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Vaccination at the workplace

A practical guide

Labor, privacy, criminal

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1.

Containment of Covid infection - 19 at the workplace. What's new at a glance.

1. Introduction

The framework of the rules for the prevention of contagion from Covid-19 at the workplace has recently been enriched with new elements that regard the delicate measure of the vaccine administration.

First of all, with the **Law by decree of April 1, 2021, no. 44**, the legislator introduced a **vaccination obligation** for certain categories of workers (the actual scope of such “obligation” will be better discussed below).

In addition, the so-called social parties (*i.e.*, on the one hand, trade unions representing the employees and, on the other hand, associations of the employers in the corresponding business sector), with the **National Protocol for the implementation of business plans aimed at the activation of extraordinary places to vaccinate in the companies** of April 6, 2021 and its **ad interim guidance by INAIL**¹ of April 8, 2021, have intervened on the issue of vaccinations at the workplace by **dictating** the rules and conditions for the implementation and management of vaccination campaigns at the workplace.

By means of this *vademecum*, the authors intend to provide companies with an easy-to-consult operational tool that illustrates the changes introduced by the mentioned provisions and also condenses some of the main technical-legal issues related to the management of Covid-19 vaccines at the workplace (vaccination requirements, processing of workers' personal data, criminal liability deriving from the vaccine administration).

On the basis of the analysis that follows, companies can assess the opportunity to implement their decisions about the correct way to start and manage the vaccination campaign in the company, maximizing the effectiveness of the process and minimizing the legal risks that the regulatory system, however favorable, involves, since it is a matter relevant to health and safety in the workplace.

2. The vaccination obligation for health professionals and workers: a summary.

In the following chapters we will summarize the changes, including procedural ones, introduced on the subject of compulsory vaccination for some categories of workers, with a focus also on criminal implications.

Law by Decree no. 44 of April 1, 2021, containing urgent measures for the containment of the epidemic, provides in fact, among other provisions, the

Law by Decree no. 44 of April 1, 2021; articles 3 and 4

¹ *I.e.*, Italian National Institute for Insurance against Accidents at Work.

introduction of the vaccination obligation for those carrying out health professions and for health workers (**article 4**).

In addition to the introduction of this obligation - which is limited in time, as it is conditional on the full implementation of the national vaccine plan and, in any case, due to expire on December 31, 2021 (at least according to its current wording, although it is not possible to exclude an extension of the deadline as needed) – it is also detailed the procedure for reporting and monitoring the vaccination status of the categories of workers affected by the provision, as well as the regulation of the legal consequences arising from failure to comply with the obligation at issue.

Article 3 is dedicated to the regulation of **criminal liability** deriving from the vaccine administration (see chapter 5), while there are no provisions specifically dedicated to the regulation of the employer's liability regime, which must, therefore, be considered unchanged for the time being.

3. Protocol for the vaccination at the workplace and *ad interim* indications by INAIL.

National Protocol of April 6 and the attached ***ad interim* indications by INAIL** provide important operational guidance for the management of vaccinations at the company.

The document aims to provide a framework of common rules for the launch of a vaccination campaign against Covid-19 that considers the company, acting in synergy with the health authorities and competent local authorities, as **a key player in the interest of public health in the pandemic context, but at the same time such document does not establish a generalized vaccination obligation.**

Before proceeding with the reconstruction and analysis of the contents in detail (chapter 3), at least two significant aspects should be highlighted.

The first is the **central role of the occupational physician or health personnel** in the management of administration activities, including the management of information flows.

Secondly, it is the role of **employers' associations** that in the structure outlined by the Institute, have the function of stakeholders and important interlocutors to facilitate the implementation of vaccination campaigns at the workplace as widely as possible.

2.

Compulsory vaccination: yes or no?

Article 32 of Italian Constitution vs article 2087 of Italian Civil Code.

1. The legal basis.

The debate on the subject of compulsory vaccination at work, in order to contain the contagion of the ongoing pandemic, is based on the **contrast between the prohibition to subject an individual to a mandatory health treatment if not by provision of law (article 32 of the Italian Constitution) and the employers' obligation to guarantee safety pursuant to article 2087 of the Italian Civil Code**, according to which the employer must take all the *"measures that, according to the particularity of the working activity, experience and technology, are necessary to protect the physical integrity and moral personality of workers"*.

The vaccination obligation could, therefore, find a legal basis in the provision of article 2087 of the Italian Civil Code, provided that it is expressly provided by law, in compliance with the conditions imposed by the constitutional provision.

At present, there are no specific regulatory provisions relating to the contingent situation. The efforts of the interpreters have, therefore, been focused on the identification of a possible regulatory foothold in the legislation in force before the pandemic; in particular, in the provisions of **Legislative Decree no. 81/2008 (the so-called Consolidated Law on health and safety at work)**.

2. The safety obligation pursuant to article 2087 of the Italian Civil Code and the Consolidated Law of 2008.

Article 279, paragraph 2, Legislative Decree no. 81/2008

According to some commentators, **article 279, paragraph 2 of Legislative Decree no. 81/2008** would have in this context a fundamental integrative function since it obliges the employer to adopt *"special protective measures for those workers for whom, also for individual health reasons, special protective measures are required, among which (...) the provision of effective vaccines for those workers who are not already immune to the biological agent present in the work, to be administered by the occupational physician"*.

