

Project CAPSULE

Collecting and sharing information on the Consumers' Awareness about the Purchase of SUBstandard and falsified medicines online to support better e-commerce practices.

SUMMARY REPORT¹

July 2024

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This study was funded by Michigan State University's Center for Anti-Counterfeiting and Product Protection (A-CAPP) through external research gifts



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1. This document is a short version of the full report of the project CAPSULE.
2. With the contribution of Mirko Nazzari (UCSC-Transcrime) and Domenico Di Giorgio (AIFA)

Introduction

The proliferation of online sales, intensified by the COVID-19 pandemic, has significantly increased opportunities for the **illicit market of substandard or falsified medicines** (SFMs) (OECD and EUIPO 2020; Europol2021; Ahmed et al. 2022; ; EUIPO and Europol 2022; Jillani, Reinhard, and Hertig 2023). Criminals exploit consumers' vulnerabilities **through deceptive advertisements**, posing considerable risks to public health and undermining regulatory efforts aimed at ensuring the safety and efficacy of pharmaceutical products (Winter, Saunders, and Hart 2003; Barbaranelli et al. 2015; Kennedy 2020).

Furthermore, diverse **regulatory landscapes** across different countries can exacerbate the problem (Sogomonjan and Forcht Dagi 2023). Stringent regulations may inadvertently limit access to legitimate channels for purchasing medicines online, thereby driving consumers toward illicit sources. Conversely, lenient regulatory frameworks may create loopholes that facilitate criminal deception, allowing illegitimate operators to thrive in an environment with minimal oversight and enforcement.

Existing efforts to combat the proliferation of SFMs primarily focus on targeting the online supply of illicit medicines, aiming to disrupt the activities of illicit vendors and websites selling counterfeit or unlicensed pharmaceutical products (Lavorgna 2015; Kennedy, Haberman, and Wilson 2018; Kennedy, Petlakh, and Wilson 2018). However, these enforcement actions often neglect to address the **demand side of the market**.

Understanding **consumers' experiences and exposure** to SFMs online is crucial for developing effective regulatory interventions and awareness campaigns. By gaining insights into consumers' behaviors, perceptions, and purchasing patterns, policymakers and regulatory authorities can devise targeted strategies to mitigate the risks associated with online pharmaceutical sales.

Empirical understanding of consumer awareness and experiences with purchasing substandard and falsified medicines online is limited, with most studies focusing on developing countries (Lybecker 2007; Alfadl, Ibrahim, and Hassali 2012; Barbaranelli et al. 2015; Ofori-Parku and Park 2022). However, the issue extends globally, as demonstrated by the widespread availability of fake medicinal products during the COVID-19 pandemic (Ziavrou, Noguera, and Boumba 2022; EMA 2023).

Project CAPSULE seeks to bridge this knowledge gap by investigating consumers' exposure, awareness, and attitudes toward the online sale of medicines.

The research questions addressed by Project CAPSULE include:

1. To what extent are consumers exposed to online advertisements for medicines, and how common is the purchasing of medicines online?
2. What is the level of consumers' awareness and attitude toward the sales of medicines online, as well as the associated risks?
3. How proficient are consumers in distinguishing between legitimate products and SFMs advertised online?
4. Which factors influence consumers' exposure to or attitude toward the purchase of medicines online, as well as their ability to distinguish between legitimate products and SFMs?

By investigating these research questions, Project CAPSULE aims to provide policymakers, regulatory authorities, brand owners, and e-commerce platforms with insights into the demand for medicines online. These insights can inform the development of **targeted interventions**, including awareness campaigns, regulatory enforcement measures, and improvements to online product listings, to effectively combat the proliferation of SFMs and safeguard public health.

Università Cattolica del Sacro Cuore (UCSC)-Transcrime led project CAPSULE, which was funded by Michigan State University's Center for Anti-Counterfeiting and Product Protection (A-CAPP) through external research gifts.

Methodology

Project CAPSULE gathered information from **two representative samples** of regular internet users in **Italy** and **Spain** through a Computer Assisted Web Interviewing (CAWI) survey. The survey aimed to assess respondents' awareness, attitudes, and experiences regarding online purchases and advertisements of medicine.

