

# Coronavirus pandemic in the EU – Fundamental Rights implications National vaccine deployment

Italy
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# 1 National vaccine deployment – planning and overview of priority groups

Please provide the title and hyperlink of the national vaccine deployment plan/s in EN and the national language/s and indicate the date of publication of the plan/s including any updates.

In **Italy**, the national vaccine deployment plan was introduced with the Decree of the Ministry of Public Health of 12 March 2021 and it is available at the following hyperlink: <a href="https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=79430">www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=79430</a> (English version not available). It is the result of two previous documents, namely: i. the "Elements of preparation of the vaccine strategy" of 2<sup>nd</sup> January 2021, available at:

www.trovanorme.salute.gov.it/norme/renderPdf.spring?seriegu=SG&datagu=24/03/2021&redaz=21A01802&artp=1&art=1&subart=1&subart1=10&vers=1&prog=001 (English version not available); and ii. The "Interim Recommendations on the Target Groups of the anti-Covid19 vaccines" of 10 March 2021, available at: www.trovanorme.salute.gov.it/norme/renderPdf.spring?seriegu=SG&datagu=24/03/2021&redaz=21A01802&artp=1&art=1&subart=1&subart1=10&vers=1&prog=002 (English version not available).

Please provide information on the planned phases of vaccination with respect to the groups to be prioritised for vaccination.

Specific groups identified in the national vaccine deployment plan	Date of plan	Date of new/revised plans
older persons; indicate age groups specified	Vaccine Deployment Plan of 12 March 2021. People aged 80+: high priority (Category 1)	Ordonnance No. 6/2021 of the Commissioner for the Covid-19 Emergency of 9 April 2021 (www.governo.it/it/articolo/
	People aged 70-79: high priority (Category 2)  People aged 60-69: medium priority (Category 3)	campagna-vaccinale- firmata-lordinanza-n-62021- del-commissario- lemergenza-covid- 19/16588): priority confirmed
persons with underlying health problems	Vaccine Deployment Plan of 12 March 2021.  People with underlying health problems that — according to scientific studies — result into a higher Covid-19 mortality rate due to insufficient immunological response (Table 1 of the Plan provides	Ordonnance No. 6/2021 of the Commissioner for the Covid-19 Emergency of 9 April 2021 (www.governo.it/it/articolo/campagna-vaccinale-firmata-lordinanza-n-62021-del-commissario-lemergenza-covid-19/16588): priority confirmed

	a list of eligible pathologies) (Category 1)	
key workers (on the basis of their job not their personal	Vaccine Deployment Plan of 12 March 2021.  People with severe disabilities, as defined by Art. 3.3 of the Law No. 104/1992: high priority (Category 1)  This priority also applies to the caregivers of people with severe disabilities (both family members, and employed caregivers)  Vaccine Deployment Plan of 12 March 2021.	Ordonnance No. 6/2021 of the Commissioner for the Covid-19 Emergency of 9 April 2021 (www.governo.it/it/articolo/campagna-vaccinale-firmata-lordinanza-n-62021-del-commissario-lemergenza-covid-19/16588): priority confirmed  Ordonnance No. 6/2021 of
characteristics) – e.g. health workers; persons working in care homes; teachers	Some professional categories are considered as a priority group in the vaccine deployment plan, regardless of health fragilities and age. These include teachers and university staff; health workers; law-enforcement officers; persons working in care homes.	the Commissioner for the Covid-19 Emergency of 9 April 2021 (www.governo.it/it/articolo/campagna-vaccinale-firmata-lordinanza-n-62021-del-commissario-lemergenza-covid-19/16588): priority confirmed
persons belonging to ethnic/national minorities	No specific measure envisaged	
persons experiencing homelessness	No specific measure envisaged	
persons with drug addiction dependencies	No specific measure envisaged	
persons with low literacy levels	No specific measure envisaged	
persons deprived of their liberty	Vaccine Deployment Plan of 12 March 2021.  Some categories are considered as a priority group in the vaccine deployment plan, regardless of health fragilities and age. These include detainees, and all the staff working in the Italian detention system.	Ordonnance No. 6/2021 of the Commissioner for the Covid-19 Emergency of 9 April 2021 (www.governo.it/it/articolo/campagna-vaccinale-firmata-lordinanza-n-62021-del-commissario-lemergenza-covid-19/16588): priority confirmed

persons without residence or with insecure legal status (such as refugees, asylum seekers, and undocumented migrants)	No specific measure envisaged	
OTHER – not specified above; e.g. 'Persons living in crowded accommodation'; etc. Please insert	According to the Vaccine Deployment Plan of 12 March 2021:  - People aged less than 60 with underlying health problems that are less severe but present a comorbidity with the Covid-19 are to be considered a priority compared to the general population aged less than 60 (Category 4); - Children aged less than 16 cannot undergo the vaccine procedure. However, if these children have severe disabilities — as defined above — their parents/guardians can undergo the vaccine as a priority group (Category 1); - Older people living in care homes are considered by the Plan as a high-priority target group	
	(Category 1).	

