Information Notice

Medical Devices

Mobile Applications in Healthcare

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ISSUE
Mobile applications (Apps) in healthcare are commonly used by healthcare professionals and the general public. Examples include: • Apps for performing medicine dosage conversions or calculations • Apps that diagnose a disease or medical condition Apps can be useful in healthcare as they can be used easily and can quickly perform various activities or provide access to information when needed. The purpose of this Information Notice is to highlight that Apps that are intended to be used for a medical purpose may fall under the definition of a medical device. The manufacturer of such medical device Apps must comply with the relevant medical devices legislation before they can be placed on the market e.g. downloaded to a mobile device for use. The CE marking process ensures the safety and performance of the App by making sure:: • the performance of the App has been adequately tested, • any medical claims are sufficiently supported by clinical data and • users are provided with information necessary for its safe use.

Users should ensure that any Apps they are using for a medical purpose, as per the definition of a medical device, are appropriately CE marked. Users of medical device Apps for the delivery of healthcare are advised to follow the recommendations indicated below.

Please note that not all Apps used in healthcare are medical devices e.g. Apps that give simple access to medical textbooks/reference materials.

RECOMMENDATIONS

The HPRA recommends the following with regards the use of Apps within healthcare:

General:

- Refer to HPRA "Guide to placing medical device standalone software on the market" to help identify whether the mobile application you are considering using is a medical device. This guide is available on the HPRA website.
- Verify that the App bears a CE mark indicating conformity to the relevant medical device legislation. The CE mark should be clearly visible on the App (e.g. on its landing or information page).
- Check that instructions for use are available for the app and make sure you read the instructions carefully and understand the functionality prior to use.
- Register with the manufacturer, where possible, in order to receive updates/ notices relating to the App. Check the website/ app store from where you have downloaded the app regularly for updates/upgrades, information regarding compatibility with hardware, Operating system requirements, notices etc.
- Ensure you update the App to the most current version. Note the reason for the update, which should be described on the download location and consider any potential impact of the change on future and/or prior use.
- Check that the contact details for the manufacturer are identified on the App to report any adverse events or issues.
- If you are in doubt or are unable to interpret the results obtained from the app e.g. diagnosis/ treatment suggestion/ dosage calculation etc., please contact a healthcare professional as soon as possible.
- If you see a medical device App that does not have a CE mark please contact the HPRA.

Selecting and using the App:

- Check for hardware requirements, operating system requirements, device compatibility and memory requirements before downloading the app.
- Check the compatibility of the app with the antivirus installed on your computer/mobile computing device.
- Always use the recommended settings for the mobile device/ computer.
- If the app is intended to be used in combination with another device ensure that the device meets the specifications provided in the description of the app.
- Always download the app from a recommended/trusted store
- Consider how the App treats sensitive personal data patient and other clinical data and understand fully the data security/ privacy /consent policy associated with the data collected by the software.
- Ensure any security controls relating to the app and/or mobile device are followed e.g. password protection, restricted access.
- Inform the manufacturer of any performance issues noted when using the App. Any incidents (see HPRA Guide linked above) relating to the App, or general concerns relating to safety and performance of the App, should be reported to the HPRA.

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