The **questionnaire** consisted of **closed-ended questions** and an **experimental section**. In the experimental section, respondents were shown three different pictures of actual online advertisements for medicines or similar products (i.e. dietary supplements), including at least one legitimate and one illicit advertisement.³ Respondents were asked to determine the legitimacy of each advertisement. Then, a recall question prompted respondents to re-evaluate one of the images for which they had provided a judgment and confirm or revise their initial responses. The questionnaire underwent validation and testing with a **pilot** group of 107 respondents (55 in Italy and 52 in Spain) before full-scale data collection.

The complete survey was administered to **2,107** regular internet users in Italy and Spain who were aware of the possibility of purchasing medicines online and had been exposed to online medicine advertisements or had purchased at least one medicine online. Respondents were selected from **two online panels** based on geographical and socio-demographic variables, aligning with the overall Italian and Spanish population distribution. Initial outreach reached a larger pool of potential respondents (3,610), with several individuals excluded after the first questions for not meeting inclusion criteria. Data on the characteristics of excluded respondents and their responses to screening questions were collected and analyzed.

Quality checks were implemented to filter out unreliable responses, and replacements were made to maintain the expected sample size. **Data collection** began on January 11, 2024, and concluded on January 26, 2024.

Responses were analyzed using **descriptive statistics** and **logistic regression models**, considering independent variables like sex, age, education, and a composite indicator measuring mistrust in online sales.⁴ Results have been **discussed** and **validated** with representatives from national health regulatory authorities in both countries and academic experts on pharmaceutical crime.

Table 1 Number of respondents by type and inclusion criteria

	Italy	Spain
Contacted respondents	1,254	2,356
Aware of the possibility of purchasing medicines online in Italy/Spain	1,151	1,268
Made an online purchase OR Have seen at least one online advertisement	1,058	1,065
<i>Made an online purchase</i>	799	654
<i>Have seen at least one online advertisement</i>	980	954
Excluded due to additional quality checks	3	13
Final samples	1,055	1,052

*Some respondents may have both seen an advertisement and made a purchase online.

3. Images were randomly chosen from a pool of six (three legitimate and three illicit) for each country, ensuring equal representation of each image in the sample. The language of the advertisements corresponds to the nationality of the respondents.

4. The composite indicator assessing the level of mistrust of respondents in purchasing products online is defined as a linear aggregation of five items encompassing judgements about regularity, attitudes, and perceived safety of online purchases.

Results

The following subsections present the findings of the Project CAPSULE.

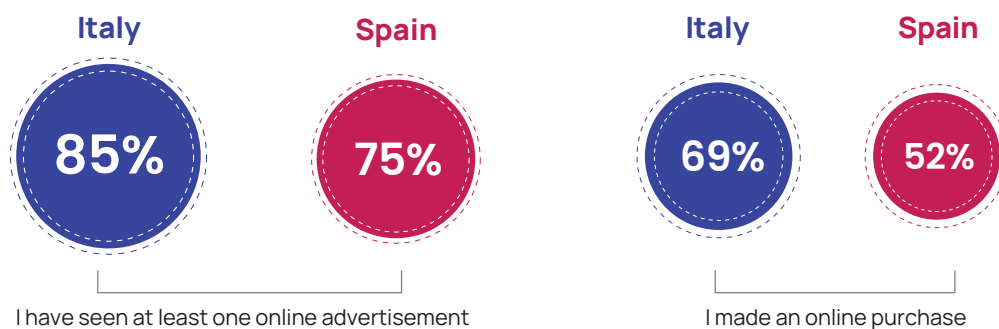
Awareness and Attitudes Toward Online Medicine Sales

