



Health Reform Monitor

Community pharmacists as vaccinators in the Italian SARS-CoV-2 immunization campaign: implications beyond the pandemic

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ABSTRACT

Italy was one of the last European countries to introduce vaccination in pharmacies. The urgent need to extend the vaccination campaign against SARS-CoV-2 led to the approval of Law no. 178/2020. The Law allowed the administration of COVID-19 vaccines in Italian pharmacies by community pharmacists on an experimental basis for the years 2021–2022. Stakeholders took contrasting positions on the idea of enabling pharmacist to vaccinate after proper training. Sometimes, controversy existed even within the same associations representing pharmacists. As observed in other countries, the medical profession in Italy also expressed its opposition to the idea of pharmacists as vaccinators, while the general public and pharmacy customers were generally in favour of the policy. Over two million doses of SARS-CoV-2 vaccines were administered in Italian pharmacies in less than one year after the introduction of the policy. Criticism and concerns raised during the debate about the introduction of vaccination in pharmacies has subsided. It is yet unclear whether vaccination in pharmacies will be prolonged after the pandemic and whether it will, in fact, be expanded to other vaccines. Potentially, this could contribute towards increasing immunisation rates, not only for COVID-19, but also for other vaccines.

1. Introduction

Vaccine induced immunity represents one of the most significant achievements in the fields of medicine and public health [1]. Thanks to vaccines, it has been possible to eradicate diseases such as smallpox [2], eliminate others such as poliomyelitis [3] and bring others such as meningitis under control [4]. Mass immunisation through vaccination, as part of national and/or international health policies, means drastically reducing the number of cases of illness and related complications, saving 4 to 5 million lives globally every year [5]. Not only do vaccines save lives, but they also represent a sound economic investment on the part of any national health service. According to a study of immunisation programmes regarding the period 2011–2022 in 94 low- and middle-income countries, the total cost of such programmes was put at \$94 million. However, the authors estimated that these programmes saved \$586 million in direct costs, and \$1.53 trillion when indirect costs are included [6].

The extent of uptake by the population is a key factor in determining the effectiveness of any vaccination campaign from a socio-health standpoint: the greater the number of subjects vaccinated, the greater the impact on the circulation of the pathogenic agent. This has a positive knock-on effect for the unvaccinated, who indirectly benefit from this protection [7,8]. It is, therefore, fundamental to ensure the greatest possible to access to vaccines in order to maximise the efficacy of the

immunisation campaign. From this point of view, the community pharmacy, thanks to its accessibility, capillary distribution over the territory, and extended opening hours represents the ideal point of contact to increase uptake in any vaccination campaign [9–11]. Besides this, community pharmacists, who have close relationships with their users, can make a significant contribution to alleviating vaccine hesitancy by dispensing scientifically sound information and allaying any doubts regarding vaccines [12–14]. There is strong evidence of a significant increase in vaccine uptake in many contexts where community pharmacists are authorised to administer vaccines [15–17].

2. Background

The range of services provided by community pharmacists in Italy has grown considerably over the last two decades [18–23]. This has brought with it greater responsibility and added duties. While the core business of a community pharmacy used to revolve around the dispensation and preparation of medicines, pharmacies now provide an ever-greater range of services to meet both the needs of users, and the requirements of the national health service. As a result of Decree-Law no. 153/2009 and the successive ministerial decrees implementing these directives [17], many new services have been introduced to pharmacies. These now offer tests for blood pressure, cholesterol, and glycemia, as well as monitoring long-term chronic patients, screening

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services, and many more [18,24]. Regarding vaccination campaigns, community pharmacies in Italy have had a longstanding involvement in raising awareness of the importance of vaccination among the population. Moreover, they work in collaboration with general practitioners and paediatricians to identify high-risk subjects. In some regions, pharmacies have been involved in the distribution of flu vaccines to general practitioners and paediatricians [15,25]. Unlike other European countries, where it has been the norm for many years, Italian pharmacists were not authorised to administer vaccines until the pre-pandemic phase. Before the pandemic, only medical doctors or nurses (under the supervision of a medical doctor) were authorized to administer vaccines in Italy. The urgent need to extend the vaccination campaign against SARS-CoV-2 finally led to the introduction of legislation allowing the administration of COVID-19 vaccines in pharmacies by community pharmacists (Law 30 December 2020, no. 178) [26].

2.1. Analysis of law 30 December 2020, n. 178 and the relevant operating protocol

The new regulations authorising Italian pharmacists to administer anti-SARS-CoV-2 vaccine directly in pharmacies were approved by parliament after a lengthy and heated debate. Law no. 178/2020 initially permitted the administration of the vaccine in community pharmacies only under the supervision of a medical doctor. However, this proviso was immediately abolished by Decree-Law 22 March 2021, no. 41, which allowed the administration of anti-COVID-19 vaccine directly in pharmacies by a pharmacist without the supervision of a medical doctor.