However, it is believed that this provision is not sufficient by itself to serve as that reservation of law that is imposed by the Constitution as the basis of a generalized vaccination obligation for all workers (at least in those working environments that are not health-related).

The issue stems from the scope of the employers' safety obligation.

In a nutshell, there are two opposing theses on this matter. The first considers this obligation as limited to the risks inherent to the company's organization, thus excluding the relevance of external risks (which would include Covid-19 contagion). The adherence to this thesis could not ground a vaccination obligation in article 279,

paragraph 2, of Legislative Decree 81/2008, as the latter refers only to risks arising from the working activity.

On the other hand, according to the opposite theses - supported by the jurisprudence of the Court of Cassation – the employers' safety obligation should include also external risks, *i.e.*, those not closely related to the working activity and business organization. On the basis of this theses, taking into account article 279, paragraph 2, it would be possible to assume the existence of a vaccination obligation.

However, not even this reasoning would seem sufficient to base the existence of a generalized vaccination obligation on the employers' obligation to guarantee safety. This is because it seems questionable the legitimate application of a specific preventive measure (provided by the abovementioned rule of the Consolidated Act of 2008 for biological agents present in the working activity) to a risk, however, generic (that of contagion to an external agent)².

3. What's new is Law by Decree no. 44 of 2021. The vaccination obligation for health professionals and practitioners.

Health professionals' vaccination obligation

The legal framework must necessarily be integrated with the recently introduced compulsory vaccination for **health professionals and health practitioners** set forth under article 4 of Law by Decree No. 44 of 2021.

The provision in question is particularly significant because, first of all, it introduces a genuine vaccine obligation (albeit, as it will be seen, temporary and in some ways mitigated) for the mentioned categories of workers, as well as providing guidance on the management of the person who has not fulfilled this obligation.

With regard to the first profile, for these categories of workers, unlike what happens for the generality of workers, **the vaccine is an essential requirement for the exercise of the profession.**

Validity

However, the obligation introduced by the new Decree is intended to apply until the full implementation of the National vaccination plan and, in any case, not later than December 31, 2021, except in case of an extension depending on the progress of the pandemic.

Furthermore, subjects for whom the doctor ascertains that they are subject to "*a health hazard, in relation to specific documented clinical conditions, certified by the same doctor*" are also exempted from the obligation.

Article 4, Law by Decree no. 44/2021 – Communication and reporting procedure

It is the same article 4 to then define the **operational procedure** to identify the workers affected by the provision, which is based on a cross-system of communications between territorially competent professional associations, regions and autonomous provinces and employers (Article 4, paragraphs 3-6, of Legislative

² See, G. Beninicasa, G. Pigliararmi, *Covid-19 e obbligo giuridico di vaccinazione per il dipendente*, Working Paper Salus, no. 1/2021. In support of the opposite theses, see P. Ichino, *Perché e come l'obbligo di vaccinazione può nascere anche solo da un contratto di diritto privato*, *Lavoro Diritti Europa*, no. 1 / 2021. Reference is made to these papers for a more extensive analysis of the issue.

Decree no. 44/2021). Such system is based on compliance with the rules on the protection of personal data as well as with the obvious need to contain the contagion.

In summary:

- **Professional associations (i.e., Ordini)** send the list of members (with indication of their residence) to the Region / Autonomous Province;
- **employers** send the list of concerned employees, together with their respective residence, to the Region / Autonomous Province;
- **within 10 days** from receipt of the lists, **Regions / Autonomous provinces**, through the vaccination information services, **verify** the vaccination status of the concerned subjects;
- **if the subject is not vaccinated** or he/she did not submit the request to be vaccinated, he/she is **reported to the local health authority** which **invites** the subject to submit within **5 days the documentation** proving the vaccination, its omission, its postponement or the absence of the conditions provided for by law, or the submission of the vaccination request;
- in the event of **non-compliance with the terms**, the local health authority **formally** and without delay **invites the concerned person to undergo the administration of the vaccine**;
- in case of presentation of the documentation certifying the **submission of the vaccination request**, the interested party shall immediately **send the documentation** certifying the administration and, in any case, no later than 3 days.

Article 4, Law by
Decree no. 44/2021 –
Non-compliance with
the vaccination
obligation

Particularly significant are the provisions relating to the **suspension of the healthcare professional/practitioner who is non-compliant with the vaccination obligation** (Article 4, paragraphs 6-10, Legislative Decree no. 44/2021).