- **Awareness toward online purchase:** out of the initial 3,610 respondents reached, Italians exhibited significantly **higher awareness** of the **possibility of purchasing medicines online** compared to Spanish respondents (92% versus 54% of the initial national samples).
- **Awareness by demographics:** **older** and **more educated** respondents showed significantly higher awareness of online purchasing of medicines.
- **Sources of awareness:** most respondents became aware of online medicine purchases through **websites** (62% in Italy and 48% in Spain), followed by **word of mouth** from friends and relatives (30% in Italy and 33% in Spain), **social networks** (26% in both countries), and **advertising emails** (19% in Italy and 18% in Spain).
- **Knowledge of regulations:** the majority of respondents knew that legitimate online medicine sales in Italy and Spain are **limited to non-prescription drugs** (73% in Italy and 66% in Spain). Many considered this the most appropriate option (72% in Italy and 74% in Spain).
- **Acceptability of risky purchases:** no significant disparities were found between the national samples regarding **acceptable circumstances** for purchasing online medicines with uncertain origins. About 40% of respondents in both countries found it **unacceptable** under any condition.
- **Motivations for risky purchases:** in both countries, the main declared motivations for purchasing potentially illicit medicines included the **unavailability** of the same medicine through other channels (23% in Italy and 26% in Spain) and **cost savings** (19% in Italy and 18% in Spain).
- **Reliance on Internet for health information:** despite **high trust in healthcare professionals** in both countries, over half of the respondents frequently **rely on the Internet for obtaining medicine information** (58% in Italy and 52% in Spain), and about 40% of respondents seek specific health solutions or look for alternative treatments.
- **Distinguishing dietary supplements from medicines:** only about one-third of the final sample correctly **differentiated dietary supplements from medicines** (34% in Italy and 32% in Spain). This highlights the difficulties in distinguishing between medicines and other similar products subjected to different regulations.
- **Convenience or trust:** most respondents found purchasing medicines online **convenient** (71% in Italy and 61% in Spain), but expressed **low trust** in receiving the correct products if purchased online (78% in Italy and 80% in Spain).
- **Concerns about counterfeit medicines:** Italians are **less concerned about counterfeit medicines** online than Spaniards, who also show more skepticism about the **safety** and **effectiveness** of medicines purchased online.

Experience with Online Medicine Advertisements and Purchases

- **Exposure to online advertisements:** respondents showed a **high exposure to online advertisements** for medicines, with 85% of Italian and 75% of Spanish respondents reporting having seen at least one form of online advertisement for medicines (Figure 1, pg.5).
- **Online purchases:** Italian respondents were more likely to have made an **online purchase** (69%) compared to Spanish ones (52%).

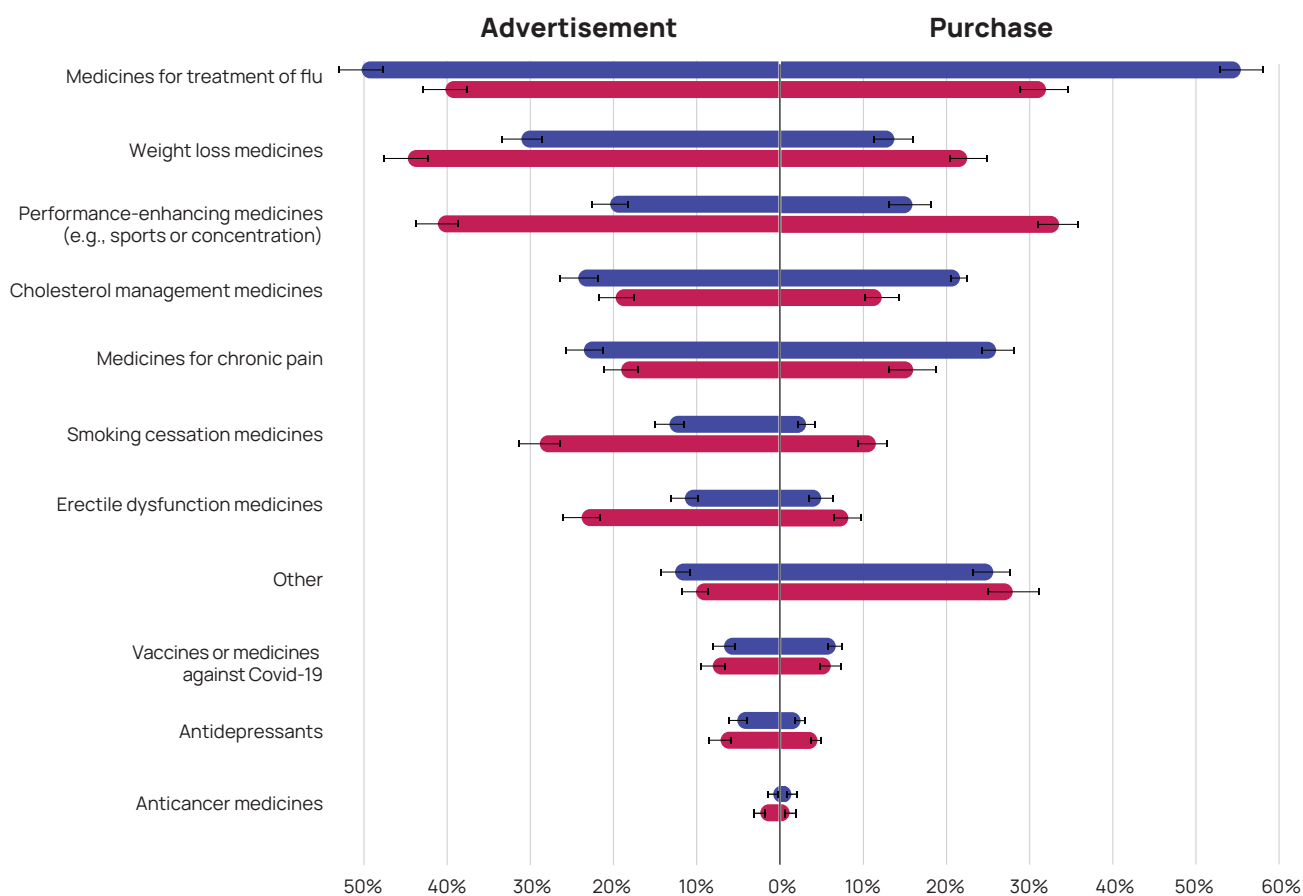
Figure 1 - Have you ever purchased medicines online or noticed online advertisements related to medicines? (N 2,419)



