WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES BY DEPUTY I. GARDINER OF ST. HELIER NORTH QUESTION SUBMITTED ON MONDAY 28th APRIL 2025 ANSWER TO BE TABLED ON TUESDAY 6th MAY 2025

Question

"Will the Minister advise what plans, if any, exist to align Jersey's regulatory framework with the World Health Organisation's recommendations on good regulatory practices and reliance mechanisms (\underline{WHA} <u>67.20</u>); and, if such plans exist, will he explain what this would involve?"

Answer

The World Health Organisation (WHO) provides principles, not operational frameworks: WHO guidance like WHA 67.20 sets high-level global best practices. These are not technical standards like EU-GMP but principles and system-level practices that guide how a regulatory authority should function.

The WHO provides guidance on good regulatory practices (GRP) and reliance mechanisms to support countries in strengthening their medicines regulation. The WHO under WHA 67.20 explicitly encourages countries to rely on the decisions of trusted regulatory authorities – such as the Medicines and Healthcare Regulatory Agency (MHRA), European Medicines Agency (EMA) and the Food and Drug Administration (FDA) – as part of its strategy to improve regulatory efficiency, reduce duplication, and facilitate faster access to quality-assured medical products.

The Government of Jersey has an MoU with the UK medicines regulator, the MHRA, and therefore uses the expertise of an internationally recognised National Regulatory Authority. Jersey aligns its medicines regulatory framework with the UK's MHRA to ensure legal, operational, and market compatibility with UK systems. All medicines placed on the Jersey market should be authorised by the MHRA and manufactured in accordance with EU-GMP standards, ensuring high-quality, safe, and effective products.

While WHO's WHA 67.20 sets out high-level best practices – such as transparent, risk-based regulation, reliance on trusted authorities, and good governance – these are already embedded within the MHRA's approach. By aligning with the MHRA, Jersey indirectly meets WHO principles.

This approach avoids duplication, ensures regulatory efficiency, and maintains public health protection.