The definitive version of the law is composed of two sections made up of twenty articles. The most salient points of the regulations are in article 1, comma 471, and can be summarised as follows:

- The administration by pharmacists of vaccines against SARS-CoV-2 in community pharmacies is authorised as an experimental project in the years 2021-2022 [27]
- The authorisation to administer vaccines in pharmacies is valid for only pharmacists who have completed an accredited training courses run by the Higher Institute for Health (ISS). The training courses shall include a theory component and practical training supervised by a subject authorised to administer vaccines.

The operating instructions for the establishment of an anti-SARS-CoV-2 vaccination service at a pharmacy were set out in a protocol agreed between the government and the main trade associations representing the pharmacies [28]. The most important measures to be adopted are reported in Table 1.

The protocol also provides instructions regarding the preparation and storage of vaccines, as well as regulations for clinical waste management for vaccination operations. The legislators fixed the reimbursement fee to be paid to the pharmacies by the National Health System at €6 per dose, while further payments could be added by special agreements at a regional level.

3. Stakeholders positions

The stakeholders took contrasting positions on the theme of pharmacist vaccinators with controversy and debate continuing even after the publication of Law no. 178/2020. The positions of the main stakeholders are outlined below.

3.1. Pharmacists

If we consider the point of view of the community pharmacists and of their trade associations, the satisfaction was generally high. In fact, even before the onset of the COVID-19 pandemic, the major trade associations representing pharmacies and pharmacists had put forward proposals to

Table 1

Main operating guidelines contained in the operating protocol for the anti-SARS-CoV-2 vaccination service in pharmacies.

Requirements for Pharmacies	Requirements for Pharmacists
<ul style="list-style-type: none"> • The protocol defines the structural requirements to be complied with in the vaccine administration area • The vaccine administration area shall guarantee the privacy of the subject being vaccinated • Vaccine administration may be performed outside of opening hours should suitable vaccination areas not be available during normal opening hours • The service may be conducted in mobile/portable units (e.g., a gazebo) • Each pharmacy shall be equipped with an emergency response kit to deal with any adverse events following immunization (AEFI) 	<ul style="list-style-type: none"> • Shall not test positive for SARS-CoV-2, nor display symptoms compatible with COVID-19 • Shall have completed an accredited training course • Shall wear appropriate PPE during the administration of the vaccine (e.g., FFP2/KN95 masks and disposable gown) • Shall ensure that the pharmacist responsible for first aid is present at all times during the vaccination session
<p>Requirements for subject to be vaccinated</p> <ul style="list-style-type: none"> • Must not test positive for SARS-CoV-2, nor have symptoms compatible with COVID-19, nor have been in contact with a positive patient in the previous 14 days • Must use appropriate PPE (e.g., surgical mask) at all times during the vaccination session • Subjects deemed extremely vulnerable and/or with a medical history of allergic reaction/ anaphylactic shock are excluded from vaccination 	<p>Regulations for Provision of the Service</p> <ul style="list-style-type: none"> • Entry and exit routes must be clearly marked; distancing measures must be respected between subjects awaiting vaccination, and after vaccination • The service is available by appointment only • The pharmacist together with the vaccinated subject shall complete the consent form and the anamnesis • The pharmacist shall ensure that the subject remains under observation on the premises for at least 15 minutes after the vaccination has been administered • After vaccination, the pharmacist shall update the vaccination records and issue the vaccination certificate

authorise pharmacies to carry out vaccination for the general public [29]. Community pharmacists themselves were in favour of being more actively involved in the vaccination campaign as vaccinators [30]. However, this authorisation had never been able to get approval in parliament before the outbreak of the pandemic [31].

Immediately after the approval of the anti-COVID-19 vaccines by the regulatory agencies, the main associations representing pharmacists pointed to the potential of pharmacies to accelerate the rate of the vaccination campaign and to reach a far greater number of people [32]. Therefore, the approval of law no. 178/2020 was greeted by FOFI (Federation of the Orders of Italian Pharmacists) and Federfarma (national association of pharmacy owners) as a major success for the Italian pharmacy sector [33,34].

FOFI as in fact declared that Italy had finally caught up with the growing number of other European countries where pharmacies and pharmacists are actively involved in vaccination campaigns. It was also underlined that the goal pursued by the pharmacists' associations was never to put themselves in competition with, let alone substitute, doctors and nurses. Instead, the objective was to build a collaborative relationship alongside these figures in order to increase the capacity of the health system by making more vaccination centres and vaccinators available to the public [32].

