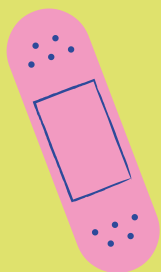
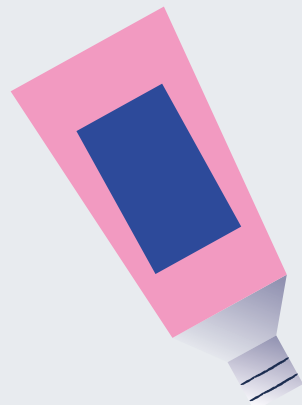


THE VALUE OF SELF-CARE MEDICAL DEVICES IN EUROPE



AESGP

VOICE OF EUROPEAN SELF-CARE INDUSTRY





This brochure is based on data and insights provided by the report "*Self-Care Medical Devices Market Insights - Europe*", conducted on behalf of AESGP by IQVIA Consumer Health. For more details, please consult the main report, accessible via the QR code on the back cover of this brochure.

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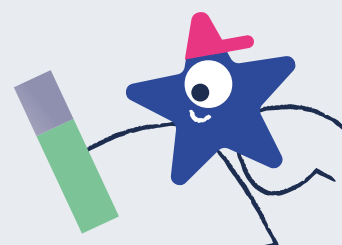
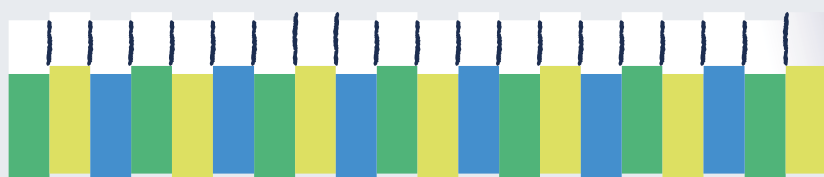
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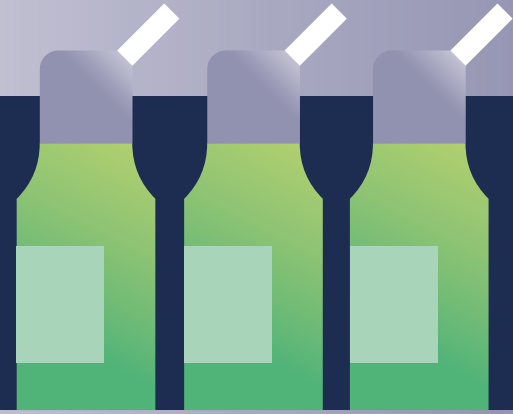
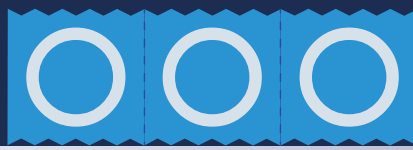
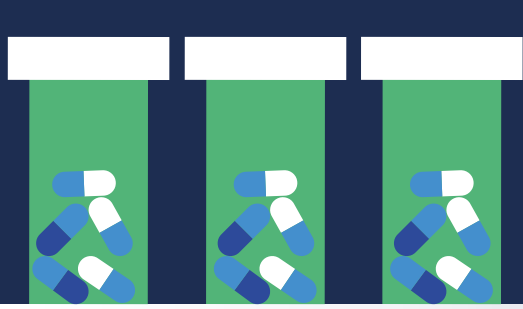
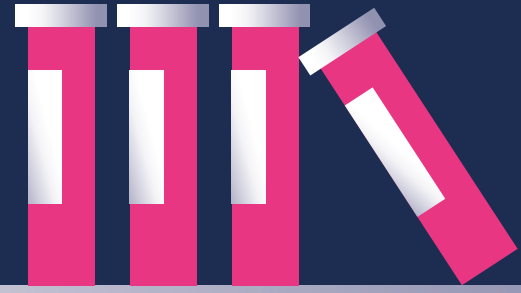
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Introduction

Medical devices encompass a broad spectrum of products that vary in their design, application area, method of use or administration, and intended medical function.

