A comparison of OTC status of medicines across Europe

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Abstract

Regulation of over-the-counter (OTC) medicines varies significantly across European Union (EU) member states due to diverse healthcare policies, cultural attitudes towards self-medication, and regulatory frameworks.

Understanding these differences is crucial for stakeholders in the pharmaceutical industry for market access and strategic planning.

A recent analysis of 250 Active Pharmaceutical Ingredients (APIs) across 30 European countries, using data from Cortellis Regulatory Intelligence™ and Competent Authorities' databases, shows that countries like the United Kingdom, Germany, and Italy have the highest number of available OTC medicines. This suggests a regulatory environment that supports self-care and greater patient autonomy in managing health conditions. In contrast, countries such as Cyprus, Denmark, Slovenia, and Croatia have fewer OTC options, reflecting a more conservative approach to OTC accessibility.

This study also emphasizes the role of the Rx-to-OTC switch, with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and Germany's Federal Institute for Drugs and Devices (BfARM) transparency efforts providing significant insights. These findings are crucial for understanding market dynamics, market access, and guiding strategic decisions in the pharmaceutical sector.

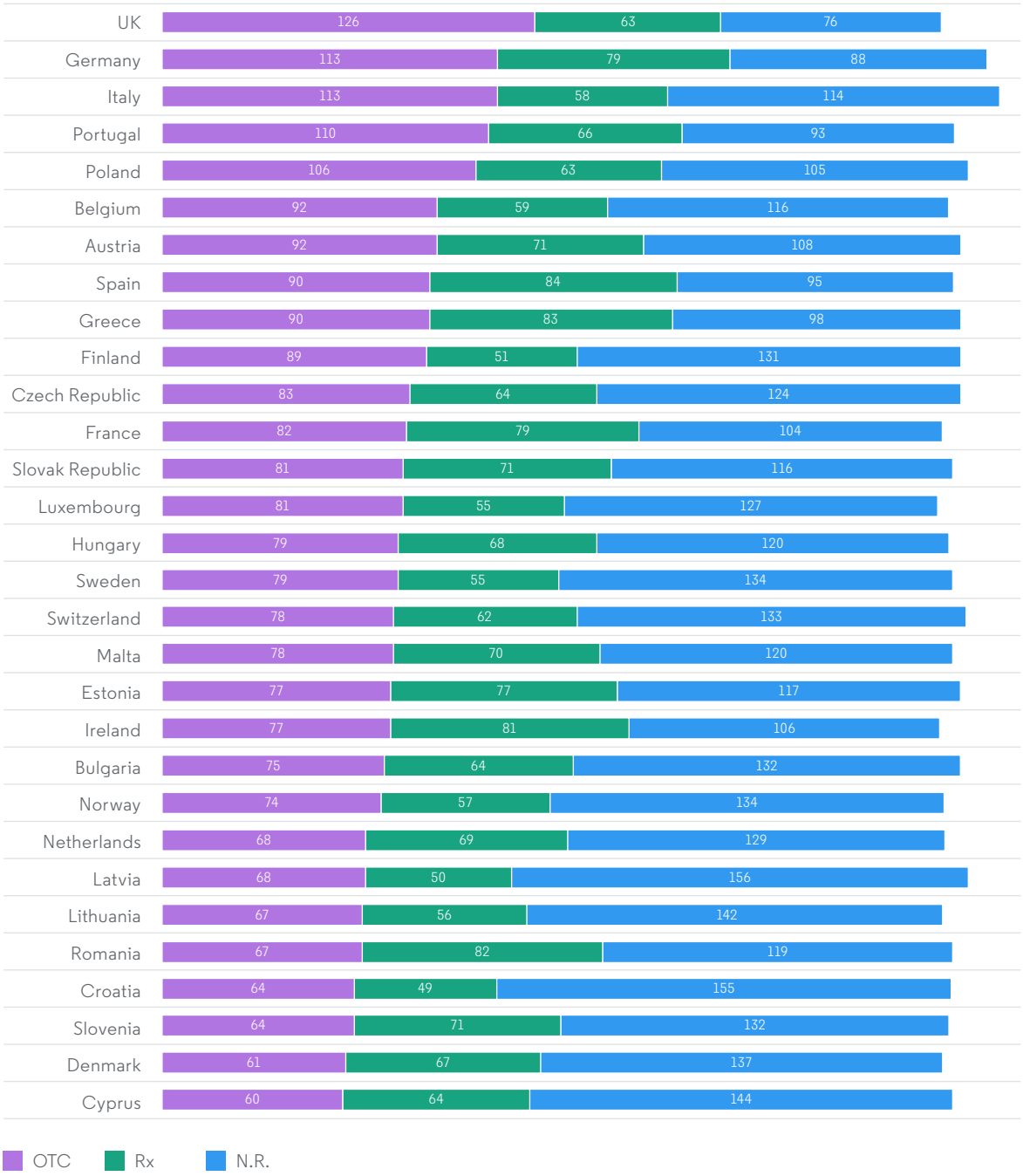
Divergent OTC regulations across EU member states

