WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES
BY DEPUTY H.L. JEUNE OF ST. JOHN, ST. LAWRENCE AND TRINITY
QUESTION SUBMITTED ON TUESDAY 6th MAY 2025
ANSWER TO BE TABLED ON WEDNESDAY 14th MAY 2025

Question

"Further to the response to Written Question 151/2025, in which the Minister explained the need for rigorous regulatory compliance with medicines legislation and strict adherence to Good Manufacturing Practice (GMP) standards and multiple licensing requirements, will he advise –

(a) whether the standards and licence requirements include the need for an independent regulatory authority or whether, in his assessment, Jersey's current process is sufficient to adhere to all requirements;

(b) what processes and framework are in place to ensure GMP compliance;

(c) how he intends to assure GMP compliance across the entire lifecycle of any medicinal products manufactured or handled in the Island;

(d) what current staff expertise there is within Government to ensure GMP compliance, including –

(i) whether there is any programme of continual training to ensure high standards of expertise; and
(ii) to what standards staff are trained; and

(e) what budget, if any, is allocated specifically for compliance within this area?"

Answer

(a) Any organisation wishing to manufacture medicines must be appropriately licensed and comply fully with the relevant legislative and regulatory standards. Currently, there are no licensed medicines manufacturing operations in Jersey, the exception to this is the issuance of a licence to Jersey Blood Service for the manufacture of blood products - specifically the collection of whole blood and processing into red cell.

It may be helpful to clarify that Jersey does already work closely with an independent regulatory authority – the UK's Medicines and Healthcare products Regulatory Agency (MHRA) – which collaborates with the Office of the Chief Pharmacist to provide high-quality regulatory oversight.

Since responding to Written Question 151/2025, I have taken time to reflect further on the longer-term arrangements required to ensure Jersey's regulatory framework continues to support high standards of safety, quality, and public confidence. I believe there is merit in exploring the potential establishment of a dedicated independent medicines regulator in Jersey. Subject to consultation with stakeholders and the development of detailed proposals, I will seek to bring forward amendments to the Medicines (Jersey) Law 1995 to enable this. Such a regulator would enhance local capacity to support Good Manufacturing Practice (GMP) compliance, operating at arm's length from the Minister.

(b) Good Manufacturing Practice (GMP) is a fundamental part of any robust medicines regulatory system, ensuring that products are consistently manufactured and controlled to quality standards appropriate to their intended use.

In Jersey, the current arrangements for ensuring GMP compliance involve close working between the Medicines and Healthcare products Regulatory Agency (MHRA) and the Office of the Chief Pharmacist. This collaboration brings together internationally recognised regulatory and inspection expertise with local clinical, legal, and policy knowledge. Together, these partners are able to provide proportionate and effective oversight for any proposed medicines manufacturing activity.

Although there is currently no active manufacture of medicinal products in Jersey (beyond blood products), these existing arrangements are considered satisfactory for the present level of activity and provide a sound basis for the rigorous assessment of any future applications.

As I have set out in response to part (a), I am currently considering proposals to establish a dedicated, independent medicines regulator in Jersey. Should that proposal be progressed following consultation and detailed development work, it will provide a strengthened local framework for GMP compliance in the future. I am confident that our current collaborative approach continues to provide the necessary safeguards

(c) Ensuring GMP compliance throughout the entire lifecycle of a medicine – from development and manufacturing through to distribution and patient use – is essential to safeguarding public health.

In Jersey, this assurance is delivered through close working between three key bodies: the MHRA, the Office of the Chief Pharmacist, and the Medicines Advisory Council. Each plays a distinct but complementary role.

As previously described, the MHRA and Chief Pharmacist provide regulatory and professional oversight of licensing and manufacturing processes. The Medicines Advisory Council contributes to ongoing monitoring and safety assurance, including through investigation of adverse reactions and pharmacovigilance reporting.

This shared model provides a strong platform for robust, proportionate, and continuous assurance across the entire medicine lifecycle.

(d) The Government of Jersey benefits from a high level of in-house expertise through the Office of the Chief Pharmacist, which leads on medicines regulation and oversight.

The Chief Pharmacist is a professionally registered UK pharmacist with extensive experience in regulatory compliance and clinical governance. The team includes pharmacy professionals trained in quality assurance, regulatory standards, and medicines law.

(i) There is a strong commitment to continuous professional development. Staff undertake accredited GMP and regulatory training, engage regularly with the General Pharmaceutical Council (GPhC), participate in UK regulatory networks, and take part in structured internal learning and quality assurance processes.

All registered professionals are also required to meet the ongoing professional standards set by the GPhC.

(ii) Training is aligned to UK professional and regulatory standards, helping ensure Jersey's regulatory approach reflects best practice.

(e) At present, there is no separate budget line allocated specifically to medicines manufacturing compliance. Instead, oversight is delivered through existing resources within the Office of the Chief Pharmacist, with expert support from the MHRA and the Medicines Advisory Council.

If manufacturing activity continues to expand in a significant way, I fully recognise that a dedicated budget would be required to support this work effectively. As noted in my response to question (a), proposals to establish a local independent regulator will be developed alongside detailed financial planning to ensure any new model is both effective and sustainable.