Unlike medicinal products, medical devices do not work primarily through pharmacological, immunological, or metabolic (PIM) processes. Instead, they typically function through physico-chemical or mechanical means. Some examples include artificial hip joints used in hip surgeries, plasters, condoms, pacemakers, medical software applications, face masks, and saline nasal sprays.

Self-care medical devices include a wide range of products and are used by individuals to address common health issues like colds, skin irritation, stomach pain, contraception, or to reduce the risk of sexually transmitted infections. What distinguishes self-care medical devices from others is that they are available without a prescription and can be used independently by individuals. Notable examples of self-care medical devices include plasters, condoms, saline nasal sprays, lubricating eye drops, sore-throat sprays, and various creams or gels for skin conditions.

As self-care is becoming increasingly important in European health systems, with people wishing to take control of their own health, self-care medical devices offer safe and effective ways to manage everyday health needs.

Regulatory context

At the European Union level, medical devices, including self-care medical devices, are subject to the provisions of Regulation (EU) 2017/745 on medical devices (MDR) that is applicable since May 2021.

The implementation of the MDR has been marked by significant challenges for all stakeholders, including companies producing self-care medical devices. Specifically, the sector has been dealing with many issues in the MDR implementation process, reflected in complex and, at times, disproportionate requirements as well as fragmented interpretation of the legal text, contributing to uncertainty and unpredictability.

Due to experienced issues, the MDR has been subject to several amendments and is still undergoing further revisions to address structural issues in the regulatory framework.

Examples of

self-care medical devices

Self-care medical devices encompass a wide variety of products that people can use for routine, minor health concerns, including:



Respiratory comfort (cough, colds & allergies)

Products that help relieve symptoms of congestion, dryness, irritation, or seasonal allergies.

Examples: saline nasal sprays, sore-throat sprays, humidifying or protective solutions.



Eye care

Devices that soothe, lubricate, clean, or protect the eyes (essential for people experiencing dryness, irritation, screen fatigue, or environmental discomfort).

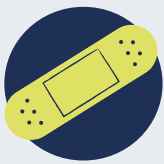
Examples: lubricating eye drops, soothing gels, eye cleansing solutions.



Oral care

Devices that support daily dental hygiene, oral comfort, and the management of denture-related needs.

Examples: toothpastes classified as medical devices, denture care products, oral hygiene gels.



Skin & wound care

Products that protect, cover, or support the healing of minor wounds or help manage skin irritation.

Examples: wart-removing devices, plasters and compresses, dermal gels or creams for irritations.



Digestive comfort

Devices that act through physical mechanisms to alleviate common digestive discomfort.

Examples: oral preparations for acid reflux, dyspepsia, aerophagia, abdominal discomfort, or colic.



Intimate health & contraception

Products used for contraception, comfort, or personal protection.

Examples: condoms, diaphragms, urinary condition products, lubricants classified as medical devices.



Pain relief

Self-care medical devices used to alleviate different types of everyday pain using physical or barrier-based mechanisms.

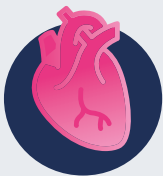
Examples: devices for muscular or joint discomfort, oral gels for mouth pain, thermotherapy or cold packs for dysmenorrhea and other forms of physical pain.



Ear care

Devices that help maintain ear hygiene, relieve discomfort, or support ear health.

Examples: ear-cleansing solutions, cerumen-softening drops, protective ear products.



Circulatory well-being

Products supporting everyday circulatory comfort, particularly when symptoms relate to venous congestion or local irritation.

Examples: devices for haemorrhoid relief (via protective or soothing barriers), topical devices offering physical mechanisms to support circulatory comfort.



Weight management

Devices that support weight-control efforts through physical modes of action.

Examples: products that modulate nutrient absorption or create a temporary feeling of fullness through non-pharmacological mechanisms.



