

Does the Italian wound care market present an opportunity to new technologies?

Author: Luciano Bongiovanni

It is estimated that in Italy approximately 2 million patients a year are treated for problems relating to skin lesions (ulcers and surgical wounds) and this figure is probably conservative as there is no national wound register.

Most complex non-healing wounds are still treated with products 15 or more years old. New technologies are needed more than ever to deal with the increasing demand for cost effective care.

Those wishing to introduce and/or adopt new technologies in Italy face similar challenges to those elsewhere in Europe, particularly with regard to the complex tender based purchasing process which sets very low reference prices.

An important difference between Italy and other European countries, is the absence of reimbursement for advanced wound dressings when prescribed for use in the community except for some rare cases, such as pressure ulcers in the elderly and disabled and for a limited period of care. This severely limits market growth and restricts the prescription of these therapies on a large scale.

Stakeholders:

The stakeholders involved in the processes for market access and the prescription pathways for new technologies are many and varied:

- Specialist Doctors are responsible for clinical evaluation of the product, for prescriptions and for drawing up a protocol of care for the use of the product which has to be approved by the management of the clinical reference centre of the local health authority. A product eligible for prescription has to be already listed on the national or regional tariff.
- Nurses play an important role in the delivery of care and follow up of the patient. In the hospital sector nurses specialising in wound care often have full responsibility for the outpatients' wound clinic and for handling referrals for wound care from the various departments.
- Pharmacists are responsible for purchasing processes, play the role of budget controller and also have a significant role in the execution of tenders.
- The Department of Clinical Engineering has responsibility for ensuring that the new device or wound dressing is compliant with all the applicable health and safety guidelines and risk management.
- The administrative staff of the Local Health Authority or Hospital are in charge of the administrative and legal purchasing procedures.

The Process:

In the Italian market the introduction of new technologies requires an administrative process and a technical evaluation to take place on at least three different geographic levels: national, regional and local in each of the institutions providing health care (such as hospitals, community or other local health authorities).

Continued over page...

The procedure for the purchase of dressings can differ from region to region and even from institution to institution, in most cases however tenders are used.

A new product must first be assessed for its clinical efficacy and it needs to be approved by the hospital clinical committee and by the department of clinical engineering.

Lack of significant technical differences or innovation means that the reference price for a product on the tender is often low. This increases the market competition and reduces margins for the companies, sometimes resulting in a negative return on the investment in the market launch.

In recent years a Health Technology Assessment (HTA) has been required for the introduction of new products. This is a new approach in the Italian wound care market and there are still many limitations and therefore it is not always applied.

In the future the HTA will become increasingly important in driving the decision-making processes of the regions, which in practice run the health care system and set and control health care spending. In many hospitals and territorial administrations (ASL) there is already an HTA department to which clinicians, economists and experts in risk management contribute.

At a national level there are regulatory and quality control agencies, such as AGENAS - National Agency for Regional Health Services and scientific societies such as SITHA - Italian Society of Health Technology Assessment which also perform studies and technical-economic evaluations.

**Despite the challenges and the market dynamics,
there is a significant opportunity for new technologies in Italy**

The introduction of new technologies in the wound care market is particularly required for the treatment of complicated ulcers, dehisced surgical wounds, burns, diabetic foot ulcers and in the management of infected wounds or wounds colonized by biofilms. In these cases the research for innovative biomaterials or diagnostic devices could support not only the healing processes but also, for example, better aesthetic outcomes.

Any company that wants to launch a new technology in Italy successfully, must take into account all of the above mentioned market characteristics and dynamics. They would not only need an efficient sales and marketing organization but would also need to invest resources in market access, clinical support, tender management and customer service.

Given the diversity and the particular dynamics of the market, it could be faster and easier to concentrate initially in a few regions or in reference centres that can influence the early adoption of new technologies even at national level. Some regions and some areas are more open than others. Universities and International Research Centres (e.g. Pisa) can act as reference centres for the adoption of innovation across the country. The clinical wound care societies (AIUC, AISLeC, CORTE) play an important role in the market and can support companies, for example, in the training of health care professionals.

A convincing dossier of clinical, safety and cost-effectiveness data can be invaluable in supporting claims relating to product quality, can justify a premium price compared to the other competitors and can accelerate market access.

Wound Market Consulting – Your Local Partner in Europe