WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES
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QUESTION SUBMITTED ON MONDAY 2nd NOVEMBER 2026
ANSWER TO BE TABLED ON MONDAY 9th NOVEMBER 2026

Question

"Further to his previous statements that the medicines regulatory framework is robust, will the Minister explain the reasons for commissioning another review of that framework and advise –

(a) what issues or developments have emerged which have led to the review;
(b) the review's aims, objectives, scope and terms of reference;
(c) the timetable for completion of the review and publication of its findings;
(d) whether any amendments to the Medicines (Jersey) Law 1995 or Misuse of Drugs (Jersey) Law 1978 are anticipated; and
(e) whether any changes are being considered to the role, responsibilities or statutory duties of the Chief Pharmacist in relation to drugs, medicines and therapeutics?"

Answer

(A), (B)
In May 2025, despite my reservations, I was advised by a senior member of staff (who is no longer in post) that our medicines regulatory framework was appropriate and robust. However, given these reservations and as set out in the answer to WQ188/2025, I had already arranged for work to commence on a review to determine whether the Medicines (Jersey) Law 1995 and the Misuse of Drugs (Jersey) Law 1978 was actually fit for purpose in a rapidly changing regulatory environment.

The review to which I refer focused on analysing:

- Jersey's current system of regulation, comparing it against recognised international regulatory standards for medicines and medical devices (such as the WHO Global Benchmarking Tool) in order to identify gaps and risks associated with that legislative framework
- how an appropriate regulatory approach could support growth in Jersey's medicines and medical technology sector, providing high level preliminary options for Jersey's regulatory approach to medicines and medical devices.

Importantly that review made it clear that our arrangements are not sufficiently robust, as I was advised, previously, and that work is urgently needed to further our compliance with international standards and support increased regulatory maturity.

A summary of the review findings has already been shared with industry and are provided as an appendix to this answer.

Subsequent to completion of that review, work has now started on developing an enhanced regulatory regime for Jersey.

(C): At this time I am unable to provide a timetable for completion for this work given its technical complexity, the requirement to amend legislation and to establish a regulatory function recognised as

competent in other jurisdictions, which is essential to facilitating import and export and our potential, emerging life sciences industry.

(D), (E): This will include:

- amendments to the Medicines (Jersey) Law 1995 and the Misuse of Drugs (Jersey) Law 1978
- consideration of the role and responsibilities of the Chief Pharmacist in relation to drugs, medicines and therapeutics
- further, detailed reviews of complex, technical areas of policy and practice (for example pharmacovigilance)

Appendix: Jersey Medicines and Medical Technologies Governance Reform: review summary

Review summary provided to Minister for Health and Social Services
15 April 2026

1. Purpose and Context

This paper summarises the findings of an initial review of Jersey's medicines and medical technologies (MMT) system[1]. It sets out why reform of the current governance arrangements is required, explains Jersey's current level of system maturity, and recommends a proportionate pathway to establish a credible, internationally recognised framework aligned to global standards whilst maintaining current business operations.

The objective of this work is to protect public health through effective oversight of medicines and medical technologies while enabling economic growth by creating conditions for a viable life sciences sector. The review concludes that the current system is not adequate to meet either objective on a credible and sustainable basis.

2. Approach and Evidence Base

The findings are based on an expert detailed review of existing legislation, policies, and operational documents, alongside assessment against international benchmarks and global standards. This was complemented by structured engagement with key stakeholders across government, healthcare, industry, and external partners with experience of comparable systems.

Stakeholders identified a clear need for reform of the current governance arrangements. There was a shared recognition that the current system is not sustainable, that greater clarity and transparency are required, and that alignment with global standards is essential for credibility and growth. Taken together, the evidence indicates a clear case for change.

3. Why Change is Necessary

Oversight of medicines and medical technologies is a core government responsibility. Current governance arrangements lack a clear end-to-end framework, with functions fragmented across departments and not consistently meeting modern expectations for transparency and accountability. This creates gaps in lifecycle oversight and increases risks.

From a macroeconomic perspective, a credible governance system aligned to global standards is essential for participation in the international life sciences economy. Other jurisdictions only accept products

where oversight meets recognised standards. Without this, Jersey-based products cannot be exported at scale, high-value activity is displaced off-island, and investor confidence is weakened.