Please briefly indicate here (not in the above table):

- the reasons behind major changes with regard to priority groups— as announced by the government.
- the overall approach behind the definition of priority groups: please identify the main ground for identifying groups as priority group (vulnerability to infection; social vulnerability; multiple criteria).

In **Italy**, there have been not major changes in the definition of the priority groups for the vaccine deployment plan. The Ordonnance of Ordonnance No. 6/2021 of the Commissioner for the Covid-19 Emergency of 9 April 2021 confirmed the priority categories defined by the Plan. The Ordonnance was passed to stress that the categories established by the Government must be implemented in all Italian regions: regional authorities do not have the power to establish a different priority order.

In **Italy**, the "Interim Recommendations on the Target Groups of the anti-Covid19 vaccines" of 10 March 2021, established the criteria to define the priority groups for the Vaccine Deployment Plan. These criteria combine those factors that – according to the available studies and scientific literature – have proven to increase the risk of infection, and mortality rate of the Covid-19. These are: age (the older the subject, the higher the mortality of the infection); underlying health conditions; working in specific settings and professional fields (this resulted into the immediate inclusion among priority groups of all health workers, followed by school and university staff, law-enforcement officers, detention-system staff, staff working for care homes for older people).

## 2 Vaccination rollout – communication, targeted outreach, registration, and administration of vaccinations

For each of the subsequent questions (2.1 and 2.2) please indicate:

Languages: If information in different languages is available. Please list those languages in which information is available (e.g. languages of recognised national or ethnic minorities and immigrant communities; as well as English and other dominant international languages).

Accessibility for persons with disabilities: If information is provided in accessible formats to ensure accessibility for people with disabilities (including easy read, in braille, sign language etc); are physical venues made accessible for persons with disabilities?

## 2.1 What are the (pre-) registration channels for vaccination put in place?

- a) What registration channels for vaccination are in place e.g. websites, apps, hotlines/call centres, letters, via family doctors, etc.?
- b) Are any alternatives to digital access to vaccine registration in place e.g. appropriate support for those who need it (such as the elderly; those without access to the internet); physical locations for registration etc?

In **Italy**, the registration channels are managed by the 20 Italian regions, according to the vaccine targets established by the Ministry of Health on grounds of the population living on the regional territory. As of April 2021, 6 regions have joined the online registration platform developed by the Italian Government, in cooperation with the Italian Postal Service<sup>1</sup>. The categories that are currently available to register through the platform are the priority groups, namely: people aged 80+; vulnerable people; school staff; health workers; law-enforcement officers; and people aged 70-79. In order to register on the platform, users are requested to provide their social security number (codice fiscale), the number of the social security card, and their mobile phone to receive the confirmation and the communication concerning the date of the vaccine. This system also envisages alternatives to the online registration: potential beneficiaries of the vaccine can call to the free helpline (Monday-Friday from 9 a.m. to 6 p.m.); or they can register using the cash-machines located in most Italian post offices. Those regions that have not joined the Government platform have developed their own registration channels: most of these regions offer online platforms requesting the same data also needed for the Government platform; but also phone helplines. Some regions – such as the Emilia-Romagna region – offer their residents the possibility to register for the vaccine through the local health departments or the pharmacies, as well as using phone apps developed at this specific purpose.

In **Italy**, both the Ministry of Public Health<sup>2</sup> and most Italian regions<sup>3</sup> have developed specific FAQs providing information on the vaccine deployment plan.

In **Italy**, an online service exists – called JumaMap - Refugees Map Services<sup>4</sup> – which provides a mapping of all services existing at local level, offering support to migrants, asylum seekers, and protection status holders. The project was developed by the toll-free number for asylum seekers and refugees from the national Arci, with the support of the UN Refugee Agency – UNHCR. During the Covid-19 emergency, the project's website was enriched with a specific information concerning the measures adopted by the Italian Government to cope

https://accesso.prenotazioni.vaccinicovid.gov.it/?c=prenotazionevaccino&cver=1&e=vaccine&man =&t=https%3A%2F%2Fprenotazioni.vaccinicovid.gov.it%2Fcit%2Findex.html&ver=v3-java-3.6.1.