Habit management

Self-care devices that assist individuals in reducing or managing certain habits by creating physical barriers or cues.

Examples: devices supporting smoking cessation, products helping reduce nail biting, and physical-action aids for moderating alcohol consumption.



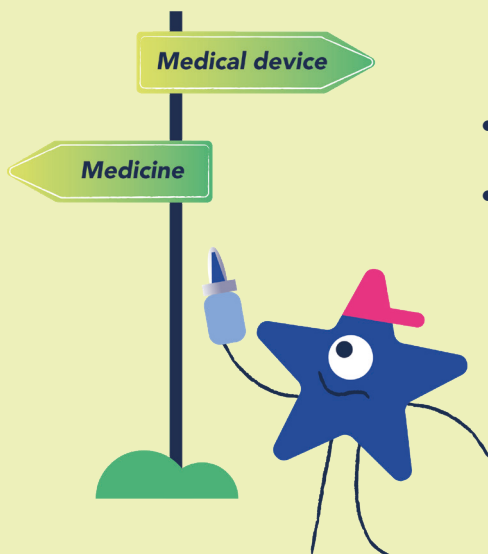
What are “substance-based” medical devices?

Self-care medical devices composed of substances or a combination of substances are called “substance-based medical devices”.

Given their intended use for medical purposes, these products are qualified as “medical devices” because of their mode of action, which relies on chemico-physical processes such as pH changes or the formation of a physical barrier.

How is a product qualified as a medical device or a medicine?

As substance-based medical devices follow the same form and route of administration as medicines, there are borderline cases where it is not immediately clear whether a particular product should be considered a “medical device” or a “medicinal product”. These products require a detailed case-by-case assessment taking into account all product characteristics to ensure that they are correctly qualified in terms of product category.



Regulators determine the category based on the primary mode of action:

- Medical devices act through physical or chemico-physical mechanisms
- Medicinal products act through pharmacological, immunological, or metabolic mechanisms

Some substances can have different modes of action based on their dosage within specific products. As a result, products containing the same substance, but at differing dosages, may fall in different product categories, subjecting them to different regulatory frameworks.

Market Insights

This section is based on key findings of IQVIA's market analysis conducted in 2025 on behalf of AESGP. It covers the size, structure, and trends of the self-care medical devices market across 26 European countries.¹

