inflexible structure for the provision of POMs. This inflexibility was felt acutely during the pandemic and whilst it was possible to navigate the challenges, there are broader examples when a more flexible and nimble response to changing circumstances would have been advantageous. Allowing changes to be made by Regulations will have significant practical benefits. It will enable the Committee to more easily respond to evolving circumstances such as the next pandemic, ensure that local legislation remains up to date with best practice, and it will make it easier to ensure health professionals can exercise the full range of care within their scope of practice so to provide the most safe and effective care in a holistic, efficient manner.
- 1.10 If granted Regulation-making powers, the Committee would prioritise phased changes to prescribing rights to align local legislation with its UK equivalent the Human Medicines Regulations 2012⁵ ('HMR 2012'). This would allow appropriately trained and registered individuals from a wider range of regulated health professions to prescribe (known as 'non-medical prescribing'), enhancing patient care and supporting recruitment and retention. This is seen as a key part of the work to transform the ways in which services are delivered to patients and at the heart of the aims of the Partnership of Purpose⁶ to deliver person-centred care.
- 1.11 The Committee is aware that a comprehensive review of the Medicines Legislation is required and the value of such a review has been identified in the Government Work Plan⁷ as a potential workstream for the next electoral term. Ahead of this longer-term commitment, the Committee wishes to change the process for amending the POM Ordinance to remedy a number of matters affecting the provision of care in some areas and to enhance flexibility within the

⁴ Misuse of Drugs (Bailiwick of Guernsey) Law, 1974

⁵ The Human Medicines Regulations 2012

⁶ <u>Transforming Health & Social Care: A Partnership of Purpose - Billet d'État XXIV of 2017</u>

⁷ Government Work Plan 2023-2025

current framework to catch up and keep pace with future developments in the supply of medicines.

2. Governance around the supply of prescription-only medicines

Legal framework

- 2.1 The Medicines Legislation provides the legal framework for the regulation of medicines in the Bailiwick of Guernsey, and the governance arrangements that exist at a clinical level to regulate their safe use. This includes their manufacture, sale and supply, import and export, labelling, advertising, and licensing and prescribing.
- 2.2 In common with the UK, medicines are subject to classification from the MHRA, with the regulatory requirements for that classification subsequently set out in the Medicines Legislation. POMs are classified so by the MHRA because they are used for conditions that are best diagnosed and managed by health professionals, and their effects need closer supervision and monitoring than medications purchased over the counter. POMs can therefore only be legally sold or supplied according to a prescription from an appropriate prescriber, most commonly a medical practitioner, and dispensed from a pharmacy or from another specifically licensed place. This system maximises their timely access to patients while minimising the potential risk of harm from inappropriate use.
- 2.3 Section 35 of the Medicines Law sets out a range of matters that may be specified by Ordinance in relation to POMs. The POM Ordinance prescribes, among other things, the types of registered professionals considered to be appropriate practitioners to prescribe POMs.
- 2.4 POMs that are also categorised as controlled drugs under the Misuse of Drugs Law, such as some analgesics or anaesthetic drugs, are subject to extra safeguards in accordance with the Misuse of Drugs (Bailiwick of Guernsey) Ordinance, 1997 ('Misuse of Drugs Ordinance').8

Clinical governance arrangements

2.5 The clinical governance around the provision of POMs is similarly strong. It is the MHRA who grants marketing authorisations for medicines having assessed their safety and efficacy. In doing so, it categorises medicinal products into one of four categories:

• **General Sales List** - for which there are few legal restrictions to their distribution and sale, such that they are available 'off the shelf' in pharmacies

