Is Prescription Support Software Classified as a Regulated Medical Device in Europe?

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Background

Relying on an unregulated app or piece of standalone software to provide a diagnosis or recommend treatment could have potentially life-threatening consequences. In June 2020, the UK's medical devices regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA) updated its **guidance** to help software and app developers in the medical field identify whether their products should be regulated as medical devices.

In particular, the MHRA endorsed the European Court of Justice (CJEU) ruling of **Snitem v Philips France C-329/16** from December 2017. This case considered whether prescription support software which used patient-specific data to detect drug interactions and excessive doses, constituted a medical device.

The CJEU's Judgment

The CJEU held that the prescription support software was a medical device under EU law for the following reasons:

- the software cross-referenced patient-specific data with the medicines that the prescriber had contemplated prescribing;
- the software automatically provided the prescriber with an analysis intended to detect possible drug interactions and excessive dosages; and
- the manufacturer intended the software to be used for one of more medical objectives specified in Article 1(2)(a) of the **Medical Devices Directive 93/42/EEC** (MDD), which include the diagnosis, prevention, monitoring, treatment or alleviation of a disease.

The CJEU further held that it is irrelevant whether the software acts directly or indirectly on the human body. According to the court, the essential criterion for being classified as a medical device is the software's medical objective, examples of which are mentioned above.

Practical Implications

The MHRA guidance provides further certainty that prescription support software and other decision support software in the medical field may be classified as medical devices and thus need to comply with the requirements under the MDD.

As a final point, the MDD is due to be replaced by the Medical Devices Regulation on 26 May 2021. A key implication is that the risk classification of a significant proportion of existing medical device software could change which would mean manufacturers will soon need to obtain regulatory approval to market such software in the EU.