4. System Maturity and Global Standards

System maturity reflects how effectively a jurisdiction's governance framework operates across the full lifecycle of medicines and medical technologies, and its alignment with the World Health Organisation's (WHO) international standards. Maturity ranges from fragmented systems (ML1) to stable, globally aligned systems (ML3), and advanced systems (ML4).

Maturity is critical to international trust and the ability to support exports. Trusted systems demonstrate transparency, consistency, and accountability through a designated Competent Authority. A Competent Authority has a clear legal mandate, defined responsibilities, established processes, technical capability, and transparent decision-making, and serves as the point of trust for other jurisdictions.

The review found that Jersey does not currently meet the standard for a globally aligned system. Responsibilities are fragmented, alignment with global standards is limited, and reliance on external partners is informal. Initial review suggests that Jersey is potentially operating at ML1–ML2 maturity so cannot be recognised as a designated Competent Authority in relation to medicines.

Note: The medical devices and diagnostics sector, which has faster and more iterative innovation cycles than the medicines sector, does not require Jersey to have a designed Competent Authority but does requires a robust legal framework and an associated regulatory authority to ensure compliance with legislation.

5. Summary of Key Findings

The central issue is not a lack of ambition, but limitations in governance and delivery capacity and capability. There is no coherent end-to-end framework, with gaps in oversight across safety monitoring, medical devices, and research. Processes and decisions are not consistently documented or transparent, and key legal provisions remain unenacted or absent.

This increases public health risk and liability, reduces investor and international confidence, and constrains economic development, as Jersey cannot yet demonstrate the governance conditions required for a sustainable sector.

In practical terms, this creates uncertainty for operators, limits market access and export potential, and weakens Jersey's ability to evidence credible end-to-end oversight.

6. Strategic Direction

A range of approaches were considered, from maintaining the current system to developing a fully advanced model. The analysis indicates that maintaining the current position is not viable, and that while short-term improvements are necessary (for example, publication of guidance on manufacturing authorization application processes) they are not sufficient. A structured move to a credible, sustainable fee-based system aligned with global standards is required.

The preferred direction is therefore a proportionate model: one that addresses potential risks, ensures continuity of existing business operations, establishes a coherent and sustainable local governance framework, and uses structured reliance to access external expertise where appropriate.

7. Recommended Approach

A phased approach is recommended. In the short term, the system should be stabilised and strengthened to address immediate risks whilst maintaining continuity for the existing operators. In the medium term, Jersey should establish a well-functioning system aligned to global standards, capable of supporting international confidence and economic activity whilst recovering costs where it is appropriate to do so. Over time, there should remain flexibility to evolve further as the number of operational businesses increases.

This approach should maintain Jersey's autonomy while adopting structured reliance on trusted partners such as the MHRA, ensuring that external expertise is used where capability is not available locally. A clear and coherent governance framework should be established, with defined roles, responsibilities, and transparent processes.

8. Financial and Economic Considerations

Reform should be viewed as economic infrastructure investment rather than departmental expenditure. A governance system aligned to global standards enables export capability, has the potential to attract high-value investment, supports skilled employment, and retains economic activity on-island. Cost recovery through industry fees can support regulatory activity, while maintaining full independence and integrity of decision-making.

Without reform, Jersey will remain excluded from high-value segments of the life sciences sector and continue to lose investment opportunities. Without alignment to global standards, economic potential cannot be realised.

Governance capability is therefore not a downstream benefit of sector growth; it is a precondition for it.

9. Conclusion

The review demonstrates that the current governance system is not adequate, and that there is strong stakeholder support for reform. Alignment with global standards is essential.

A phased transition from stabilisation to a credible, standards-aligned system represents the most proportionate and deliverable approach. This will strengthen patient safety, establish international credibility, enable economic growth, and preserve Jersey's autonomy while leveraging trusted partners.

The conclusion is clear: Jersey cannot rely on current arrangements if it is to protect public health, support regulated activity, and participate meaningfully in the international life sciences economy. Reform is therefore necessary, proportionate, and timely**.**