Defining innovativeness of high-technology medical devices in an Italian region

In the field of medical devices, innovation has been debated to a much less extent when compared with pharmaceutical products. In Italy, the regulation of innovative pharmaceutical products was established in 2017, through a resolution issued by the national medicines agency (AIFA) after the adoption of a national law. According to this regulation, innovative medicines (reported in a national list) are made immediately available to patients, even without formal inclusion in the regional hospital therapeutic schedules.

As regards medical devices, a first attempt to issue a regulation on innovative devices has been made at the regional level in the Tuscany region. A multidisciplinary group of healthcare professionals (eight members of the so-called ‘Gruppo Regionale permanente sui dispositivi medici’, GRDM) from different regional institutions of the national health service has been assigned the responsibility of managing the list of innovative devices since November 2019. This list is restricted to high-technology devices (identifying according to their risk class IIb, III, or active implantable).

Briefly, the main implication of this list is that these devices are made immediately available to Tuscan hospitals. The criterion of innovativeness adopted by GRDM relies, as examples of innovation, on the historical approvals made for these classes of devices between 2019 and 2021. For this purpose, the GRDM has evaluated the following items: (1) the need for the medical device in clinical practice in relation to the regional context; (2) the benefits and risks of its use; and (3) the organisational and economic impact. These evaluations have been made according to the principles of evidence-based medicine and the criteria of the health technology assessment.

In more detail, a retrospective evaluation has been made of 45 innovative devices approved consecutively by GRDM from its inception to October 2021. A Health Technology Assessment (HTA) report has accompanied each of these decisions. According to these data, innovativeness of a new medical device compared with devices already in use was related in 60% of cases (26/45) to a ‘documented advantage’ of clinical, economic or organisational nature, and in 35% of cases (15/45) to covering an ‘unmet clinical need’. Two devices (5%) satisfied both criteria. This is a ‘decide by example’ approach that originates from 45 historical evaluations. As a result, innovative devices are directed towards a rapid procurement without any competitive tender, whereas all other devices undergo the usual procurement paths (in most cases a competitive tender). Even if the distinction between rapid procurement versus ‘normal’ procurement timing has been applied for years, it has been substantially an unconscious application of this principle. The proposal described herein mainly aims at minimising two risks: (1) delaying access to innovative devices by subjecting them to a normal procurement path and its slow turnaround time; and (2) granting immediate access to devices that lack any important advantage. In conclusion, our expectation is that this proposal focused on these criteria of innovativeness can improve the decision-making process on medical devices in the Tuscany region and hopefully in other Italian regions.

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