The British Association of
Prosthetists and Orthotists

MHRA GUIDANCE
FOR BAPO MEMBERS

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MHRA GUIDANCE APPLICABLE TO PROSTHETICS & ORTHOTICS

The Medicines and Healthcare Regulatory Agency (MHRA) oversees legislation and regulation of medical devices on the UK market, including prostheses and orthoses. It has been appointed as the EU as the UK 'notified body for medical devices'.

Prostheses and orthoses are considered 'general medical devices' and are currently covered by 'The Medical Devices Directive 93/42/EEC':
https://eur-lex.europa.eu/LexUriServ/LexUriServdo?uri= CONSLEG: 1993L0042:20071011:EN:PDF

In 2017 new regulation was set out - 'The EU regulations on Medical Devices 2017/745' which will come into full effect by May 2020. An interactive tool has been launched by MHRA to help clarify aspects in preparation for this change:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/640404/MDR_IVDR_guidance_Print_13.pdf

The MHRA have also outset how medical devices will be regulated in a no deal Brexit scenario:
https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario

Further MHRA publications provide greater detail on certain aspects which may be relevant to those working in the Prosthetic and Orthotic industry, these are outset in the pages which follow.

NB: BAPO advise members to contact MHRA directly if they have uncertainty on their compliance with these regulations or if they require further clarity on legislation.

It is important to note that regional health boards and local hospital trusts may have their additional guidance or best practice statements for use of medical devices, such as publications by Health Services Scotland. BAPO members should adhere to these where applicable.

ALERTS AND RECALLS OF MEDICAL DEVICES

- MHRA publish a weekly industry wide lists of field safety notices with links to further detail from manufacturer.
- **https://www.gov.uk/drug-device-alerts**

CLASSIFICATION OF MEDICAL DEVICES

- Most prostheses and orthoses are identified as 'class 1' medical devices, these are regarded as low risk medical devices. Some externally powered devices may be categorised as 'class 2a' 'class 2b' and are regarded as medium risk medical devices. This document outsets the logic for determining the class of a medical device
- **http://ec.europa.eu/DocsRoom/documents/10337/attachments/1/translations**

CONFORMITY ASSESSMENT AND THE CE MARK

- Manufactures need to demonstrate that the medical device meets the requirements as set out in the 'Medical Devices Directive'. The assessment route depends upon the classification of the device (as per above). This guidance outsets the various assessments routes for devices.
- **https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark**

CUSTOM MADE DEVICES

- This guidance discusses prescription, conformity, labelling, CE marking, compliance statements, retention of documentation and post-supply surveillance of devices.
- **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/398428/Custom_made_devices.pdf**
- **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/398323/Examples_of_statements_for_custom-made_medical_devices.pdf**

EXCEPTIONAL USE OF NON-CE MARKED MEDICAL DEVICES

- Covers how a manufacturer and clinician can jointly apply for approval to supply a non-compliant medical device on humanitarian grounds.
- **https://www.gov.uk/guidance/exceptional-use-of-non-ce-marked-medical-devices#criteria-for-exceptional-use-of-non-complying-medical-devices**

EXPORT MEDICAL DEVICES

- You don't need a certificate of free sale to move medical devices within the EU. Outside the EU, you may need a Certificate of free sale to export medical devices. This guidance outlines the application process.
- **https://www.gov.uk/guidance/export-medical-devices-special-rules**

DEVICES IN PRACTICE

- This is a checklist outlaying detail that should be considered before, during and after device use. It also outlines responsibility of the users and carers, record keeping and reporting of problems.
- **https://www.gov.uk/government/publications/devices-in-practice-checklists-for-using-medical-devices**

GUIDANCE FOR MANUFACTURERS ON VIGILANCE

- Information for manufacturers of medical devices about reporting adverse incidents and corrective actions to the MHRA.
- **https://www.gov.uk/government/collections/medical-devices-guidance-for-manufacturers-on-vigilance**

IN-HOUSE MANUFACTURE OF MEDICAL DEVICES

- In-house manufacture refers to medical devices that are made in a healthcare establishment to be used for patients within that establishment. A healthcare establishment is a body that provides care for patients and promotes public health (eg an NHS hospital).
- This guideline covers legal requirements, exemptions from regulations, transfer of devices between hospitals, clinical investigations and R&D.
- **https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices**
- This guideline covers legal requirements, exemptions from regulations, transfer of devices between hospitals, clinical investigations and R&D.
- **https://www.gov.uk/government/consultations/health-institution-exemption-for-ivdrmdr**

MANAGING MEDICAL DEVICES

- The MHRA produce guidance for managing reusable medical devices. These covers acquiring devices, training, maintenance & repair, reporting adverse incidents, decontamination and decommissioning/dispoal.
- **https://www.gov.uk/government/publications/managing-medical-devices#history**

NOTIFYING MHRA ABOUT A CLINICAL INVESTIGATION FOR A MEDICAL DEVICE

- You may need to carry out a clinical investigation as part of the process to obtain a CE marking for your medical device. You must inform MHRA if you are planning to do this at least 60 days before starting your investigation.
- **https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device**

OFF-LABEL USE OF A MEDICAL DEVICE

- Medical devices are intended to be used as set out in manufacturer's instructions. If using the device in any other way, this is considered 'off-label use'.
- This guidance covers medical devices without a CE mark, modifying medical devices, risk assessment and third-party accessories.
- **https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device**

PARALLEL IMPORTS OF MEDICAL DEVICES

- If you want to put a medical device which is already marketed in an EU country on the market in another EU country not intended by the manufacturer this is a parallel import.
- **https://www.gov.uk/government/publications/parallel-imports-of-medical-devices/parallel-imports-of-medical-devices**

REGISTER AS A MANUFACTURER TO SELL MEDICAL DEVICES

- If you place certain medical devices on the EU market you or your designated authorised representative must register with the MHRA.
- **https://www.gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices**

SOFTWARE APPLICATIONS

- Guidance is provided on when software applications are a medical device and how these are regulated.
- **https://www.gov.uk/government/publications/medical-devices-software-applications-apps**

'VIRTUAL' MANUFACTURERS (PREVIOUSLY KNOWN AS 'OWN BRAND LABELLING')

- A virtual manufacturer is an organisation that fully sources its own named product from another company (sometimes known as the 'original equipment manufacturer'), which has designed and manufactured an identical CE marked product. By placing their own name and address on the product, the virtual manufacturer takes on the legal responsibilities for the medical device and is therefore regarded as the manufacturer in accordance with the medical device regulations. Note that in practice there is no difference in the regulatory requirements applying to a manufacturer and a virtual manufacturer.
- This guidance discusses responsibilities of the 'virtual' manufacturer, technical documentation, contractual agreements, CE marking and distributor status.
- **https://www.gov.uk/government/publications/medical-devices-virtual-manufacturing-replaces-own-brand-labelling**

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