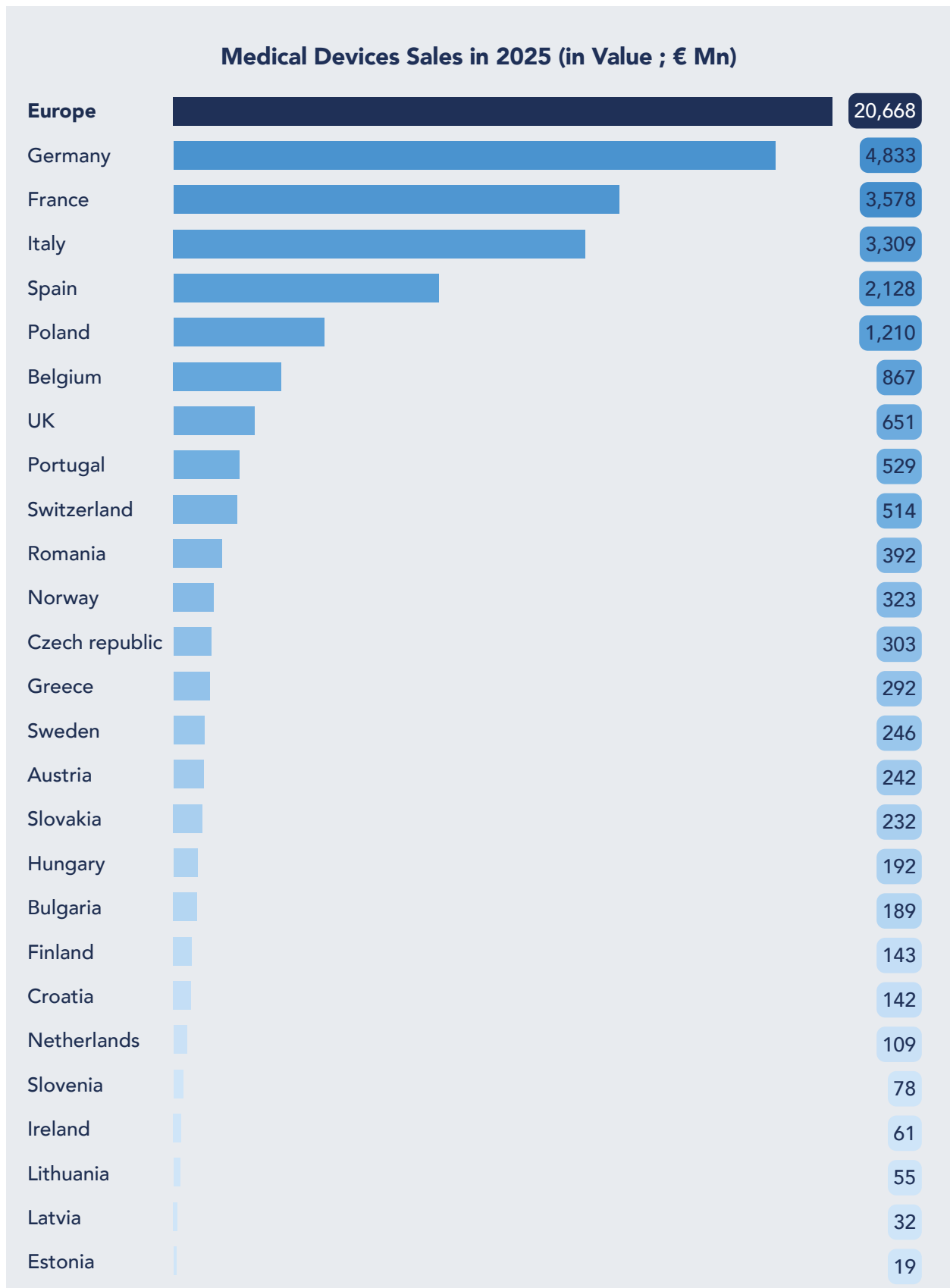
Market share of self-care medical devices

The European self-care market continues to expand, reaching **€250 billion in value in 2025**. Within this landscape, self-care medical devices hold a significant place, representing around **one-third (~31%) of total packs of self-care products** and contributing **€20.7 billion in 2025**.

Self-care product volumes increased by **less than 2% in 2025**, while medical device volumes show a **slight decline**, shaped by post-pandemic adjustments, supply chain pressures, and broader regulatory and economic constraints.



¹ – For more details on methodology and country data, please consult the full report “IQVIA Global CH Insights - MAT Q2 2025”, accessible via the QR code on the back cover of this brochure.



Trends and challenges

The European self-care medical devices market is evolving in a context marked by strong self-care demand, post-pandemic adjustments, and increasing regulatory complexity. While people continue to rely on these products every day, their overall share within the self-care market has decreased in recent years, falling from **34%** in 2022 to **31%** in 2025.

At the same time, manufacturers of self-care medical devices face significant challenges linked to the **Medical Device Regulation (MDR)**. The requirements introduced since 2021 have made conformity assessments more costly and time-consuming, and there is fragmentation in the interpretation of regulatory requirements across countries. These hurdles have reduced industry agility and, in some cases, led manufacturers to scale back launches or withdraw products from the European market.

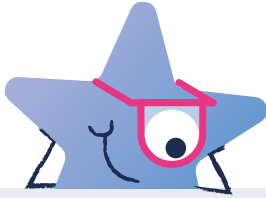
Despite this, the sector remains dynamic. Self-care medical devices accounted for 43% of total new pack launches over the past years, and innovation is now significantly higher than in previous years (three times higher than in 2022). This momentum reflects the ongoing need for a regulatory framework and structural environment that facilitate access to innovative and reliable self-care solutions.

