EURO BIOM

UK MHRA LICENSED PHARMACEUTICAL WHOLESALE EXPORTER

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Quality Policy

Pharmaceutical Wholesale Distribution & Export Operations

Euro Biom Ltd is a UK-based pharmaceutical wholesale exporter operating under MHRA Wholesale Dealer Authorisation WDA(H) 59239, supplying licensed, unlicensed and shortage medicines to hospitals, ministries, NGOs and institutional buyers across more than 40 countries. This Quality Policy sets out our commitment to patient safety, regulatory compliance and operational excellence across every transaction we handle.

1. AUTHORISED SUPPLY

Every product sourced from MHRA or EMA-authorised manufacturers and wholesalers. No grey-market intermediaries, no unverified provenance.

2. GDP END-TO-END

Good Distribution Practice governs procurement, storage, handling, transport and documentation through our qualified partners.

3. VALIDATED COLD CHAIN

Qualified 2-8 C and 15-25 C chains with calibrated data loggers, validated passive packaging and documented excursion control.

4. RESPONSIBLE PERSON RELEASE

Every consignment assessed and released under the authority of our named MHRA-approved Responsible Person before dispatch.

01 Purpose

This Quality Policy defines the principles, responsibilities and standards by which Euro Biom Ltd conducts its pharmaceutical wholesale and export activities. It establishes our commitment to protecting patient safety, maintaining medicinal product integrity and meeting the regulatory expectations of the Medicines and Healthcare products Regulatory Agency (MHRA) and the national regulators of every country we supply.

02 Scope

This policy applies to all activities carried out under Wholesale Dealer Authorisation WDA(H) 59239, including procurement of licensed and unlicensed medicinal products, storage through qualified contract warehousing, export distribution, named patient supply, shortage medicines supply, institutional tender supply, cold chain handling and all associated documentation, labelling and pharmacovigilance obligations. It applies to every member of Euro Biom staff, every contracted partner and every third party acting on behalf of Euro Biom.

03 Regulatory Framework

Euro Biom operates in compliance with the Human Medicines Regulations 2012 (as amended), the UK Good Distribution Practice guidelines aligned with the EU GDP guidance of 5 November 2013 (2013/C 343/01), the Falsified Medicines Directive, and the MHRA Orange and Green Guides. Export activities additionally comply with the regulatory requirements of the destination jurisdiction, including but not limited to registration, import permit, Certificate of Pharmaceutical Product (CPP) and batch-specific documentation requirements issued by SFDA (Saudi Arabia), MoHAP / DHA / DoH (UAE), NAFDAC (Nigeria), PPB (Kenya), FDA Ghana, MoPH Qatar, KDFCA (Kuwait), NHRA (Bahrain), MoH Oman, TITCK (Turkey), SAHPRA (South Africa), EFDA (Ethiopia), TMDA (Tanzania), EDA (Egypt), DMP (Morocco), Rwanda FDA, NDA (Uganda), DPML (Cameroon), DPM (Senegal), ANARME (Mozambique), MCAZ (Zimbabwe), HPRA (Ireland), BfArM (Germany), ANSM (France), CBG-MEB (Netherlands), FAMHP (Belgium) and other competent authorities.

04 Leadership & Responsibility

Overall responsibility for this Quality Policy rests with the Board of Directors of Euro Biom Ltd. Day-to-day responsibility for the Quality System is delegated to the Responsible Person named on the MHRA licence, Mr Brian Lindsay, who has the authority to suspend supply, reject product, initiate recall and represent Euro Biom before the MHRA and other competent authorities in any quality matter. All staff are empowered and expected to raise any quality concern without fear of retaliation.

05 Quality Commitments

Euro Biom commits to the following principles in every transaction:

- **Patient safety first.** No commercial consideration overrides patient safety. Product is withheld or suspended whenever integrity, identity, strength, quality, purity or provenance cannot be demonstrated.
- **Licensed sourcing.** Medicinal products are procured exclusively from suppliers that hold a valid Manufacturing Authorisation, Wholesale Dealer Authorisation or equivalent authorisation issued by the MHRA or an equivalent European competent authority.
- **Documented supply chain.** Full batch-level traceability is maintained from the originating manufacturer through to the receiving customer. Invoices, delivery notes, Certificates of Analysis, Certificates of Conformity and transport records are retained in accordance with UK GDP requirements.

