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 10th FEBRUARY 2025 ANSWER TO BE TABLED ON MONDAY 17th FEBRUARY 2025

Ouestion

"In relation to Jersey's regulatory system for medicines, will the Minister detail –

- (a) the maturity level of the system as assessed against World Health Organization (WHO) standards;
- (b) how the system compares to global benchmarks for regulatory systems; and
- (c) any reports on, or evaluations of, Jersey's system, including any references to WHO's Global Benchmarking Tool (GBT)?"

Answer

The following answer will cover (a), (b) & (c):

Good Manufacturing Practice (GMP) is the standard for production of medicines. There are many different versions of GMP for different parts of the world, however the aim is always the same – to protect patients from harm from poor quality medicines.

Jersey, as with the EU and the UK, operate to EU GMP standards and EU Good Distribution Practice (GDP) standards – *not* the WHO-GMP. This is for all medicines. Therefore, the system of assessment used by the World Health Organisation (WHO) is not relevant in the Jersey, EU and UK context.

Medicines placed on the market in Jersey are subject to regulation by the Medicines and Health care products Regulatory Agency (MHRA). The MHRA is the UK medicines regulator and is recognised globally as a National Regulatory Authority. This is applicable to Jersey.

The WHO GMP guide can be used in countries where there is no recognised pharmaceutical inspection system – for example parts of Africa, South America and Asia. This is not applicable in Jersey.

Further information

- For companies in Jersey wishing to set up as a pharmaceutical manufacturer or wholesaler, there is an MoU in place with the UK medicines regulator, the MHRA. The MHRA will provide technical support through inspection against EU GMP and EU GDP standards.
- The Government of Jersey uses the expertise of MHRA, as a globally recognised National Regulatory Authority, to confirm whether or not any operator is compliance with GMP or GDP. This will form the basis of any licences issued by the Minister for Health and Social Services under the Medicines (Jersey) Law.