Is my product a UK medical device?

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Reading time 8 mins

Key Points

- The WHO estimates that there are currently 2 million types of medical devices on the world market

- The Healthcare products Regulatory Agency (MHRA) is the executive agency that oversees the regulation of UK medical devices and medicines
- The intended use of a product, substance, or device determines whether it will be classified as a medical device, medicinal product or other borderline product such as a biocide, food, or cosmetic
- Medical device regulations created before digital healthcare technologies existed need to be updated to avoid stifling innovation
- One of the key areas under review is software as a medical device (SaMD), including AI
- Data protection and privacy remain a key concern

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Ben Mazur

Managing Director

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With digital health solutions and wearables becoming increasingly popular worldwide, a grey area of

what constitutes a medical device becomes just as apparent. What's the difference between a UK medical device and a medicinal product? Can a product such as a fitness tracker that monitors your heart rate or software such as a mobile app be considered a medical device?

Regardless of whether you're a user, device designer, or manufacturer, it's important to bear in mind that what constitutes a medical device can change – depending on legislation – from one country to the next. Especially when it comes to borderline products such as cosmetics, whose status can vary depending on their intended use.

What is a medical device?

The answer to this question isn't straightforward. The World Health Organisation defines this as " any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose [1].

- Medical devices are not restricted to medical environments and can be used in various settings – from the home and workplace to remote clinics, and dentists' offices
- They are used to diagnose illnesses, monitor/provide treatments, assist the disabled, and for interventions
- There are currently an estimated 2 million types of medical devices on the world market

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency that regulates medicines and medical devices. It highlights that some products cannot easily be placed into one category or the other as they are considered borderline [2]. Their status is determined according to what the intended use is, and this includes:

- Cosmetics. Contact lenses, for example, that help correct eyesight problems are medical devices, but cosmetic if being used to change eye colour for aesthetic purposes
- Food products such as nutraceuticals, e.g. dietary supplements
- Biocides such as hand sanitisers
- Medical products
- Machinery or laboratory equipment

For medical devices specifically, this intended use is for [3]:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap

- Investigation, replacement or modification of the anatomy or a physiological process,
- Contraception

How to tell the difference between a medical device and a medicinal product

Medical devices and medicinal products are sometimes used interchangeably to mean the same thing. Probably because they are similar in nature and often used in combination. Most medicinal products (e.g. vaccines) depend on a medical device (e.g. syringe) for their administration or contain medical substances to support their function.

However, the MHRA stipulates that the intended purpose of a medical device is not to have an action in or on the human body by pharmacological, immunological or metabolic means (even if assisted in its function by such means). This includes devices intended to administer a medicinal product or contain a medical substance that, if used separately, would be a medicinal product.

Take, for example, an IUD (intrauterine device), a form of contraception. On its own, it's classified as a medical device. But when modified to deliver drugs such as levonorgestrel, their classification changes to that of a medicinal product [4]:

- This drug-device combination technology (LNG-IUD) is used to treat diseases such as heavy menstrual bleeding, and endometriotic cysts
- The drug can be used separately as an oral therapy but is more effective when incorporated into a device
- A medicinal substance is what achieves the principal intended action – the device part solely acts as the administration method
- LNG-IUD are therefore marketed and classified as medicinal products

On the other hand, if an integrated medical substance/product has an effect on the body that is secondary to the device itself, then it is still classified as a medical device. For example, bone cement used to secure bone implants or as spacers in orthopaedic surgery. It can be loaded with antibiotics (antibiotic-loaded bone cement or ALBC) [5]:

- Used to prevent and treat prosthetic infections
- Provides a high antibiotic concentration around the implanted prosthesis
- The antibiotic function is secondary to that of the bone cement
- Bone cement, even when combined with a medicinal product, is classified as a medical

device [6]

When determining which side of the line a product or device falls, it's always best to check to see which body it will be regulated by. Medical devices are regulated by Medical Devices Regulations (UK MDR 2002), whereas medicinal products are regulated by Human Medicines Regulations 2012.

Digital Health Innovation vs Regulation

Conventional health and medical devices (e.g. syringes or stethoscopes) on their own have a stringent set of UK compliance requirements to meet. However, with IoT in healthcare becoming more mainstream, medical device regulations (created before these technologies existed) need to be updated to avoid stifling innovation, and to overhaul frameworks based on outdated legislation. With this in mind, MHRA opened consultations in 2021 on the future regulation of medical devices.

One of the key areas under review is software as a medical device (SaMD), including AI. Because software is a relatively new tool in healthcare (e.g. applications that allow medical practitioners to look at scans from an MRI on their smartphone), it presents both risks and benefits. Legislation is currently being amended to protect patients (i.e. data protection and privacy) and support responsible innovation in digital health.

We'll keep a close eye on these amendments as we delve deeper into our series on IoT in healthcare,

medical design, compliance and regulation. Would you like us to keep you in the loop? Send us a message to let us know, and we'll do just that!

1. Medical devices. (2020, July 2). https://www.who.int/health-topics/medical-devices
2. Decide if your product is a medicine or a medical device. (2020, October 20). GOV.UK. https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device
3. Borderlines between medical devices and medicinal products in Great Britain. (2021, January). Medicines & Healthcare Products Regulatory Agency. https://www.gov.uk/government/publications/borderlines-with-medical-devices
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6. Borderlines between medical devices and medicinal products in Great Britain. (2021, January). Medicines & Healthcare Products Regulatory Agency. https://www.gov.uk/government/publications/borderlines-with-medical-devices

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+44(0)117 329 3420
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