 $\underline{www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=italiano\&id=255.$  Available also in English:

 $\frac{http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=english\&id=230\#15.$ 

<sup>&</sup>lt;sup>1</sup> Available at:

<sup>&</sup>lt;sup>2</sup> The Ministry's FAQs are available at:

<sup>&</sup>lt;sup>3</sup> These are, for instance, the FAQs developed by the Lazio region: <a href="www.salutelazio.it/faq-domande-e-risposte-sul-sistema-di-prenotazione-vaccino-anti-covid-19">www.salutelazio.it/faq-domande-e-risposte-sul-sistema-di-prenotazione-vaccino-anti-covid-19</a>.

<sup>&</sup>lt;sup>4</sup> Information on the project available at: <a href="www.jumamap.it/en/the-project/">www.jumamap.it/en/the-project/</a>.

with the emergency, including – in recent times – information on how to register for the vaccine at local level. This information is available in many languages<sup>5</sup>.

#### 2.2 How are the vaccinations administered?

a) Where are the vaccinations administered e.g. vaccination centres, via mobile units, via family doctors, etc.?

In **Italy**, as of 4 May 2021, there were 2,472 vaccination administration points existing on the entire national territory<sup>6</sup>. This data includes vaccination centres located in hospitals and local services: mobile units are not mapped by the Government's period report. Information concerning where the facilities administrating the vaccines are located are available at regional and local level: the lists of the facilities are available in most websites of the Italian regions<sup>7</sup>.

In **Italy**, according to the Vaccine Deployment Plan, the number of facilities to be used as vaccination centres must be progressively increased using other facilities originally destined to different purposes, such as centres used for other vaccination campaigns, military facilities, factory sites, large retailers, fitness centres, schools, associations, facilities belonging to the Italian Episcopal Conference (*Conferenza Episcopale Italiana* – CEI).

b) For those being vaccinated - how is information about the actual vaccination process, the vaccine and any potential side effects provided?

In **Italy**, information concerning the vaccines are provided both at national and regional/local level. As far as the national level is concerned, the Italian Government has developed a specific section of its website, reporting – in Italian and English – the most relevant FAQs on the vaccines<sup>8</sup>, including potential side

 $\frac{\text{https://www.salutelazio.it/documents/10182/59078875/12}}{\text{d-aa98-66cd-39f1-bc4b6cb11477}}; \\$ 

https://www.regione.lombardia.it/wps/portal/istituzionale/HP/vaccinazionicovid.

http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=italiano&id=255. English version:

<sup>&</sup>lt;sup>5</sup> Information available at: <u>www.jumamap.it/en/2021/01/26/how-to-sign-up-for-immunization-campaing-against-covid-19/.</u>

<sup>&</sup>lt;sup>6</sup> This data is provided by the Government's periodic report on the implementation of the Plan, available – in its most updated version – at: <a href="https://www.governo.it/it/cscovid19/report-vaccini/">www.governo.it/it/cscovid19/report-vaccini/</a>.

<sup>&</sup>lt;sup>7</sup> This are some examples:

<sup>&</sup>lt;sup>8</sup> Available at:

effects of the vaccines, which vaccines are currently available in Italy, specific concerns on vulnerable subjects, the vaccination certificate. Similar FAQs were developed also by the Superior Health Institute (*Istituto Superiore di Sanità* – ISS)<sup>9</sup>.

c) Are there any circumstances where fees are applicable for receiving the vaccine – e.g. for third country nationals?

In **Italy**, the Covid-19 vaccines are included in the public vaccine campaigns and cannot be by any means be subject to fees.

## 3 Challenges and promising practices

### 3.1 Challenges

In **Italy**, two major challenges have emerged so far in the implementation of the Vaccine Deployment Plan. The first challenge concerns the delays in the implementation of the Plan – mostly due to the shortages in the supply of vaccines (especially AstraZeneca vaccines) which occurred in many EU member States, and to the temporary and precautionary suspension of the administration of the AstraZeneca vaccine decided by the Italian Drug Agency (*Agenzia Italiana del Farmaco* – AIFA) on 15 March 2021<sup>10</sup> because of suspect side effects - and the differences existing at regional level with some regions at a more advanced implementation level compared to others. More specifically, as of 4 May<sup>11</sup>, the first dose of the vaccine was administered to 24.5% of the Italian population; only 10.6% of the population had concluded the vaccine procedure (both doses and mono-dose vaccines). As per regional differences, as of 4 May, some regions have reached a vaccination rate of more than 40% of the regional population (such as

 $\frac{http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=english\&id=230#15.$ 

<sup>9</sup> Available at: www.iss.it/covid19-faq.