Varying levels of access in Europe

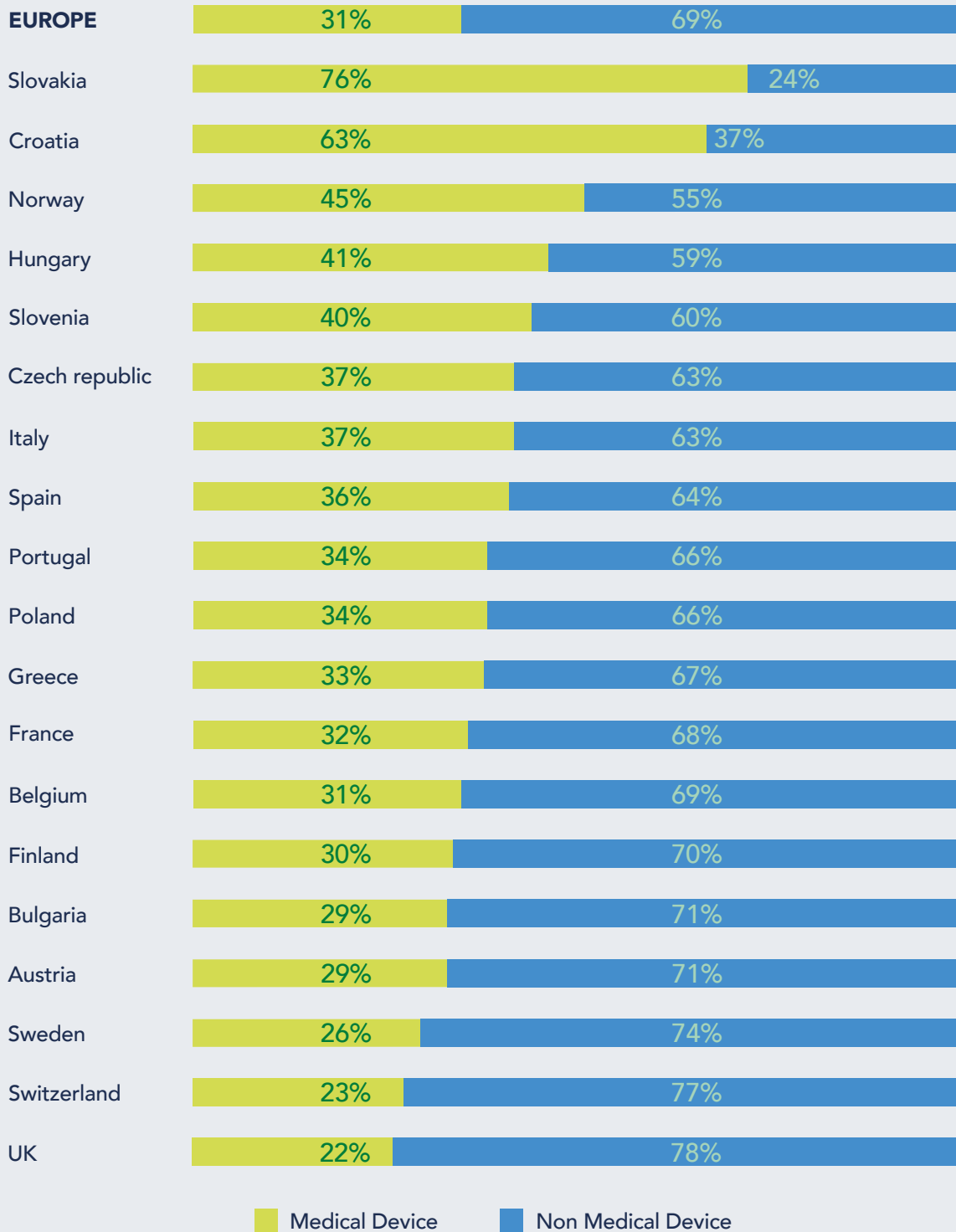
The presence of medical devices within the wider self-care market varies significantly from one European country to another. While, on average, medical devices represent **around one-third of the self-care market in Europe (~31% of volumes)**, individual country shares can be considerably higher or lower.

