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 MONDAY 24th MARCH 2025
ANSWER TO BE TABLED ON MONDAY 31st MARCH 2025

Question

"Further to Written Question 39/2025, in relation to Jersey's regulatory system for medicines, will the Minister advise –

(a) whether the absence of a National Regulatory Authority means that medicinal products manufactured in Jersey are subject to additional regulatory controls when exported, and if they are, how is this made explicit to those in the industry; and
(b) how the Government intends to ensure that products developed under healthcare innovation initiatives, such as the CareTech Challenge, will meet the international regulatory standards for export?"

Answer

(a) I am – as the Minister for Health and Social Services – the regulatory authority for medicinal products in Jersey, including any manufacture of medicines. These regulatory functions are discharged by the Chief Pharmacist.

Any regulatory requirements for medicinal products manufactured in Jersey when exported will depend on several factors – including the importing country's requirements and the nature of the medicinal product itself.

By way of an example, if the medicinal product is also a controlled drug and controlled under the Misuse of Drugs (Jersey) Law – there may be additional controls and licence requirements on export from Jersey.

In order to manufacture medicines, a company must be licensed to do so. There are currently no medicines manufactured in Jersey and as such no manufacturing licences for finished medicinal products have been issued in Jersey.

Becoming a pharmaceutical manufacturer is highly complex. It involves rigorous regulatory compliance with medicines legislation and strict adherence to Good Manufacturing Practice (GMP) standards and multiple licensing requirements. Establishing robust quality assurance systems, managing extensive documentation, and undergoing regular inspections add to the complexity. Additionally, significant financial investment and specialised expertise are essential to navigate the evolving regulatory landscape and maintain continuous compliance.

The Government of Jersey provides guidance through the Office of the Chief Pharmacist, which works directly with applicants to explain any processes involved in applications.

(b) The Government of Jersey is committed to ensuring that products developed under healthcare innovation initiatives, such as the CareTech Challenge, meet international regulatory standards for export. These standards are a range of **technical, clinical, data protection, and user experience**

standards to ensure safety, efficacy, interoperability, and trustworthiness. With the NHS being one of the largest and closest market, the products must meet NHS standards as a minimum. These standards are set by bodies such as **NHS England**, **NHS Digital (now part of NHS England Transformation Directorate)**, **NICE**, and **MHRA.** To achieve this, the Government mandates that all products must meet the following standards:

1. **Adherence to International Standards**: Products developed under the CareTech Challenge will be designed and tested in accordance with international regulatory standards, including those set by the World Health Organization (WHO) for quality, safety, and efficacy. This includes compliance with guidelines on stability, packaging, storage, and bioequivalence.
2. **Technical standards:** Interoperability and Integration: Must comply with Interoperability Standards such as: FHIR (Fast Healthcare Interoperability Resources), NHS Spine integration for accessing patient data (e.g. Summary Care Records) and GP Connect and PDS (Personal Demographics Service).
3. **Cyber Security:** Must align with the Cyber Essentials scheme or Cyber Essentials Plus and must undergo Data Security and Protection Toolkit (DSPT) assessment.
4. **NHS DCB Standards:** All healthcare products must meet the NHS Digital Clinical Risk Management standards, specifically DCB0129 and DCB0160. These standards provide a framework for manufacturers to evidence the clinical safety of their products, ensuring they are suitable for use within the health and care environment.
5. **Rigorous Assessment and Certification:** Once developed, products must undergo rigorous assessment and certification processes to verify their compliance with international standards. This includes obtaining necessary certifications from recognized bodies such as the WHO and evidence that products meet the NHS Clinical Digital Safety standards
6. **Collaboration with Regulatory Bodies:** The Government will collaborate with international regulatory bodies to stay updated on the latest standards and requirements. This will ensure that products are continuously aligned with global best practices and can be successfully exported to international markets.
7. **Continuous Improvement and Innovation:** The Government will foster a culture of continuous improvement and innovation, encouraging developers to adopt the latest advancements in healthcare technology and clinical practice. This will help maintain high standards and ensure products remain competitive in the global market.