From the start of the pandemic, the number of users entering pharmacies grew significantly when access to doctors' surgeries and clinics was severely restricted in the early stages of the emergency [18,19]. Pharmacies made a good contribution to containing the spread of the virus during the emergency phase, and still play a important role today, processing more than 500.000 COVID-19 antigen tests [35]. When pharmacists were granted the authorisation to vaccinate in pharmacies, the response was overwhelmingly positive: within a few months of the

approval of Law no. 178/2020, more than 44,000 pharmacists had already completed the training course and qualified as vaccinators. In the 2-month period between August and September 2021, more than 400,000 doses of vaccine were administered in Italian pharmacies [36].

As regards the pharmacists employed in commercial activities that in Italy are authorized to sell only human medicines without prescription (called "parapharmacies"), the representatives of the sector welcomed the introduction of the pharmacist vaccinator as a turning point, but expressing their regret that pharmacists employed in parapharmacies had been excluded from working as vaccinators [37].

However, pharmacists have not always expressed positive comments. Especially staff pharmacists, expressed their fears, and even opposition, regarding the figure of the pharmacist vaccinator. Their main objections centred on the added duties and responsibilities that the pharmacist vaccinator would have to assume, and the risks linked to the vaccination process [38–41].

As well as the concerns of individual pharmacists, the unions representing staff pharmacists used the added responsibilities associated with this new activity, which arose with the pandemic – from performing antigen tests to administering vaccines, as grounds to call for the renegotiation of the national contract for pharmacists [42]. Some unions and associations of staff pharmacists did not dismiss the introduction of vaccination services in pharmacies outright, but emphasised the need for a fair remuneration and proper legal safeguards for any pharmacist involved in the new service. Other unions, instead, sided with the medical organisations. They affirmed that clinical assessment and the management of any adverse reactions were the exclusive competence of doctors. Hence, the administration of vaccines by a pharmacist should only take place under the supervision of a medical doctor [43]. The majority of associations representing staff pharmacists did not approve of the stipulation that only pharmacists employed in a pharmacy were authorised to administer vaccines: thus, excluding those who had retired, or were working in other sectors such as medical sales representatives for example [43,44].

3.2. Other healthcare professionals

As regards other health professions, specifically medical doctors and nurses, opinions are very different.

As in other countries where the role of pharmacist vaccinator had existed for some time, the medical profession in Italy also expressed its complete opposition to the proposed authorisation of pharmacists to administer vaccines [45,46]. The main objections they raised were the presumed lack of competence among pharmacists in managing the patient's clinical history, the diagnosis and evaluation of the clinical condition of a subject, as well as the identification and management of any AEFI [45].

On the other hand, the nursing profession was not opposed to the figure of the pharmacist vaccinator; instead, the representatives of this sector hoped that the same degree of independence granted to the pharmacists in managing the entire vaccination process from the clinical history to the management of adverse reactions, would also be extended to nurses [47]. The collaboration between the two categories was sealed by the agreement between the two main federations: the National Federation of Professional Nursing Organisations (FNOP), and Federfarma. This agreement set out that nurses would provide the practical training which pharmacists needed to qualify as pharmacist vaccinators [48].

3.3. Public authorities

The Minister for Health welcomed the agreement with the pharmacy associations regarding the in-pharmacy vaccination programme. It highlighted, in particular, the opportunities to exploit the network of pharmacies to reach a far greater portion of the population [49]. Words of praise for the creation of the pharmacist vaccinator also came from

other institutional figures such as the president of the Italian Pharmaceutical Agency (AIFA) [50], from the junior Minister for Health [51], and the emergency committee for COVID-19 [52].

3.4. Citizens

The secretary of "Cittadinanzattiva", one of the main organisations promoting citizen activism [53], gave its approval to the proposed authorisation for pharmacists to administer vaccines on condition that they received proper training [54]. Moreover, a number of surveys carried out among the general public [30] and pharmacy customers [55] indicated that these groups were in favor of the pharmacist vaccinators.

4. Considerations on law 178/2020 in light of the experience of other countries

As noted previously, Italy was one of the last countries to institute pharmacist vaccinators. Comparing the provision of an in-pharmacy vaccination service in Italy with that in other countries where it has been operating for many years (Australia), or for a short time (France), it is possible to observe many significant similarities. Despite different socio-political and economic-sanitary backgrounds among the three countries in consideration, the legislative guidelines for the provision of this in-pharmacy vaccination service are quite similar. Specific training for anti-COVID-19 vaccines is an indispensable requirement to be able to provide this service in all of the countries with, however, some differences. One instance is that the training course in Australia included a section on basic life support, while the law in Italy required the presence of an emergency care provider, who is not necessarily the vaccinator [15,28]. None of the countries required a doctor's prescription in order to be vaccinated [15,28,56–58] to simplify the process for individuals seeking vaccination; in addition, the pharmacist was made responsible for updating the vaccination records to ensure the traceability of vaccinated subjects [15,59,60]. A major barrier to the introduction of this service is the limited financial support of the government/healthcare system [15]. However, just as in France and in Australia, Italy was forced to act quickly to slow the rate of COVID-19 transmission by raising the percentage of the immunised among the population. The effect was that the government made vaccination available free of charge, even in pharmacies, for all citizens entitled to it (Table 2).