Dashed lines depict a 90% confidence interval around estimated percentages.

- **Advertised medicines:** **flu treatments** were the most advertised medicines in Italy, whereas in Spain there was also high visibility for **weight loss** and **performance-enhancing** products (Figure 2).
- **Purchased medicines:** in Italy, **flu treatments** were the most popular online purchases, while in Spain, they ranked second to **performance-enhancing** drugs. Spanish consumers bought more weight loss and smoking cessation products than Italians, who, conversely, purchased more chronic pain and cholesterol management medicines.

Figure 2 - Which types of medicines⁵ have you seen in online advertisements (N 1,922) and/or have you purchased online (N 1,439)?



Error bars depict a 90% confidence interval around estimated percentages.

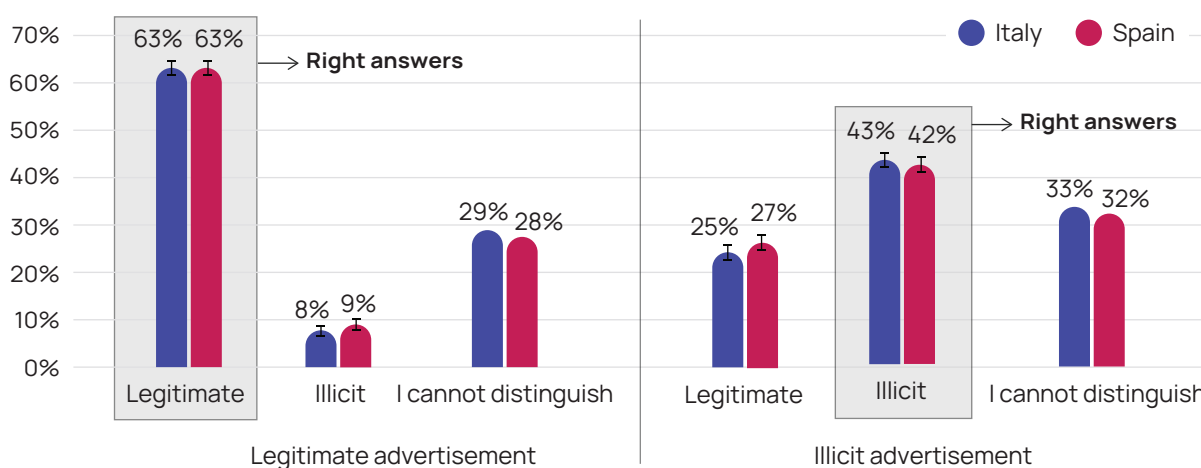
5. The categories of products were chosen and defined to encompass a broad range of the most commonly sold licit and illicit medicines online, while also accounting for slight differences in the definitions of medicine between Italian and Spanish regulations.

- **Popular channels:** **websites** were the primary channel for both advertisement exposure and purchases, followed by **social networks** and **e-commerce platforms**.
- **Trends in online purchase:** a comparison with a previous survey conducted in 2015-2016 by AIFA and Sapienza University of Rome revealed a **significant increase in online medicine purchases** in both countries.
- **Trends in perceptions and safety concerns:** here was also a notable increase in the percentage of respondents viewing the possibility of purchasing medicines online positively. However, **concerns about the safety** of medicines purchased online remained consistent between the two surveys.

