



# Medical Devices

QUICK REFERENCE GUIDE

## Why this guidance is important for you?

As well as dealing with medicinal products pharmacists are also involved in the sale and provision of numerous medical devices for use either by themselves or by other healthcare professionals. In addition, with more patients wanting to diagnose and manage their own medical conditions, purchases of medical devices directly from pharmacies are also being undertaken. The types of medical devices pharmacists encounter are diverse, ranging from glucose monitors to walking sticks. It is important therefore as part of our role in ensuring the safe and effective use of medical devices that we are also aware of the numerous factors we need to consider when recommending, selling or purchasing a medical device.

## Who needs to read this?

This guidance is for pharmacists who handle, use and sell/supply medical devices.

## What this guidance will tell you

This guidance will highlight questions you need to consider when dealing with medical devices. These include:

- What factors to consider when purchasing a medical device
- What factors to consider when selling/supplying a medical device
- How to report adverse events associated with medical devices
- What to do with Medical Device Alerts

## What is a medical device?

A medical device is

“any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used on human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means”.

## What types of medical devices are sold in pharmacies?

Examples of medical devices (not exhaustive) available from pharmacy include:

- Dressings
- Thermometers
- Needles, syringes
- Blood pressure monitors
- Stoma care products
- Condoms
- Test kits, e.g. cholesterol test kits, pregnancy test kit
- Inhalers
- Glucose meters and test strips
- Screening tests

## How are medical devices regulated?

All medical devices are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

All devices are required to carry the CE mark denoting

compliance with the medical devices regulations and indicating that the device performs as intended, is fit for purpose with all associated risks reduced as far as possible.

### **What factors do I need to consider when obtaining medical devices for pharmacy use and onward sale/supply?**

The following should be considered when deciding to purchase a medical device for retail sale over the counter and for use in pharmacy screening and diagnostic services.

- Ensure the device is CE marked
- Ensure suitable for the population
- Ensure it is suitable for intended use/purpose
- Ensure suitability for service being provided
- Ensure instructions for use are appropriate and easy to read
- Consider accessories that may be required, ease of use and maintenance
- Be aware of counterfeits

### **What do I need to know about devices I use, sell or supply?**

It is vital that you are:

- Aware of any special conditions for use, storage, calibration, cleaning, maintenance and repair for medical devices used within your pharmacy
- Able to give advice and answer questions on these same issues when providing medical devices to patients and purchasers
- Able to obtain written guidance to support the use of the device either through requests for spare instructions for use from the distributor or downloading from the internet in accordance with copyright restrictions

### **How should I report any adverse events associated with medical devices?**

You should encourage and empower purchasers of medical devices to report all device related adverse events because this leads to corrective actions, improvements in design and safer devices.

Reports can be made online on the MHRA website at <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm>

Alternatively a report can be made by email to [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk) or by calling the Adverse Incident Centre on 020 3080 7080.

### **What should I do with Medical Device Alerts?**

Medical Device Alerts are published by the MHRA and you would be most likely to receive one from your Primary Care Organisation, Trust advisor or through your parent organisation.

Always read Medical Device Alerts issued by the MHRA:

- take action as indicated
- be prepared to offer advice to purchasers
- copy any patient instructions attached to the back of the alert and hand these to patients as appropriate

### **Where can I find out more information?**

Further general information on the purchase, use and management of medical devices can be found in the MHRA document *Devices in practice*. A number of advisory pamphlets linked to the use of medical devices are also available on the MHRA website, e.g. cholesterol testing.

#### **Where to go for further information**

RPS members can contact:

**RPS Support:** 0845 257 2570

Email [support@rpharms.com](mailto:support@rpharms.com) or complete an online web form at [www.rpharms.com](http://www.rpharms.com)

- MHRA website  
<http://www.mhra.gov.uk/Safetyinformation/Healthcareproviders/Pharmacy/index.htm>
- CPPE Screening populations, monitoring people, examining patients  
<http://www.cppe.ac.uk/learning/Details.asp?TemplateID=screen-D-01&Format=D&ID=31&EventID=38660>
- RPS Diagnostic testing and screening quick reference guide  
<http://www.rpharms.com/clinical-aspects-of-pharmacy/diagnostic-testing-and-screening-services.asp>
- NHS health check tools and guidance on devices  
[http://www.healthcheck.nhs.uk/\\_GuidanceDocuments.aspx](http://www.healthcheck.nhs.uk/_GuidanceDocuments.aspx)

**In Scotland**  
**Report online at [www.hfs.scot.nhs.uk](http://www.hfs.scot.nhs.uk)**  
**Alternatively, email [nss.irc@nhs.net](mailto:nss.irc@nhs.net)**  
**or telephone the IRIC helpline 0131 275 7575**