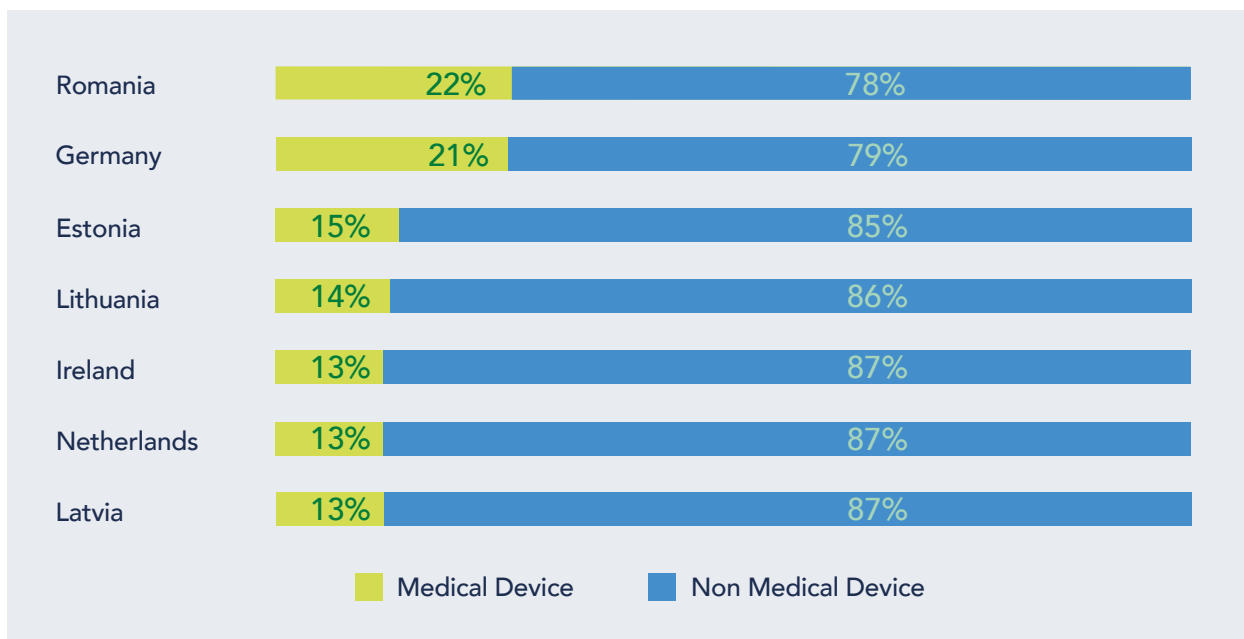
In some markets, medical devices account for a particularly large share of self-care products, such as in Slovakia (76%) and Croatia (63%), reflecting strong traditions of self-care and widespread use of self-care medical devices versus other self-care categories, such as non-prescription medicines.

These differences result in varying levels of access, familiarity, and product choice. For manufacturers, this translates into a complex operating environment, with diverse regulatory expectations and market structures to navigate. For people, it can mean different levels of access to similar self-care medical device solutions depending on where they live.



Medical Devices Shares of Total Self-Care Market in 2025 (in volume)





IQVIA Global CH Insights - MAT Q2 2025



What these trends show

Across Europe, the medical devices market remains resilient, relevant, and firmly embedded in daily self-care practices. At the same time, the market is navigating a complex mix of opportunity and pressure: demand remains solid, and people continue to value the role of self-care medical devices in everyday care, yet regulatory requirements and broader structural shifts are shaping the pace of innovation and influencing the availability of products.

