
Memorandum of Understanding
between
the MHRA and the Government of Jersey Health and Community Services
Department

The MHRA and the Jersey Health and Community Services Department in the Bailiwick of Jersey (hereinafter referred to as “the Parties”), desiring to further enhance the cooperation in the field of inspection of pharmaceutical manufacturers and wholesale distributors and blood establishments located in the Bailiwick of Jersey, through amicable negotiation, have set out the following understandings which they have jointly agreed:

Article I Purpose

The purpose of this MOU is to establish a mechanism under which the MHRA provide technical support to the Jersey Health and Community Services Department through the conduct of inspection of pharmaceutical manufacturers and wholesale distributors and blood establishments located in the Bailiwick of Jersey, on which the Government of Jersey will then base their licensing and approval decisions.

Article II Areas of Cooperation

This MOU represents the understanding reached by the Parties and is intended to cover the conduct of inspections of pharmaceutical manufacturers and wholesale distributors and blood establishments located in the Bailiwick of Jersey.

Article III Activities

The MHRA recognises that The Bailiwick of Jersey is a British Crown Dependency, and will provide the Jersey Health and Community Services Department with technical support through the conduct of inspections of pharmaceutical manufacturers and wholesalers and blood establishments, on which the Government of Jersey will then base their licensing and approval decisions.

The standards which the MHRA will inspect against are:

- EU Good manufacturing practice (GMP)
- EU Good distribution practice (GDP)
- EU Good Practice Guide for Blood

For any products entering the EU market, where a UK based company names a site in Jersey as the site of manufacture on a Marketing Authorisation a third country inspection will be triggered in accordance with MHRA’s standard inspection procedures. Such inspections are outside the scope of this MOU.

Article IV Expenditure and Fees

For inspections conducted under this MOU the MHRA will charge the Jersey Health and Community Services Department a fee for the inspection at the standard rate. The most up to date fees are outlined in www.gov.uk/government/publications/mhra-fees/current-mhra-fees and will apply.

Article V Confidentiality

Any proprietary information shared by the parties, under this MOU shall, in so far as it is possible in accordance with their respective national laws, be treated as confidential. Where information is required to be shared under national legislation, the party concerned will give notice to the other party and take all reasonable measures open to it to protect it from disclosure. Information that is shared in support of projects where the output is intended to be disseminated into the public domain is not covered by this clause.

Article VI Amendments

Any change to this MOU shall be made by mutual consent of the Parties.

Article VII Disputes

Any dispute between the Parties concerning the implementation and interpretation of this MOU shall be settled amicably through bilateral consultations and negotiations.

Article VIII Status

The MoU is not a legally binding obligation.

Article IX Supplementary Provisions

This MOU shall come into effect on the date of its signature and will continue in effect until terminated, in writing, by either Party.

SIGNED in _____ on the _____ of _____, with two original copies in the English languages, both texts being equally authentic.

[Redacted]

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Caroline Landon, Director General, Health and Community Services Department, Government of Jersey

[Redacted]

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Ian Hudson, Chief Executive of The Medicines and Healthcare products Regulatory Agency (MHRA), UK

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