



*"The self-medication sector could also help define new governance structures for the healthcare system, by improving collaborative models between GPs and pharmacists as first points of reference for minor ailments."*

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#### Could you introduce Assosalute to our audience?

Assosalute is the Association within the Italian Federation of Chemical Industry (Federchimica) that represents non-prescription medicinal products authorized to be advertised to the public.

#### How important is the non-prescription market to the broader Italian life sciences ecosystem?

The non-prescription medicines sector accounts for 14.5% of the retail pharmaceutical market in Italy. The level of innovation of non-prescription medicines is, by definition, lower compared to other pharmaceutical products, and it is exclusively linked to updates and replacements (switches) of already existing medicines. However, OTC companies invest consistently in order to innovate and renew existing products, looking at innovation areas such as the optimization of dosage forms or routes of administration, with the goal of improving product effectiveness and reducing the risk of contraindications or undesired effects.

The sector offers therapeutic solutions for the treatment of minor ailments, thus supporting individuals' health and, potentially, the health care system. Increasing the offer of non-prescription active ingredients that are currently unavailable in Italy would allow savings on public pharmaceutical expenditure and a reallocation of resources in favor of the research and modernization of the Italian National Health System.

#### Could you give us an overview of the main regulations in the OTC and other non-prescription medicines?

The Italian regulation of non-prescription medicinal products follows the European regulatory framework. The Italian Ministry of Health must approve advertising in advance, while the switch criteria are the same as established in the European Medicine Agency Guidelines on the classification of OTC medicines.

#### How has the sector performed during the pandemic?

In 2020 the sector registered negative growth: The sector saw a contraction of 8.8%, with a turnover reduction of 6.6% - the equivalent of €2.3 million. In total 235 million boxes were sold. The use of masks, social distancing, greater hands hygiene, and the overall contagion containment measures have significantly reduced the circulation of influenzas and parainfluenza viruses. Cough and cold OTC represent the biggest therapy by market share in the OTC sector, and, consequently, there has been an acerb contraction in this segment, driving down the sector's overall performance.

At the same time, the pandemic brought more awareness about health and prevention, also shifting more emphasis to the importance of general wellbeing. Because of these trends, the food supplements sector enjoys a positive sales curve, continuing a trend started over the last decade. The high growth in nutraceuticals and food supplements has eroded the market share of non-prescription medicines used in minor ailments, also because these are subject to stricter regulations in terms of marketing and advertising.

#### What are the main growth areas in the Italian non-prescription drugs sector? What are your projections for the industry going ahead?

The 2020 sales decline risks to damage a sector already hampered by stagnant growth in the last decade; from 2010 to 2020, the average annual contraction of consumption was of -3.3%. To reverse this trend the sector needs recognition for its contribution in supporting the challenges of the National Health System. In this context, the expansion of the self-medication sector can make room for economic resources to be deployed where they are most needed. The self-medication sector could also help define new governance structures for the healthcare system, by improving collaborative models between GPs and pharmacists as first points of reference for minor ailments.

#### What are Assosalute's objectives for 2021-2022?

In 2021 Assosalute will launch a national project for a new model of collaboration between medical doctors and pharmacists. We are looking to make a case for the importance of OTCs for citizens' health, as well as the sector's contribution to the national health system and its long-term viability, highlighting how pharmacists and doctors can play a role in redefining this sector.