⁸ Misuse of Drugs (Bailiwick of Guernsey) Ordinance 1997

- and supermarkets;
- **Pharmacy Medicines** which are only available to purchase behind a pharmacy counter;
- **Prescription-only Medicines** which, as above, can only be supplied in accordance with a prescription from an appropriate prescriber; and
- **Controlled Drugs** which also require a prescription but are subject to further regulations regarding their dispensing, storage and administration as required by the Misuse of Drugs Ordinance.
- 2.6 Medical practitioners can prescribe medicines upon qualification as a doctor because the necessary education to do so safely is included as part of their medical training. They are required to maintain their registration with and a licence to practice from the General Medical Council. This system of continuous regulation is set out on a statutory footing.9 Other registered clinical practitioners must successfully complete Higher Education training, supplementary to their professional training, before they can prescribe POMs. For example, Registered Nurses who have met the standards for prescribing set by the Nursing and Midwifery Council (NMC) and whose registration with the NMC has a specific annotation that they are also a Nurse Prescriber can prescribe medicines. Equivalent requirements and annotations to professional registers are in place for other clinicians, such as pharmacists, dieticians, physiotherapists or paramedics. All registered practitioners working in Guernsey require registration with their UK regulator. There is, therefore, a robust regulatory framework governing the supply of POMs. These arrangements, in their entirety, would remain in place should the States agree the Committee's proposals.
- 2.7 It should be noted that while legislative changes were made in 2017¹⁰ to enable nurses and pharmacists to prescribe, the Medicines Legislation does not currently facilitate non-medical prescribing of POMs in other health professional groups. The Committee wishes to change this situation and indeed it underpins its recommendations to the States so that the process to do so can be more easily achieved.
- 3. Making or amending provisions relating to POMS by Regulations of the Committee *for* Health & Social Care
- 3.1 Section 35 of the Medicines Law currently authorises the States to make legislative provisions relating to POMs through Ordinances
 - (a) To specify descriptions or classes of medicinal products which are prescription-only medicines;

⁹ <u>Regulation of Health Professions (Medical Practitioners) (Guernsey and Alderney)</u> <u>Ordinance, 2015</u>

¹⁰ Health Service (Benefit) (Approved Pres<u>cribers) Ordinance, 2017</u>

- (b) To specify descriptions or classes of health or care professionals who are authorised (as 'appropriate practitioners') to prescribe medicines;
- (c) To specify conditions under which appropriate practitioners may prescribe, give directions for, or administer medicines to another person; and
- (d) To provide for exemptions from prohibitions in section 35 relating to the retail sale, supply in circumstances corresponding to retail sale or administration of medicines to another person, or to modify prohibitions.
- 3.2 The Committee recommends that it be given powers to make Regulations for matters which section 35 of the Medicines Law currently requires to be provided by Ordinance, and to further amend the POM Ordinance by Regulations. There is currently no requirement under the Medicines Law to lay Regulations or Orders before the States, other than Orders made under section 5. The Committee therefore recommends that legislative changes are made so that all future Regulations and Orders are laid before the States (**Proposition 2**).
- 3.3 It is proposed to save the POM Ordinance which sets out the current provisions so that it continues in effect (**Proposition 3**). However, giving the Committee the power to amend this Ordinance by regulations would have a number of benefits:

The ability to keep pace with developments in the UK in relation to the supply of POMs

- 3.4 The provision of health and social care in the Bailiwick broadly mirrors that in the UK. Most practitioners in Guernsey undertake their professional training in the UK and islanders can receive specialist care from the National Health Service (NHS) through pathways commissioned by Health & Social Care. It is therefore important that clinical practice locally keeps pace with the UK to ensure seamless delivery of care. Medicine provision in the UK is governed by HMR 2012. These Regulations are amended frequently to reflect best practice and to respond promptly to constitutional matters like Brexit, or public health emergencies such as the SARS-CoV-2 pandemic.
- 3.5 The prolonged process to amend POM provisions was felt particularly keenly by the Committee when legislative changes were required to the POM Ordinance before the COVID-19 Bailiwick Voluntary Vaccination Programme ('the vaccination programme') could take place. With the grateful permission of the Presiding Officer, the Committee presented an emergency Policy Letter and The Prescription Only Medicines (Human) (Bailiwick of Guernsey) (Amendment) Ordinance, 2020 ('Amendment Ordinance') to the States concurrently. The States of Alderney and the Chief Pleas similarly expedited the passing of the Amendment Ordinance in Alderney and Sark. While these actions fortunately accomplished the necessary arrangements to facilitate the vaccination programme, the Committee considers that the process was unnecessarily arduous and long for what was a clinical matter, and one of urgency. Whilst it

was possible to navigate the challenges, it was at the expense of other important policy and legislative work.

