WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES BY DEPUTY I. GARDINER OF ST. HELIER NORTH QUESTION SUBMITTED ON TUESDAY 6th MAY 2025 ANSWER TO BE TABLED ON WEDNESDAY 14th MAY 2025

Ouestion

"Further to the response to <u>Written Question 151/2025</u>, in which the Minister stated that he was the regulatory authority for medicinal products in Jersey, including any manufacture of medicines, will he advise whether it is his assessment that Jersey has a sufficient framework in place to ensure that the development of medical technology in the Island can be fully supported and certified (including NHS and WHO recognition)?"

Answer

Further to my response to Written Question 151/2025, I can confirm that, under the current legislation, the Minister for Health and Social Services is designated as the regulatory authority for medicinal products in Jersey, including any proposed manufacture of medicines.

As previously explained, no medicinal products are currently manufactured in Jersey.

The existing regulatory framework involves close collaboration between the Medicines and Healthcare products Regulatory Agency (MHRA), the Office of the Chief Pharmacist, and the Medicines Advisory Council. This model provides effective oversight for the Island's current level of activity and includes professional regulation, inspection, and ongoing pharmacovigilance functions.

However, having reflected on the current arrangement – and in light of the Island's interest in supporting the development of medical technology and potential medicines manufacture – I have determined that subject to consultation with key stakeholders and the development of detailed proposals, the Medicines (Jersey) Law 1995 should be amended to provide for the establishment of an independent medicines regulator. This regulator would operate at arm's length from ministerial authority and would facilitate compliance with the relevant Good Manufacturing Practice (GMP) standards.

Medical technology developed in Jersey, should be supported where they meet international standards for safety, efficacy, and innovation. To assess which medical technologies to support, a structured evaluation process should be followed, which would include clinical effectiveness and safety, as well as cost-effectiveness. To try and ensure the eventual product will be able to compete for a national and international market, including NHS and WHO recognition, the product developer should be able to demonstrate success with national and international fundraising for example National Institute for Health Research (NIHR), or Horizon Europe.