

# The role of pharmacies in the implementation of vaccination coverage in Italy. Insights from the preliminary data of the Lombardy Region

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## Abstract

**Introduction.** The administration of vaccines in pharmacies was not allowed in Italy until 2021. During the COVID-19 pandemic, legislative innovations were introduced that now allow qualified pharmacists to administer anti-flu and anti-COVID-19 vaccines after completing specific training.

**Methods.** The article provides an overview of legislation concerning vaccinations in Italian pharmacies, followed by a description of the vaccinations carried out by pharmacies participating in the regional vaccination campaign from 2021 to 2023. The study relies on data extracted from the Lombardy Region's database on vaccine administration in pharmacies. Furthermore, innovative vaccination practices from the Marche Region were also taken into consideration.

**Study Design.** Observational Study

**Results.** Lombardy became the Italian pioneer region in extensively incorporating pharmacy-based vaccinations, starting in 2021. This initiative reached its zenith with 46% of anti-COVID vaccines and 17% of flu vaccines administered within the first six weeks of the autumn 2023 campaign. Pharmacies played a crucial role in meeting the targets outlined in the Italian National Vaccine Prevention Plan for 2023-25. As part of an experimental program, the Marche Region has further expanded pharmacy-based vaccinations, now including anti-zoster and anti-pneumococcus vaccines for the 2023-24 campaign.

**Conclusions.** The promising outcomes observed in Lombardy and the ongoing experimental efforts in the Marche are encouraging steps toward achieving vaccination coverage targets, albeit still falling below the objectives set by the National Vaccination Plan for 2023-25. The widespread presence of pharmacies throughout the territory makes them well-suited as support structures for vaccination campaigns, especially in reaching the adult, the elderly, and the vulnerable populations.

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## Introduction

Community pharmacies, in conjunction with the National Health Service (NHS), play a pivotal role in ensuring universal access to medications and other health services for all citizens and actively contribute to safeguarding public health. Their distinctive characteristics, including widespread community presence, proximity to citizens, professional staff, utilization of advanced information technologies and network connectivity, coupled with their contractual ties with the NHS, empowered Italian pharmacies to deliver a targeted and effective response during the pandemic. Pharmacies demonstrated a versatile range of interventions during and after the COVID-19 pandemic, encompassing not only their traditional role in dispensing medications but also providing testing services. This multifaceted approach significantly alleviated the burden on other healthcare services.

The administration of vaccines in pharmacies was prohibited in Italy until 2021, constrained by historical laws such as the “Testo unico delle leggi sanitarie” (“Consolidated text of health laws of 1938 (1,2). According to these regulations, neither pharmacists nor medical doctors were authorized to administer vaccines in pharmacies. The question of vaccination in pharmacies gained prominence in Italy during and after the COVID-19 pandemic, particularly following the approval of the National Vaccination Plan (PNPV) 2023-25 (3). Italy subsequently became the third EU country to permit community pharmacists to administer COVID-19 vaccines, with specific legislation and standardized procedures officially adopted in March 2021 (4).

In Italy, the first laws expanding the role of pharmacies date back to 2009, with the establishment of the “Pharmacy of Services” (5). This legislation allowed pharmacies to provide first-level analytical services, nursing and physiotherapy services, integrated home care services, and the right to book specialist medical visits and to implement prevention and health education campaigns.

During the initial stages of the mass anti-COVID-19 vaccination campaign, pharmacies played a vital role in the Vaccine Prevention Network, actively engaging in the distribution of vaccines. In the spring of 2021, the experimental administration of anti-SARS-CoV-2 vaccines by pharmacists was sanctioned, contingent on their completion of suitable training through online courses organized by the Italian National Institute of Health (ISS) (as outlined in section 465 of law 178/2021) (6). The legislators aimed to foster a novel

pharmacy model that provides citizens with an array of supplementary services alongside pharmaceuticals.

Building on the experience gained, the administration of flu vaccinations was authorized for the 2021/2022 season, as outlined in Decree-Law No. 105 of 23 July 2021, subsequently amended and enacted as Law No. 126 of 16 September 2021 (7,8). Community pharmacists were empowered to actively participate in the flu vaccination campaign, concentrating on individuals aged 18 and above. This innovative approach, known as the Pharmacy of Services, aimed to streamline citizens’ access to vaccinations and alleviate the strain on other healthcare facilities and GPs.

In 2022, the practice of pharmacists administering both COVID-19 and flu vaccines in pharmacies was formally integrated into the healthcare system (9). Ministerial Decree 77, a primary healthcare reform component, officially acknowledged community pharmacies as essential local facilities within the healthcare system. Recognizing their pivotal role, pharmacies were designated as crucial health service providers, serving as representatives of the public institution in the administration of drugs and other healthcare services (10). The “Accordo Quadro,” (“Framework Agreement”) dated 28 July 2022, established regulations for pharmacies administering flu and/or COVID-19 vaccines, solidifying their role as key contributors to public health. According to the latest legislation, pharmacists are mandated to gather the patient’s clinical history before administering vaccinations. Furthermore, pharmacies are authorized to administer vaccines solely to individuals who have previously received the same type of vaccine and to those who have never experienced severe allergic reactions to vaccine components (11).