Figure 1 demonstrates the significant number of OTC medicines in the United Kingdom, Germany, and Italy, indicating a greater focus on self-care medicines and potentially a larger market for OTC medicines. This may reflect divergent healthcare policies or regulatory frameworks that favor wider OTC availability. Following these three countries, Portugal, Poland, Belgium, Austria, Spain, Greece, and Finland comprise the remaining top ten countries in terms of OTC medication accessibility in Europe.

In contrast, the lower number of OTC medicines in Cyprus, Denmark, Croatia, and Slovenia could indicate a more conservative approach to OTC drug accessibility. These variations might be attributable to distinct healthcare priorities or regulatory frameworks in these nations. Additionally, the number of non-registered APIs in the most restrictive OTC markets is remarkably higher than in the top-tier markets with higher numbers of OTC APIs.

The analysis identified 2,520 products with OTC status from 48 ATC therapeutic areas across 30 markets. Of those, 26 Rx-to-OTC switches by national procedure were identified in the last 4 years (2020-2024 to date), and 2 Rx-to-OTC switches by centralized procedure were done in 2020, namely for oral desloratadine indicated for the relief of allergic rhinitis and chronic idiopathic urticaria symptoms, and topical lidocaine/prilocaine to treat primary premature ejaculation in adult men.

Figure 1: Legal status per country.



The graphic illustrates the legal status — Over-the-Counter (OTC), Prescription (Rx), or Not Registered (N.R.) — for 250 Active Pharmaceutical Ingredients (APIs) across 30 European countries. The volume of data varies per country due to differences in legal status. In some instances, an API may have multiple legal statuses within the same country, depending on factors such as dosage, indication, or other specific conditions.

Leading competent authorities in Rx-to-OTC switches

The transition of medicines from prescription (Rx) to OTC status, known as the Rx-to-OTC switch, is an important aspect of pharmaceutical regulation.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is notable for its transparency and accessibility regarding these switches. The MHRA maintains a publicly accessible database that provides insights into the decision-making process behind OTC approvals. Germany's Federal Institute for Drugs and Medical Devices (BfArM) also plays a pivotal role by publishing detailed minutes of meetings where Rx-to-OTC transitions are discussed. These practices underscore both countries' commitment to ensuring that the decision-making process surrounding drug accessibility is transparent and accessible to stakeholders. However, BfArM has adopted a more cautious stance on certain medications, as seen in its recent decisions regarding sildenafil.

Impact of Rx-to-OTC switches on the pharmaceutical industry

The increasing trend of Rx-to-OTC switches presents both challenges and opportunities for the pharmaceutical industry.

For companies, switching a product to OTC status can open new revenue streams and broaden market reach. This shift allows pharmaceutical firms to reposition their products for self-medication, tapping into the growing consumer demand for accessible healthcare solutions. Moreover, the successful transition of drugs to OTC status can enhance competition within the market. With more options available to consumers, companies are incentivized to innovate and improve their offerings. However, this trend also requires companies to invest in consumer education and marketing strategies to ensure that patients understand how to use these medications safely.

Effects on national healthcare systems

The transition of a drug from Rx to OTC status can significantly improve patient access to medicines deemed safe for self-medication, potentially impacting market dynamics and healthcare delivery.

From a healthcare systems perspective, facilitating Rx-to-OTC switches can lead to more efficient resource allocation. By empowering patients to manage minor health conditions independently, healthcare providers can focus their resources on more complex cases that require professional intervention. This could alleviate some pressure on public health systems, particularly in countries with high patient loads. However, there are potential risks associated with increased OTC availability. Concerns about patient safety arise when individuals self-diagnose and self-medicate without professional guidance. Therefore, it is crucial for regulatory authorities to strike a balance between promoting self-care and ensuring patient safety through proper oversight.

