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Continued Growth of Self-Care Med Devices Market Rests On Addressing MDR Challenges

by David Ridley

A report by AESGP and IQVIA Consumer Health finds that self-care medical devices account for a significant proportion of Europe's OTC market, and as a category is growing rapidly. However, only by "retaining the same favorable market conditions, notably in terms of efficiency, transparency, predictability and innovation" as under previous medical device regulations can this category continue to thrive, they argue.

An analysis of the European Union's self-care medical devices market by IQVIA Consumer Health and the Association of the European Self-Care Industry shows the significant and growing contribution these products make to the region's consumer healthcare sector.

However, this contribution is at risk of being jeopardized by the "significant challenges" posed by the implementation process of the EU Medical Devices Regulation (MDR), they argue in a recently-published study.

"Self-care medical devices are an established and vital part of the European consumer health market," AESGP commented. "While ensuring a high level of safety and health protection, it is essential to sustain the volume and growth potential of those products under the MDR by retaining the same favorable market conditions, notably in terms of efficiency, transparency, predictability and innovation."

"Addressing these challenges properly will create the adequate regulatory conditions for the self-care medical devices market," the association continued, "ensuring swift market access for new products and reinforcing its the crucial role in supporting the health and well-being of

consumers across Europe."

Big Slice

IQVIA CH reviewed the market across 19 countries and select categories and found that self-care device volume sales grew by 21% in 2022. Self-care devices accounted for 40% of value sales of the total consumer health market across these countries and categories.

Within the EU self-care medical devices market, "patient care" – which includes for example at-home test kits and glucose measuring devices – was by far the most dominant sub-category, accounting for 70% of sales in 2022.

"Value sales in this category have been driven over the past three years by a surge in at-home COVID-19 tests which accounted for 45% of value sales in the category in 2022," the report notes.

"This is also reflected in the categories contribution to new product launches over the past two years," it continues. "Across the self-care medical devices market in Europe, 86% of new launches have come in the patient care sector, driving volume growth of 25.9% in 2022."

Accounting for 27% of medical devices sales in 2022, the OTC devices category – which includes eye care and cough, cold and respiratory products – holds the second largest share.

Finally, personal care devices such as dentures and intimate hygiene products accounted for just 3% of value sales in 2022. "The category is seemingly stagnating in terms of innovation, contributing just 1% of new product launches in the two years to 2022," the report notes.

MDR Threat

To ensure that the EU self-care medical devices market continues to grow, IQVIA CH and AESGP insisted that challenges relating to the implementation of the MDR must be addressed as soon as possible.

Applicable since May 2021, the MDR largely follows the same basic regulatory requirements as the previous medical device directives but introduces stricter and additional requirements.

By June last year, applications for only 13,000 of the 24,000 certificates issued under the previous legal framework had been submitted for transitioning to the MDR, and only 3,900 MDR certificates actually issued.

To deal with potential bottlenecks resulting from MDR implementation, regulators have extended the transition period to December 2027 or 2028 depending on the risk class of the given device and subject to conditions that must be fulfilled.

Nevertheless, manufacturers must submit an application by 26 May 2024 to benefit from the extended transition period.

“A particular challenge industry faces relates to the unpredictable and inefficient timelines for conformity assessments when transitioning to the MDR,” IQVIA CH and AESGP pointed out. “Time to obtain a MDR certificate may range between 12 to 24 months.”

“Similarly challenging is the lack of predictability in regard to notified body expectations when it comes to technical documentation in advance of the conformity assessment,” they added.

“While structured dialogues between notified bodies and manufacturers before and during the conformity assessment process have been identified as a useful instrument to enhance the efficiency and predictability of the conformity assessment process under the MDR, it has not been implemented in practice to a great extent,”

Doubts Raised

“As a consequence of the foregoing issues, business operators are not able to anticipate costs at the beginning of the process to obtain regulatory approval,” IQVIA CH and AESGP warned. “These key challenges for the medical device industry as a whole raise doubts as to whether the presented figures relating to self-care medical devices can be indeed transferred to the MDR regulatory framework.”

“Only if these challenges are properly addressed by streamlining the certification process under the MDR to allow for an efficient, predictable and transparent transition to the MDR, will it create the adequate regulatory conditions for the self-care medical devices market,” they concluded.