This study focused on the experience of the Lombardy Region because it was the first Italian region to introduce vaccination in pharmacies on a large scale, through Resolution No. XII/848 of 8 August 2023 (12). It established clear and uniform rules for all pharmacies in the Region providing services to citizens, including collaboration with other health professionals. The document also allowed pharmacies to gather in networks to provide health services in locations outside pharmacies’ premises. The involvement of pharmacies in these activities was also facilitated by the well-established mixed delivery model in the Lombardy Health Service (13,14).

This study aims to assess the role of pharmacies in Lombardy in administering vaccines, specifically examining total vaccinations, the count of participating pharmacies, and the distribution of both COVID-19

and flu vaccinations. Through this comprehensive approach, we aim to offer valuable insights into the diverse contributions of Lombardy's pharmacies to broader vaccination initiatives. Additionally, we have included a focus on the Marche Region, the first Italian region to expand pharmacy vaccination to encompass additional adult vaccines.

## Methods

Our survey relies on data provided by the Ministry of Health and the Lombardy Region, encompassing the period from July 2021 to December 2023. We conducted a thorough examination of essential metrics, such as the quantity of participating pharmacies, the overall number of vaccinations administered for both COVID-19 and flu, and the demographic distribution of age groups benefiting from these vaccinations. This timeframe was chosen to facilitate an evaluation of the pharmacies' contribution to the vaccination campaigns. The 2023 data are updated as of 4 December 2023 and refer to the first 7 weeks of the anti-flu campaign and the first 3 weeks of anti-COVID-19 vaccination in Lombardy.

## Results

### Vaccination in 2021

Since the beginning of the mass anti-COVID-19 vaccination campaign in January 2021, individuals have had the option to use pharmacies to book vaccinations at one of the authorized regional hubs. Starting from July 2021, residents of Lombardy have had the convenience of receiving COVID-19 vaccinations directly at pharmacies. This initiative saw the

engagement of affiliated pharmacies, where trained pharmacists administered the vaccines in adherence to the new national legislation.

The involvement in this endeavor was implemented gradually, commencing with an initial experimental phase that included 21 pharmacies and subsequently expanding to encompass 500 pharmacies. In the year 2021, a total of 19,541,241 doses of the COVID-19 vaccine were administered in Lombardy, and pharmacies contributed with 106,702 doses (0.5%) (Table 1).

### Vaccination in 2022

On September 22, 2022, the updated bivalent COVID-19 vaccine formulation for the Omicron Ba.1 variant became available. This vaccine has received approval for individuals aged 12 years and older requiring a third or fourth dose, encompassing healthcare workers, residents of residential care homes (RSA), individuals over 60 years old, individuals with underlying health conditions such as transplant recipients, those with compromised immune systems, and pregnant women. In Lombardy, the number of participating pharmacies increased to 605, administering a total of 5,998,571 doses of the COVID-19 vaccine, with pharmacists responsible for administering 891,696 doses (14.8%). Among the vaccines administered in pharmacies, 189,193 (21%) were given to individuals aged over 80 years, 200,889 (23%) to those aged between 70 and 79 years, and 172,362 (19%) to individuals aged between 60 and 69 years. These data underscore the effectiveness of this proximity service, particularly in providing vaccination options for the vulnerable population.

### Vaccination in 2023

The 2023 vaccination campaign encouraged the co-administration of boosters for Covid-19 and seasonal flu, in implementation of the ministerial circulars of April (13) and August (14). In 2023, the anti-flu vaccination campaign in Lombardy started on the 16<sup>th</sup> of October, targeting people (over 60 and at risk categories). The COVID-19 vaccination campaign started on 20<sup>th</sup> November using the updated COVID-19 vaccine, which offers protection against the XBB 1.5 variant. This campaign involves 1,010 (20,2%) pharmacies in Lombardy (over a total of 5,000).

As of 4<sup>th</sup> December 2023, a total of 363,026 doses of COVID-19 vaccine and 1,577,653 of Flu vaccine have been administered in the Lombardy region.

Table 1. Covid-19 Vaccinations in Lombardy – Year 2021.

| Month     | N. of COVID-19 vaccinations |
|-----------|-----------------------------|
| July      | 1                           |
| August    | 1,226                       |
| September | 980                         |
| October   | 468                         |
| November  | 23,642                      |
| December  | 80,385                      |
| Total     | 106,702                     |

Places of administration of the two vaccines are listed in Table 2 and Table 3.