- The Committee is also aware of various amendments made to HMR 2012 in recent years that are not yet reflected in the POM Ordinance, most notably exempting some of the restrictions on the sale, supply and administration of POMs in schools. These exemptions relate to salbutamol inhalers for asthma and adrenaline auto-injectors for use in cases of anaphylaxis. The amendments allow schools, but do not oblige them, to obtain without a prescription 'spare' inhalers and adrenaline auto-injectors for administration to pupils in an emergency when their own device is not available or not working (because it has broken or expired).
- 3.7 The Committee understands that parents of children who are prescribed these medications currently provide them to schools to be safely stored in case they are needed, but would nonetheless wish to mitigate any potential risk by allowing schools to hold a small general stock of these medications.

Non-medical prescribing

- 3.8 The Committee further considers the current process to make provisions relating to POMs by Ordinance to be unnecessarily onerous as it does not easily facilitate the more frequent changes required to keep pace with best practice. By way of example, this situation is a contributing factor to the increasing divergence between prescribing permissions locally and in the UK, affecting both recruitment and the provision of care in some areas. The Committee has not been able to allocate the resources needed to bring multiple, sporadic Policy Letters to the Assembly.
- 3.9 Non-medical prescribing expands the right to prescribe autonomously, beyond medical professionals and dentists, to other professions within their clinical competence¹¹. There are two main types of non-medical prescribing:
 - Independent prescribers (IPs)

IPs can prescribe any medicine provided it is in their competency to do so. This includes unlicensed medicines and controlled drugs.

Supplementary prescribers (SPs)

With the patient's agreement, SPs can prescribe medicines within an agreed patient-specific clinical management plan.

¹¹ Non-medical prescribers must have completed the relevant training directed by their UK regulator and this qualification be appropriately annotated on their professional registration.

- 3.10 Non-medical prescribing has been increasingly adopted internationally because it enhances the multidisciplinary nature of care provision, and improves access to care and patient safety. As pressures on health and care providers have increased, it has additionally enabled maximising the expertise of the existing workforce by allowing professionals to work across the full scope of their professional practice, and reducing the need for service users to have multiple appointments with different professionals.
- 3.11 The benefits of non-medical prescribing are already recognised locally. The legislative changes to enable nurses and pharmacists to prescribe occurred in 2017 but since that time, non-medical prescribing in other jurisdictions has and continues to extend to other regulated professions.
- 3.12 Paramedics, physiotherapists and dieticians are some of the professions affected by the current prolonged process for amending provisions relating to POMs, for which the resources are not readily available against competing demands. This means that they are unable to prescribe POMs locally, despite having undertaken the necessary higher education programme and met the regulatory standards of their professional body allowing them to do so. This has a number of practical consequences, including:
 - Making recruitment more difficult in those professions as it reduces the scope of professional practice, making locally based roles less attractive than UK-based equivalent positions¹²;
 - Making staff retention potentially more difficult as it limits the opportunities to support professional training and development onisland; and
 - Reducing the opportunities to transform how health and social care is coordinated and delivered.
- 3.13 The Committee wishes to see non-medical prescribing expanded locally, considering that it can only enhance the health and care offering in the Bailiwick. It sees this move as a key part of the work to transform the ways in which services are delivered to patients and at the heart of the aims of the Partnership of Purpose to deliver person-centred care.
- 3.14 For example, paramedics are highly skilled practitioners who predominantly respond to emergencies in community settings. They play a vital role that requires precise clinical judgement and skill to assess patient condition, and the ability to make potentially life-saving decisions in often very difficult and uncontrolled circumstances. Paramedics in the UK are able to prescribe as IPs.

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¹² This has been particularly evident in the Emergency Department and has resulted in challenges to the appointment of Advanced Critical Care Practitioners, a position for which an Advanced Care Paramedic, amongst others, may apply.

For many patients this means more care can be received in their home, avoiding unnecessary attendances to the Emergency Department (ED). Whether or not a paramedic treats the patient in their home or transfers them to a hospital, the ability to prescribe ensures that all patients receive those medications in a timelier manner. The Committee considers that paramedics would play a fundamental role in supporting the transformation of health care provision and are integral to providing patient-centred care.