Ability to Recognize Illicit Online Advertisement

- **The experiment:** an **experimental section** of the survey assessed respondents' ability to **distinguish** between legitimate and illicit online advertisements. The results show notable similarities between the two countries.
- **Overall recognition:** approximately half (53%) of the online advertisements were **correctly categorized** as legitimate or illicit, with only about one respondent out of five correctly identifying the legitimacy of all three proposed images.
- **Legitimate advertisements:** **legitimate advertisements** were correctly identified more often, with about 63% of the shown images in both countries correctly recognized. However, in a considerable number of cases, respondents were unable to provide a judgment on the proposed images (29% in Italy and 27% in Spain) (Figure 3).
- **Illicit advertisements:** **illicit advertisements** were correctly identified in only four out of ten responses (43% in Italy and 42% in Spain).
- **Demographic influence:** **older respondents** and consumers with **lower trust in online sales** exhibited lower accuracy in identifying both legitimate and illicit advertisements.
- **Consistency of responses:** when asked to confirm one of their previous answers regarding the legitimate nature of the advertisements, respondents generally **confirmed their initial judgment**, especially if their previous answer was correct. However, 20% to 25% of respondents changed their original answer declaring that they were no longer able to distinguish the legitimacy of the advertisement.
- **Evaluation criteria:** respondents declared to assess the possible illegality of an online advertisement primarily by looking at the **absence of the label** certifying authorization from the Ministry of Health, followed by the **absence of a medicine description** or the **presence of errors** in the medicine description. Photos and packaging details were deemed relevant by only a minority of respondents in both countries.

Figure 3 - Type of provided answers on the total number of legitimate (N 3,162) or illicit (N 3,159) advertisements.



Conclusions and Recommendations

Project CAPSULE provided insights into Italian and Spanish consumers' behavior and attitudes towards online medicine sales. These results could lead to more targeted and effective actions by both public authorities and private stakeholders. Specifically, the study highlights:

- An **increase in awareness and practices regarding online medicine purchases** was observed compared to a previous survey conducted in 2015-2016, aligning with the worldwide increased in e-commerce and online pharmacies market share (TMR 2022). Italian consumers exhibited higher **awareness** and **trust** in online medicine purchases compared to Spanish ones.
- **Elderly respondents** were found to be more aware of online medicine purchases but less capable of recognizing the legitimacy of the advertisements. This highlights the need for targeted awareness campaigns aimed at older populations, who may have increased internet access but limited knowledge to identify potential threats in online purchases.
- **Younger respondents** showed better identification of illicit advertisements but expressed lower trust in healthcare professionals and a higher tendency to use the Internet to retrieve health-related information. This underscores the importance of efforts to enhance trust in medical professionals and reduce exposure to unreliable information or deceptive practices.
- While consumers in both countries demonstrated good overall **knowledge of regulations** governing online medicine sales, they faced challenges in **distinguishing medicines** from other health-related products. This highlights the need for improved product labeling and consumer education to prevent misguided purchases.
- **Differences in advertised and purchased products** were observed between Italy and Spain. This may suggest variations on both the demand and supply sides of the market that should be monitored to ensure that advertising and selling practices are compliant with national regulations.
- **Websites** are the primary access points for both advertising and purchases, with **social media** and **e-commerce platforms** having a secondary, but not negligible, role. Specifically, social media emerges as a prominent platform for advertising medicines online.
- This highlights the predominant risk coming from **illicit online pharmacies** and **deceptive websites**, but also suggests the need for **collaboration** between authorities, pharmaceutical companies, and online platforms to prevent illicit activities and protect consumers.
- Enhancing the security of legitimate websites requires a **consumer-centric approach** to help identify potential weaknesses and mitigate or prevent criminal threats. This is particularly relevant given the negligible percentage of legitimate websites compared to illicit ones (Limbu and Huhmann 2023). Therefore, there is a need to design **crime-proof websites**, incorporating unique features like the Ministry's logo, and launch campaigns to increase consumer awareness about them.
- The design of **informative campaigns** should consider the diverse needs of the target populations, and the channels used by consumers to access health-related information. This underscores the necessity of defining communicative strategies that extend beyond institutional channels.
- Continued **research** in this area is crucial to understand evolving consumer behaviors and market dynamics, allowing for the development of effective countermeasures tailored to specific regions and market changes over time.

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