Table 2. Location category for COVID-19 vaccinations - Year 2023.

| Location category            | N. of COVID-19 vaccinations | %    |
|------------------------------|-----------------------------|------|
| Pharmacy                     | 165,521                     | 46%  |
| ASST*                        | 102,025                     | 28%  |
| Family doctors (GPs)         | 62,184                      | 17%  |
| Local social-welfare service | 22,657                      | 6%   |
| Hospital                     | 6,171                       | 2%   |
| IRCCS**                      | 4,261                       | 1%   |
| Other                        | 207                         | 0%   |
| TOTAL                        | 363,026                     | 100% |

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Table 3. Location category for flu vaccinations - Year 2023.

| Location category            | N. of flu vaccinations | %    |
|------------------------------|------------------------|------|
| Family doctors (GPs)         | 1,077,188              | 68%  |
| Pharmacy                     | 262,646                | 17%  |
| ASST *                       | 161,867                | 10%  |
| Local social-welfare service | 54,491                 | 4%   |
| Hospital                     | 12,933                 | 1%   |
| IRCCS **                     | 6,776                  | 0%   |
| Other                        | 1,752                  | 0%   |
| TOTAL                        | 1,577,653              | 100% |

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In addition to a general decline in participation to the two vaccination campaigns compared to previous years, the 2023 data highlight that, for flu shots, the key role of the family doctors (GPs) is consolidated; while shots for COVID-19, pharmacies have become the first place of administration with almost half of booster doses administered. Both for flu and COVID-19 vaccinations, most of doses were administered to the people over-60 (64% for boths), followed by people

at risk (13% and 12% respectively) and healthcare workers (7% for both).

### New vaccination initiatives in the Marche Region: tackling Covid, Flu, Herpes zoster and beyond

Under a regional experiment, since 12<sup>th</sup> October 2023, more than 170 (36,7%) pharmacies in the Marche region (over a total of 463) have been administering vaccines to citizens, including the updated COVID-19 vaccine against the latest variants and the flu vaccine. In early December, 5,000 doses of the flu vaccine were administered by the 130 participating pharmacies, along with an additional 10,000 doses of the new mRNA-based COVID-19 vaccine adapted to the new variants.

A notable addition introduced by the Region was the administration of anti-herpes zoster and anti-pneumococcus vaccines. These vaccinations have been available since 1 December 2023, with around 120 pharmacies actively participating in this new initiative, offering one thousand doses of vaccine (15). The vaccination is recommended, free of charge, to people aged 65 and over, people aged 50 and over with diabetes mellitus, cardiovascular disease, or chronic lung disease. No data on that experimentation are available so far. Data will become available in the next months.

## Discussion

Between 2021 and 2023, Italian pharmacies officially joined the ranks of vaccination providers, aiming to counter the decline in coverage observed in the post-COVID period (16, 17). This study highlighted the contribution of pharmacies to COVID-19 and flu vaccination campaigns from 2021. The data of the Lombardy Region showed the increasing role of pharmacies, culminating with 46% of COVID-19 vaccinations and 17% of flu vaccinations during the first part of the last autumn vaccination campaign (2023/2024). Although the situation is not the same in all regions, the data and experiences presented can be a stimulus for larger use of pharmacies – as well as other facilities used for the mass vaccination campaign of COVID-19 (3,18) – within the priorities of the National Vaccine Plan.

This study sheds light on pharmacies' significant role in the COVID-19 and flu vaccination campaigns starting in 2021. Data from the Lombardy Region illustrates the growing importance of pharmacies with

one third of them (1,000 out of 3,000) able to deliver vaccines. While the situation may vary across regions, the presented data and experiences serve as an impetus for more extensive utilization of pharmacies within the priorities outlined in the National Vaccine Plan (3).

The integration of vaccine administration into pharmacies stands out as a paramount innovation in the Italian vaccination system in recent years, albeit with only a handful of regions fully implementing and adhering to national regulations. Before the onset of COVID-19, consideration was given to the potential role of pharmacists in public health, with a specific emphasis on vaccination practices (19,20). The initial skepticism expressed by medical associations (21) and public health physicians (22) has evolved into a more favorable perception of the role that pharmacies can play in attaining optimal vaccination coverage. Notably, the extensive presence of pharmacies, their expanding role as community hubs, extended operating hours, and the established reciprocal trust between citizens and pharmacists, collectively advocate for a broader utilization in the future of these facilities for vaccine administration (23). This recent survey, commissioned by the Federation of the Orders of Italian Pharmacists (FOFI), underlines that the public holds a high level of trust in pharmacists, with 77% considering them reliable and competent healthcare professionals. Pharmacies, chosen for trust (37%), proximity (57%), and satisfaction (42%), have become a vital healthcare resource for 93% of Italians. A majority (80%) were willing to receive vaccinations from pharmacists, and 64% saw the expanded roles granted by recent regulations as positive, though a third expressed concerns over challenges outweighing benefits. Many countries in the EU and worldwide are involved in vaccinations: currently, pharmacists can vaccinate in their pharmacies in 15 European countries for flu and/or COVID-19 (4). In more than half of these countries, pharmacists can administer other vaccines and drugs such as Pneumococcal, Herpes Zoster (shingles), Cholera, Diphtheria, Tetanus and Pertussis, Anti-Tetanus Serum injection, Meningococcal, Tick-borne Encephalitis, Typhoid Fever and Hepatitis A, Japanese-Encephalitis, Hepatitis A, Hepatitis B, Human Papillomavirus (HPV), Rabies, Human rotavirus, and Varicella.