Conclusion

The assessment of the legal status of 250 Active Pharmaceutical Ingredients (APIs) across 30 European countries reveals significant regional differences in the availability of OTC medicines across Europe, shedding light on the varying regulatory approaches and healthcare priorities of each country.

The substantial number of OTC medicines in the United Kingdom, Germany, and Italy points to a higher focus on self-care medicines from a regulatory standpoint. This may potentially be driven by healthcare policies that favor wider accessibility to OTC medicines, like the availability of Pharmacy-only medicines (also known as Behind-the-Counter, BTC status) that enables customers to obtain their medicines with the professional guidance of a pharmacist. This trend suggests that these countries view self-medication as a viable component of healthcare, allowing patients greater autonomy in managing their health conditions. As a result, the OTC market in these regions may be larger and more lucrative for pharmaceutical companies seeking to expand their product offerings.

In contrast, the lower number of OTC medicines in countries such as Cyprus, Denmark, Croatia, and Slovenia indicates a lower focus on self-care medicines from a regulatory standpoint. This could be reflective of more conservative healthcare systems that prioritize stricter oversight and control over the availability of non-prescription medicines. This may potentially be driven by concerns over patient safety or a desire to ensure more rigorous medical supervision. These variations in regulatory approaches may stem from distinct national healthcare priorities and cultural differences in how self-medication is perceived.

A critical component of this regulatory landscape is the Rx-to-OTC switch. This transition can significantly enhance patient access to treatments deemed safe for self-medication, which in turn may lead to a shift in market dynamics and healthcare delivery.

The UK's MHRA plays a pioneering role in this area, providing exceptional visibility through a publicly accessible database dedicated to OTC switches. One of its most distinct actions was the switch of sildenafil (Viagra) in 2017, becoming the first country to allow non-prescription sales of this drug for erectile dysfunction.

Germany is known for its transparency in regulatory decision-making, as evidenced by the detailed minutes published by the BfArM regarding discussions on Rx-to-OTC switches. However, the BfArM takes a more cautious approach to switching certain active pharmaceutical ingredients (APIs), as shown by its rejection of sildenafil's non-prescription status in both 2022 and 2023. These efforts demonstrate both countries' commitment to transparency, helping stakeholders better understand the processes that influence drug availability.

The increasing trend of Rx-to-OTC switches has significant implications for the pharmaceutical sector, providing opportunities for companies to reposition products and expand market reach. Easier access to safe and effective OTC medicines can also contribute to more efficient resource allocation within healthcare systems, as patients can manage minor conditions independently. These findings underscore the importance for pharmaceutical companies to closely monitor regulatory developments across Europe to tailor their market entry strategies and capitalize on the evolving OTC landscape.

The differences in OTC medicine regulation among EU member states highlight the complexity of the pharmaceutical landscape in Europe. With leading authorities such as the MHRA and BfArM spearheading Rx-to-OTC switches, stakeholders must remain vigilant in monitoring regulatory developments that could impact market access strategies. As the trend toward Rx-to-OTC switches continues to grow, both the pharmaceutical industry and national healthcare systems must adapt to these changes. By creating an environment that promotes responsible self-medication while upholding strict safety standards, Europe can pave the way for a more accessible and efficient healthcare future.

Methodology

This analysis is based on the curation of publicly available data retrieved until June 2024, covering 30 European countries. The Clarivate Life Science and Healthcare Regulatory Consulting team assessed the legal status of 250 Active Pharmaceutical Ingredients (APIs), categorizing them as Prescription (Rx), Over-the-Counter (OTC), or Not Registered (N.R.). Each API was analyzed according to its route of administration, as some APIs exhibited different legal statuses based on factors such as route of administration, strength, and indication.

Data for this analysis were obtained from Cortellis Regulatory Intelligence as well as Competent Authorities' websites and databases. For the purpose of this study, the OTC status also includes Behind-the-Counter (BTC) status, which is referred to as Pharmacy only status in the United Kingdom. This comprehensive approach ensures a detailed understanding of the regulatory classifications of APIs across the selected European countries.

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