- **Regulatory accuracy.** Export documentation including Certificate of Pharmaceutical Product, Free Sale Certificate, Certificate of Origin, batch release statements, commercial invoice, packing list and air waybill is prepared to the standard required by the destination regulator.
- **Validated cold chain.** Temperature-sensitive products are shipped in qualified passive packaging with calibrated electronic data loggers. Any temperature excursion is investigated, documented and assessed for product impact before onward release.
- **Named patient & unlicensed supply.** Supply of unlicensed medicinal products is conducted under the notification framework required by the MHRA and the equivalent framework in the destination country. Clinical justification, prescriber details and onward consignee details are recorded for every shipment.
- **Pharmacovigilance.** Adverse drug reactions, suspected product defects and counterfeit suspicions are reported through the appropriate channels to the MHRA, the marketing authorisation holder and the destination regulator as required.
- **Data integrity.** All quality records are complete, contemporaneous, legible, attributable, original and accurate. Electronic records are stored under controlled access with backup.
- **Continuous improvement.** Deviations, complaints and audit findings are recorded, investigated, assigned corrective and preventive actions (CAPA), and reviewed by management.

06 Supplier & Customer Qualification

Before any commercial relationship is established, Euro Biom qualifies each supplier and each customer. Supplier qualification includes verification of MHRA or EMA authorisation status, GDP or GMP certificate status, corporate standing and regulatory history. Customer qualification includes verification of the customer's wholesale, manufacturing, hospital or institutional authorisation in the destination jurisdiction; Euro Biom does not supply products to unauthorised recipients or to purposes inconsistent with the customer's licence. Qualification records are maintained and reviewed periodically.

07 Cold Chain Handling

Products requiring controlled temperature storage and transport are handled through qualified warehouse partners with temperature-mapped storage zones at 2-8 C, 15-25 C and, where required, below minus 15 C. Shipments are prepared in validated passive packaging selected on the basis of transit duration, route and season. Calibrated electronic data loggers accompany every temperature-sensitive consignment. On delivery, the recipient is provided with the temperature record together with the batch documentation so that release at destination can be assessed against the manufacturer's stability profile.

08 Recall, Complaints & Pharmacovigilance

Euro Biom operates a documented recall procedure capable of retrieving product from all customers within 24 hours of receipt of a recall notice at any level (precautionary, Class 1, Class 2, Class 3). Product complaints are logged, acknowledged and investigated within defined timelines. Suspected falsified medicines are quarantined and reported to the MHRA Defective Medicines Report Centre and to the originating marketing authorisation holder. Suspected serious adverse drug reactions are reported to the MHRA Yellow Card scheme and to the equivalent reporting system of the destination country.

09 Audit, Inspection & Management Review

The Quality System is subject to internal self-inspection on a scheduled basis and to external inspection by the MHRA and, where applicable, destination regulators. Audit findings, deviations and CAPA are reviewed by management at least annually. This Quality Policy is reviewed at least annually and updated whenever there is a material change in regulations, operations, supplier base or destination markets.

10 Contact & Feedback

Quality concerns, complaints, recall notifications and regulatory correspondence may be directed to the Responsible Person via **work@eurobiom.co.uk** or by post to Euro Biom Ltd, Unit-5 Skyport Drive, Harmondsworth, London, UB7 0LJ, United Kingdom. Telephone: +44 7492 670948.

Signed and Authorised

This Quality Policy has been reviewed, approved and signed by the Responsible Person and the Board of Directors of Euro Biom Ltd. It is binding on all Euro Biom personnel, contracted service providers and parties acting on behalf of the company.

RESPONSIBLE PERSON (MHRA)

Mr Brian Lindsay

Responsible Person, WDA(H) 59239
Signed at London, United Kingdom
Date: 27 December 2025

SIGNATURE

ON BEHALF OF THE BOARD

Mr Akhlesh Mathur

Director, Euro Biom Ltd
Signed at London, United Kingdom
Date: 27 December 2025

SIGNATURE

Euro Biom Ltd Company No. 15380737 Registered in England & Wales
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