Most used self-care medical devices in Europe

Across Europe, people turn to self-care medical devices every day to manage common health needs, from easing cold symptoms to contraception or maintaining oral health. While the category is broad, a few indications stand out as the ones individuals reach for most often.

Devices for **respiratory comfort** and **eye care** are among the most widely used. Nasal sprays, sore-throat and cough solutions are staples during the cold season, while eye drops and related products have become everyday essentials for those dealing with screen fatigue, environmental irritation, or dry eyes. **Oral care** accessories, including denture care products and other specialised oral hygiene tools, such as toothpastes, play a central role in daily routines and help people preserve comfort and confidence in their smiles.

Self-care medical devices are also key in **wound and skin care**, where plasters and compresses, wart/corn removal, disinfectants, and soothing dermal gels or creams support the protection and recovery of minor cuts, scrapes, and irritations. In **digestive health**, laxatives and devices providing physical relief from heartburn, acid reflux, and other common digestive discomforts help people feel better and stay active. For **intimate health** and **contraception**, products such as condoms, diaphragms, and selected intimate care devices offer safe, reliable options that support personal well-being and prevention.

Taken together, these trends show that Europe's most popular self-care medical devices are those that meet every day, highly prevalent needs: soothing cold and allergy symptoms, managing eye and skin discomfort, supporting digestive and intimate health, or maintaining good oral hygiene. Their widespread use illustrates how self-care helps people feel better, stay independent, and play an active role in maintaining their health.

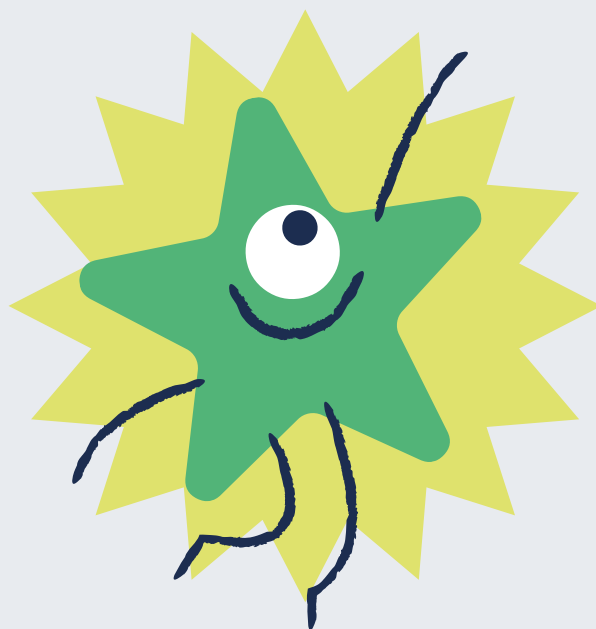


Conclusion

Self-care medical devices continue to be a reliable choice for people looking to support their daily health needs, even as the market navigates regulatory pressure, supply constraints, and the gradual normalisation following the COVID-19 years. People rely on these products every day – from nasal sprays and eye drops to contraception and oral care – to manage common conditions, maintain well-being, prevent illness, and take an active role in their own health.

Although volumes have slowed and the share of self-care medical devices within the wider self-care market has declined, demand remains strong. Innovation continues to deliver new solutions with the potential to improve people's quality of life. At the same time, challenges linked to the implementation of the Medical Device Regulation (MDR) – including high compliance costs, lengthy conformity assessments, and reduced manufacturer agility – are placing pressure on product availability and on companies' ability to bring new products to market.

With the right policy and regulatory support fostering innovation and competitiveness, Europe can sustain a self-care environment where people have access to safe, effective, and diverse self-care medical devices. This will empower individuals and families to take charge of their health, ease pressure on healthcare systems, and help build a dynamic, future-ready self-care industry.



Scan the QR code and read the IQVIA report

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