<sup>&</sup>lt;sup>10</sup> AIFA decision available at: <a href="https://www.aifa.gov.it/-/aifa-sospensione-precauzionale-del-vaccino-astrazeneca">www.aifa.gov.it/-/aifa-sospensione-precauzionale-del-vaccino-astrazeneca</a>.

<sup>&</sup>lt;sup>11</sup> Data provided by the monitoring system developed by GEDI Visual, based on official data released by the Commissioner for the Covid-19 Emergency. The data system is available at: <a href="https://lab.gedidigital.it/gedi-visual/2021/report-vaccini-anti-covid-aggiornamento-vaccinazioni-italia/">https://lab.gedidigital.it/gedi-visual/2021/report-vaccini-anti-covid-aggiornamento-vaccinazioni-italia/</a>.

Liguria and Molise), while others have only reached the 30% of the regional population (such as Calabria and Sicily).

The second challenge concerns the coordination in place between the decisions adopted at central level – through the above-mentioned plan –, and the decisions adopted by regional authorities. A public and political debate started after the attempt of some regional authorities to decide different priority groups in the implementation of the Covid-19 vaccine campaign. In order to solve this political issue, a meeting between the Government and the Regions' Conference was held: according to the press release issued by the President of the Regions' Conference on 29 March<sup>12</sup>, it was clarified that the priority categories for the vaccines were negotiated and decided by both the Government and the Italian regions, and that all levels of government were eager to cooperate for the successful implementation of the Vaccine Deployment Plan. Eventually, in order to better clarify how to proceed in the Plan's implementation on the entire national territory, the Commissioner for the Covid-19 Emergency adopted the Ordonnance No. 6/2021 of 9 April 2021<sup>13</sup>, confirming the priority population categories, and establishing that all regions must adjust to this strategy.

#### 3.2 Promising practices

In **Italy**, some promising practices were implemented to provide complete and correct information on the Covid-19 vaccines. First, the Government releases a period report on the implementation of the Vaccine Deployment Plan<sup>14</sup>. Second, the Italian Drug Agency (*Agenzia Italiana del Farmaco* – AIFA) issues a period surveillance report<sup>15</sup> on the vaccines available in Italy, providing information and update data on possible and registered side effects of the vaccines. Third, both the Ministry of Health<sup>16</sup> and the ISS<sup>17</sup> developed a specific section on their

 $\underline{www.salute.gov.it/portale/nuovocoronavirus/archivioFakeNewsNuovoCoronavirus.jsp?lingua=italia\\ \underline{no\&tagId=911}.$ 

Available at: <a href="https://www.regioni.it/comunicato-stampa/2021/03/29/bonaccini-regioni-impegno-comune-col-governo-per-campagna-vaccinale-poi-ridare-presto-fiducia-al-paese-lavoriamo-insieme-per-una-prospettiva-di-ripartenza-in-sicurezza-632470/">https://www.regioni.it/comunicato-stampa/2021/03/29/bonaccini-regioni-impegno-comune-col-governo-per-campagna-vaccinale-poi-ridare-presto-fiducia-al-paese-lavoriamo-insieme-per-una-prospettiva-di-ripartenza-in-sicurezza-632470/</a>.

<sup>&</sup>lt;sup>13</sup> Available at: <a href="https://www.governo.it/it/articolo/campagna-vaccinale-firmata-lordinanza-n-62021-del-commissario-lemergenza-covid-19/16588">www.governo.it/it/articolo/campagna-vaccinale-firmata-lordinanza-n-62021-del-commissario-lemergenza-covid-19/16588</a>.

<sup>&</sup>lt;sup>14</sup> The report is available at: <a href="https://www.governo.it/it/cscovid19/report-vaccini/">www.governo.it/it/cscovid19/report-vaccini/</a>.

The most updated version of the surveillance report is available at: www.aifa.gov.it/documents/20142/1315190/Rapporto sorveglianza vaccini COVID-19 3.pdf.

<sup>&</sup>lt;sup>16</sup> Available at:

<sup>&</sup>lt;sup>17</sup> Available at: www.iss.it/covid19-fake-news.

websites, providing information on the most frequent fake news on the Covid-19 vaccines: the aim of this practice is to provide correct information, and deactivate concerns and public panic concerning the side effects of the vaccines.