The attendance of appropriate training, the availability of suitable premises - with a possible improvement in the current rules on minimum requirements - and the adoption of safety procedures in the event of adverse reactions are indispensable elements for safe and effective vaccination. In the future pharmacies could be places for administering a greater number of

vaccines, and in this sense, the ongoing experiments in the Marche region with additional immunizations may yield interesting results.

## Conclusions

The COVID-19 pandemic has been a powerful catalyst for changes in the organizational structures of healthcare, profoundly affecting the delivery of health services (24-27). This has paved the way for the inclusion of pharmacies as permanent vaccination sites, building on their crucial role in supporting mass COVID-19 vaccination efforts. The National Vaccination Plan 2023-25 embraces this direction (3,24), recognizing that pharmacies, alongside other innovative vaccine providers like hospitals, family doctors, and hubs, can significantly contribute to increasing vaccination coverage.

While the establishment of pharmacies as vaccination sites will require time, pharmacists are well-positioned to play an ideal professional role in explaining vaccine mechanisms, dispelling myths, and actively combating misinformation (23). Leveraging their proximity to communities, pharmacies can conduct impactful vaccination awareness and advocacy campaigns, utilizing their visible and well-distributed network across Europe (4).

Hygiene and public health experts, traditionally involved in planning vaccination campaigns at regional and local levels, should seize this new opportunity. Their primary focus should be on ensuring safety and privacy standards for vaccination practices in pharmacies. The proximity of pharmacies, combined with the current shortage of health personnel in traditional immunization services, extended operating hours, and the trust citizens place in pharmacists, present positive elements for enhancing vaccination coverage rates. This approach also facilitates the dissemination of accurate information, contributing to rebuilding trust in vaccines, which has been compromised by misinformation circulating through various media channels and the internet (28).

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## Riassunto

*Il ruolo delle farmacie nell'implementazione della copertura vaccinale in Italia. Dati preliminari della Regione Lombardia*

**Introduzione.** La somministrazione di vaccini in farmacia non era consentita in Italia fino al 2021. Durante la pandemia di COVID-19 sono state introdotte innovazioni legislative che, oggi, consentono la

somministrazione di vaccini antinfluenzali e anti-COVID-19 da parte di farmacisti qualificati, dopo aver seguito un corso specifico.

**Metodi.** Viene presentata una revisione legislativa sulle vaccinazioni in farmacia, seguita da una descrizione delle vaccinazioni effettuate nelle farmacie che hanno partecipato alla campagna vaccinale regionale dal 2020 al 2023. Lo studio si basa sui dati relativi alla somministrazione dei vaccini in farmacia estratti dai database della Regione Lombardia, valutando le esperienze fatte finora e le prospettive future. Inoltre, sono state descritte le novità introdotte dalla Regione Marche con l'offerta, su base sperimentale, delle vaccinazioni anti-zoster e anti-pneumococco.

**Disegno dello studio.** Studio osservazionale

**Risultati.** La prima regione ad aver introdotto in modo estensivo la vaccinazione in farmacia è stata la Lombardia a partire dal 2021, con risultati rilevanti culminati nel 46% dei vaccini anti-Covid e nel 17% dei vaccini antinfluenzali somministrati nelle prime 6 settimane della campagna vaccinale dell'autunno 2023. Le farmacie sono state coinvolte nel raggiungimento degli obiettivi fissati dal Piano Nazionale di Prevenzione Vaccinale 2023-25. In via sperimentale la Regione Marche ha ampliato le vaccinazioni offerte in farmacia, includendo anche i vaccini anti-zoster e anti-pneumococco.

**Conclusioni.** I promettenti risultati in Lombardia e la sperimentazione in corso nelle Marche sono elementi incoraggianti per il raggiungimento degli obiettivi di copertura vaccinale, ancora inferiori agli obiettivi fissati dal Piano vaccinale 2023-25. La capillarità delle farmacie sul territorio le rende idonee come strutture di supporto per le campagne vaccinali nella popolazione adulta, anziana e fragile.

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