

# Drug Shortage in Italy: Retrospective Analysis from 2018 to 2024

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To the Editor,

A “shortage” medicine refers to a drug that is temporarily unavailable in the national territory because the Marketing Authorization Holder (MAH), the legal entity responsible for the authorization and commercialization of the medicine, cannot ensure a continuous supply.<sup>1</sup>

Drug shortages are repeatedly in the media spotlight. The first drug shortages were reported during the First World War, but the number has increased in recent years,<sup>2</sup> making it difficult or impossible to meet the therapeutic needs of individual patients or populations.<sup>3</sup>

Currently, drug shortages continue to be a threat to the health and well-being of many patients in Italy and are carefully managed by the Italian Medicines Agency (AIFA).

AIFA regularly updates and publishes a list of shortage medicines on its institutional portal. This list contains the following essential information:

- Trade name of the unavailable medicine: The name under which the medicine is marketed.
- Active ingredient: The chemical substance that produces the desired therapeutic effect.
- Pharmaceutical form: The type of formulation of the medicine, such as tablets, capsules, injections, etc.
- Packaging: Details about the presentation of the medicine, such as the number of units per package.
- Name of the MAH (Marketing Authorization Holder): The name of the company holding the Marketing Authorization.
- Start and expected end date of the shortage: The period during which the medicine is expected to be unavailable.
- Existence of therapeutic alternatives: Whether there are other therapeutic options available.
- Reasons for the shortage: The factors that have caused the shortage.
- Suggestions and/or measures adopted by AIFA: Recommendations and actions taken by AIFA.

This list is updated based on the information provided by the MAHs and the reports received and verified by the Office.<sup>4</sup>

Considering the above, it was decided to analyze the data published by AIFA in the period from July 2018 to July 2024. The aim of the study was to evaluate the trend of drug short-

ages over the years, the potential resolution with an equivalent drug, and the primary reason that led to the shortage.

The number of shortages increased from 1618 in 2018 to 3652 in 2024, showing a consistent upward trend. Specifically, the number of shortages recorded were 2145 in 2019, 2607 in 2020, 2422 in 2021, 2798 in 2022, and 3438 in 2023 (Figure 1).

The year-by-year analysis (Table 1) highlighted a significant incidence of shortages due to the definitive cessation of production, consistently above 42% and even exceeding 50% in some cases. Fortunately, it is observed that most of the recorded shortages can be largely resolved with a generic drug, with a frequency never below 74.5%. These data highlight a continuous and concerning trend of increasing drug shortages.

The shortage of medications has always existed, but various factors have further aggravated the situation. For example, the COVID-19 pandemic<sup>5,6</sup> which caused disruptions in the supply chains of raw materials and finished pharmaceutical products.

To manage drug shortages effectively, a comprehensive approach is crucial. This involves collaboration among international bodies, regulatory authorities, and healthcare providers, as well as utilizing technology to monitor and predict shortages. Establishing clear guidelines and adequately training healthcare personnel to identify and manage shortages is essential. Additionally, optimizing drug use and minimizing waste, including the use of customized formulations when necessary, are key strategies to ensure access to therapies despite shortages.<sup>7</sup>

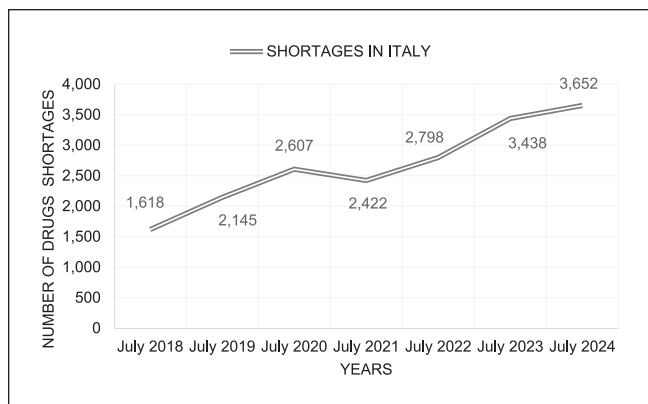
In this context, the role of the hospital pharmacist is crucial in managing drug shortages. Hospital pharmacists are responsible for the management and optimization of drug use within hospitals. During shortages, their role becomes even more critical: they must ensure that patients receive appropriate therapies, seek therapeutic alternatives<sup>8</sup> when

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**Figure 1.** Trend of drug shortages in Italy from July 2018 to July 2024.

**Table 1.** Trend in the Availability of an Equivalent Drug and Main Cause of Drug Shortages in Italy from July 2018 to July 2024.

Year	Shortages with an equivalent drug	Shortages without an equivalent	Cases due to permanent discontinuation
2018	74.5% (n = 1205)	25.5% (n = 412)	50.7% (n = 821)
2019	76.3% (n = 1638)	23.6% (n = 507)	45.2% (n = 970)
2020	78.3% (n = 2042)	21.7% (n = 565)	41.6% (n = 1084)
2021	77.1% (n = 1868)	22.9% (n = 554)	49.7% (n = 1204)
2022	77.7% (n = 2175)	22.3% (n = 623)	49.7% (n = 1302)
2023	78.4% (n = 2629)	21.6% (n = 744)	42% (n = 1417)
2024	78.4% (n = 2881)	21.6% (n = 771)	42% (n = 1566)

possible, and collaborate with other healthcare professionals to minimize the impact of shortages. Additionally, hospital pharmacists play an important role in communicating with suppliers and monitoring inventory levels to prevent therapy interruptions.

### Author Contributions

I took care of conceiving, writing and revising the article myself.

### Declaration of Conflicting Interests

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### Ethical Considerations

Since all data were processed from sources with anonymized data and the study does not include any information that could make the patient identifiable, the approval of the Ethics Committee was not considered necessary.

### Consent to Participate

Not applicable.

### Consent for Publication

Not applicable.

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