5. Discussion: evaluation and future perspectives

The aim of this article is to inform the reader of the growing role of Italian community pharmacies in the vaccination campaign against COVID-19. It can be said that, with the ratification of Law no. 178/2020, Italy aligned its vaccination services with the broader European context.

It is certain that the possibility to evaluate the performance, both from the point of view of the general public and the national health system, seen in those countries that entrusted pharmacies with

Table 2
Remuneration for anti-SARS-CoV-2 vaccination for pharmacists in Italy, Australia, and France.

	Italy	Australia	France
Vaccine administration fee for the pharmacist	The fees paid to the pharmacist is 6€ per dose. With additional payments from individual regions [28]	The fees paid to the pharmacist varies between 16 AUD (10,14€) and 29 AUD (18,39€) according to the Modified Monash Model (MMM) category [61]	The fees paid to the pharmacist varies between 7,90€ a 15,40€, according to the region and administration on business days or at weekend [62]

vaccination was important in the establishment of a pilot scheme in Italy too. However, the determining factor for the institution of the pharmacist vaccinator in Italy was, without doubt, the urgency in expanding and accelerating the anti-COVID-19 vaccination campaign. This exploited the capillary network of pharmacies on the territory and the close relationship of pharmacists with their users. This, therefore, underlines the fact that parliament's hesitancy in finally authorising in-pharmacy vaccination was probably due to political rather than health motives.

It is probably premature to draw conclusions, however, with over two million [63] doses administered in Italian pharmacies during the first year, much of the criticism and concerns raised during the debate on Law no. 178/2020 have been dampened. Any criticalities that may have arisen after vaccination were managed either in the pharmacy by the pharmacist or with the support of the Public-Safety Answering Point in accordance with the protocol. The staff pharmacists have had their contract renewed with increased pay rates for the specific services provided by pharmacies in this SARS-CoV-2 pandemic [64]; from the perspective of the users, the preliminary response appears to be positive: the data from a survey about to be published by our group suggests that most users were satisfied with the in-pharmacy vaccination service [65]. The positive outcome observed so far of this experiment may encourage a greater number of pharmacies to provide this service.

The in-pharmacy SARS-CoV-2 vaccination service has been an experimental project: the representatives of the sector may intend to start negotiations to make this service permanent and extend the range of vaccines available in pharmacies, as already happened for anti-influenza vaccines [66].

Furthermore, it must be pointed out that in most Italian regions, no dedicated IT system has been set up for the management of the vaccination service; instead, the campaign has relied on the IT systems already in use in pharmacies for the management of other services. The rollout of a national platform for this specific service and the simplification of the booking process for tests and vaccines, and data transmission would facilitate the pharmacist's work.

Another aspect which requires attention is the harmonisation of the service at a national level. It is a fact that the fees for the pharmacist vary considerably between regions [28,67]. This may represent an obstacle to offer a homogenous territorial coverage to citizens.

Finally, one of the most serious concerns is the fact that some regions have yet to sign the necessary agreements to set up this service in pharmacies; thus, in Sardinia, Friuli Venezia Giulia and Basilicata, it is still not possible to be vaccinated in a pharmacy [68]. This leads to inequalities in the healthcare service available to citizens.

6. Conclusion

Preliminary data of the Italian anti-SARS-CoV-2 vaccination campaign show that pharmacists and community pharmacies can support immunization activities. This is similar to observations in other countries [15]. The introduction of a permanent vaccination service in community pharmacies has generated considerable debates amongst pharmacists and opposition from medical doctors, especially in the initial period. Potentially, if vaccination by pharmacies is continued into the future, this could contribute towards increasing the immunisation rate, not only for COVID-19, but also for other pathologies. This would be particularly important for higher-risk members of the population (e. g., increasing the vaccine coverage against influenza among the over-65s), or for areas where access to health services is limited, such as mountainous areas. Legislative procedures would be needed to make vaccination services in pharmacies permanent and to extend it to further types of vaccines. The experience with the administration of anti-SARS-CoV-2 vaccines in pharmacies may also lay the foundation for the provision in pharmacies of other services, which entail intramuscular administration e.g., intramuscular injections of antibiotics. However, an expansion of services provided by pharmacies would need to be

accompanied by an expansion of pharmacist training programmes because vaccinations or intramuscular administration of medicines is not (yet) part of the standard curriculum.

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Declarations of Competing Interest

None.

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