- 3.15 Given their skill and experience in responding to emergencies, paramedics are also ideally placed to triage patients in other areas of health and social care and in the UK in recent years Advanced Paramedic Practitioners (APP) have been increasingly based in primary care centres, Intensive Care Units and Emergency Departments. The inclusion of APPs in the wider multidisciplinary team in this way is not only possible due to their clinical skills but also because of their status as independent prescribers. The increasing workload of the ED at the Princess Elizabeth Hospital can, at times, overwhelm the medical staff available on shift which can lead to delays in patients receiving care and/or ward admission. It has been identified by the ED that the recruitment of APPs would help to improve this situation for service users and expressions of interest from APPs have indeed been received. However, there has been no successful recruitment of an APP because they, understandably, did not want to move to a jurisdiction where they would not be able to maintain their independent prescriber status with their regulatory body and practice the full scope of their profession for which they are trained.
- 3.16 Dieticians may hold supplementary prescribing rights, enabling them to prescribe total parenteral nutrition (TPN) for their patients. TPN describes nutrition that is delivered intravenously to people who cannot use their digestive system because they have a condition that impairs their ability to process and absorb food and nutrients or because there is a need to aid healing within their digestive system. Locally, because the legislative provisions are not in place to enable prescribing by dieticians, the prescribing of TPN can only be undertaken by a gastroenterologist. While it is not suggested that the well documented waiting list for surgery in this area is caused by this situation, it serves to highlight the needless use of a gastroenterologist's time when a suitably qualified alternative specialist is available to undertake this prescribing and for care to be provided in a timelier manner. It is possible that dieticians will become IPs in the future as the British Dietetic Association is calling for this change to enable advanced clinical practice dietitians to deliver the best possible care for patients. The Committee would similarly consider mirroring this change to further facilitate efficient, high level dietetic care and encourage and maintain dietetic establishment in the future.
- 3.17 Before implementing any changes, the Committee would need to satisfy itself that non-medical prescribing, both independent and supplementary, could

operate effectively within the particular profession in the Bailiwick context, taking into account the leadership and technology in place as well as the anticipated demand. As a programme of work, this is likely to lead to an incremental extension of prescribing rights¹³. If the Committee remained under a requirement to return to the Assembly to seek amendment by way of Ordinance, it would be resource intensive and likely to cause additional delay to expand the non-medical prescribing programme or other important policy and legislative work within the Committee's mandate.

3.18 The Committee is aware that a comprehensive review of the Medicines Legislation is required and the value of such a review has been identified in the Government Work Plan as a potential workstream for the next electoral term. Ahead of this longer-term commitment, the Committee wishes to change the process for amending provisions relating to POMs, including amendments to the existing POM Ordinance, to enhance flexibility within the current framework to catch up and keep pace with future developments in the supply of medicines. The resulting improvements of the recommended legislative change would align with the principles of the Partnership of Purpose, and with the States' objective for sustainable health and social care services.

4. Compliance with Rule 4

4.1 Rule 4 of the Rules of Procedure of the States of Deliberation and their Committees sets out the information which must be included in, or appended to, motions laid before the States.

4.2 In accordance with Rule 4(1):

- a) The Propositions have been submitted to His Majesty's Procureur for advice on any legal or constitutional implications.
- b) The Propositions contribute to the Government Work Plan priority to increase service resilience to deliver more sustainable health and care services.
- c) The Committee has consulted the States of Alderney, the Chief Pleas, the Medical Specialist Group, the Medicines Committee, Ambulance and Rescue Guernsey, and CareWatch, alongside organisations impacted by the proposed amendment. All consulted parties have provided their support to the recommendations.

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¹³ The Health Service (Benefit) (Guernsey) Law, 1990, which outlines prescribers who may issue medical prescriptions eligible for pharmaceutical benefit may also require subsequent amendment, by Regulations made by the *CfHSC*, to extend the list of those health professionals deemed "Approved Prescribers."

- d) There should be no additional financial implications to the States of Guernsey by allowing the POM Ordinance to be amended by Regulation.
- 4.3 In accordance with Rule 4(2) of the Rules of Procedure of the States of Deliberation and their Committees, it is confirmed that the propositions above have the unanimous support of the Committee.
- 4.4 In further accordance with Rule 4(2), the Propositions relate to the duties of the Committee *for* Health & Social Care to protect, promote and improve the health and wellbeing of individuals and the community.

Yours faithfully

A H Brouard President

M P Leadbeater Vice-President

A D S Matthews A Snowdon G A St Pier

G A Oswald Non-States Member