DIGITAL THERAPY IN THE EU

According to ISO standards of December 2023, **digital therapy** is defined as "***health software intended to treat or alleviate a disease, disorder, condition or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on the patient's health.***" (ISO/TR 11147:2023).

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Each **DTx** can be used independently or combined with drugs, devices or other therapies, provided that the software is the driving component of the therapeutic effect. Indeed, **DTx**s comprise a digital active ingredient (the therapeutic algorithm responsible for the clinical outcome) and digital excipients such as, services to remind people to take their medication or other support functions such as remote assistance from healthcare professionals, or even virtual assistants to keep the patient engaged.

DTxs fall under the category of medical devices (Regulation (EU) 2017/745 (MDR)). Regulation 11, in fact, states that medical device software is divided into four categories based on the risks associated with the intended use: from Class I (low risk) to Class III (high risk).

For class I devices, only a self-declaration by the manufacturer is necessary for CE marking, whereas for all other classes, the involvement of a certified body is required. The MDR explicitly classifies two categories of software for medical devices:

- Software intended to provide information used to make decisions for diagnostic or therapeutic purposes (Class IIa or IIb or III, depending on the severity of the potential consequences for a person's health);
- Software intended to monitor physiological processes (Class IIa or IIb).

All other software falls under Class I. Therefore, since software for therapeutic purposes is not specifically mentioned, it could be argued that **DTxs** fall under Class I. However, **it is puzzling that highly innovative software with a huge potential impact on patients' health is not assessed by a certified body.**

Other issues of concern regarding DTx are:

- The rapid developments and changes in **DTx**;
- The lack of harmonisation of applicable regulations;
- The absence of an EU Standardised Framework for assessing the possibility of reimbursement by SSNs.

To date, two digital therapies are being tested in Italy and have been given the green light by the Ministry of Health. The first is KidneYou, an application developed by AstraZeneca and AdvicePharma for the treatment of CKD (chronic kidney disease) that provides therapeutic interventions for the management of patients' eating and exercise habits, constantly monitoring their health status. The second is DTxO, a digital therapy for the outpatient management of obesity, developed by AdvicePharma with Theras Lifetech, which provides personalised diet plans, counselling, exercise programmes, assessment programmes and cognitive-behavioural support.