Specifically, after having ascertained the non-compliance with the vaccination obligation and the elapsing of the terms summarized above, **the local health authority immediately informs in writing the concerned person, the professional association to which he/she belongs and the employer.**

Such information notice **determines the suspension from the right to perform the services or tasks involving interpersonal contact or otherwise the risk of spreading the virus. The suspension is communicated to the worker concerned directly from his/her professional association.**

The employer who receives the information notice from the local health authority:

- **assigns the unvaccinated worker, if possible, to different duties** that do not involve the risk of contagion, even corresponding to a lower level than those originally performed (with treatment corresponding to the exercised duties); **or** in case of impossibility of relocation

- **suspends the worker without remuneration** or other compensation until the fulfillment of the vaccination obligation or, in case of persistent non-compliance with the obligation, until the end of the validity of the legal measure (i.e., until the completion of the national vaccination plan and in any case not later than December 31, 2021).

Vaccination can be omitted or postponed only in cases of ascertained danger to health in relation to specific clinical conditions documented by the doctor. In these cases, although the procedures summarized above do not automatically apply, the worker concerned must be assigned, again for a limited period of time as prescribed for other cases, to different duties, with the same economical treatment, to avoid the risk of contagion.

No specific legal provision is set forth for workers with different professional qualifications.

4. What to do?

On the basis of current law provisions, it is not possible to affirm the existence of a real obligation to vaccinate, unless one falls into one of the cases referred to under article 4 of Law by Decree no. 44 of 2021, which, however, as mentioned, currently has a limited duration.

As for the consequences of failure to comply with the vaccination obligation by the categories of workers concerned, the current regulatory framework does not seem to open the door to hypotheses of legitimacy of the dismissal of non-compliant health professional or practitioner, despite the vaccine is a necessary condition for the exercise of the working activity.

Law on this point is clear in indicating the feasible solutions: **change of duties or, if not possible, unpaid suspension**; measures, however, with a limited duration in time, corresponding to the duration of the vaccination obligation itself, which shows a certain adversity of the legislator towards less conservative measures.

There remains an issue regarding the relationship between the demotion of the non-compliant worker and the guarantees provided for under article 2103 of the Italian Civil Code.

The law says nothing about the need to proceed with a settlement before one of the so-called protected venues (*i.e.*, “*sedi protette*”). Given the nature of the measure, which is not based on one of the hypotheses of mandatory settlement before the protected venues - provided for by the Civil Code in case of demotion and which operates by law - it could be argued that it is not strictly necessary to execute a demotion agreement in the venues referred to under article 2103 of the Italian Civil Code.

However, an agreement in a protected venue may still be necessary to prevent the possibility that the worker requests to be assigned to alternative duties in the event of suspension or in any case contests the measure applied by the employer.

Finally, there is the issue of **how to manage the generality of workers**.

In particular, the question arises whether the refusal to undergo vaccination, by a worker excluded from the subjective scope of the examined rule, may constitute a breach of his/her contractual obligations and, therefore, can be considered a valid reason for terminating the employment relationship.

Article 4, Law by Decree no. 44/2021 – Non-compliance with the vaccination obligation

How to manage the generality of workers.

The answer is inevitably affected by the strong uncertainty about the possibility of establishing a widespread vaccination obligation on the basis of the current legal framework (in particular Article 2087 of the Italian Civil Code and Consolidated Law of 2008).

Under the current framework, the preferable hypotheses are:

- (a) to place the worker in a place that prevents / limits contacts with other subjects (also requiring the worker to work remotely);
- (b) assign the worker to tasks compatible with the choice not to get vaccinated;
- (c) in the event that it is not possible to proceed as indicated under the points above, suspend the worker from work, without the right to remuneration³.

The interpreters also explored the possibility that the worker's refusal constitutes a case of total or partial impossibility to perform the working activity. However, this is an even more uncertain scenario, since the loss of interest in the working activity by the employer must be assessed taking into account the several variables of the case, including the time factor, to ascertain whether it is an irreversible situation⁴.

However, when the refusal to undergo the vaccination is based on a justified impediment of a medical nature, it has been hypothesized - in addition to the solutions referred to under points (a) and (b) above - the possibility to resort to the suspension from the working activity pursuant to art. 2110 of the Italian Civil Code (with the payment of the salary) or, where possible, to wage integration funds⁵.

3.

What to do and how to administer the vaccine in the workplace. The Protocol and INAIL indications

1. Preliminary remarks

The activation of territorial vaccination venues for workers can be carried out, also with the involvement of occupational physicians, by both individual companies and groups of companies, by means of employers' associations.

Indications provided by INAIL, in addition to the provisions of the Protocol, first of all specify that the conditions for the implementation of the vaccination campaign in the workplace are:

- 1. the availability of vaccines;*
- 2. the availability of the company;*

³ See Tribunal of Belluno, judgement no. 12/2021.

⁴ See O. Mazzotta, *Vaccino anti-Covid e rapporto di lavoro*, Lavoro Diritti Europa, no. 1/ 2021, pages 5-8.

⁵ See P. Ichino, *op. cit.*, page 7.

3. *the presence / availability of the occupational physician or health personnel;*
4. *the existence of safety conditions for the administration of vaccines;*
5. *voluntary and informed subscription by the employees;*
6. *the protection of privacy and the prevention of all forms of discrimination against employees.*

COVID-19 vaccination, although carried out at the workplace, is considered as a public health measure and, therefore, **the general responsibility and supervision of the process is attributable to the Regional Health Service**, through the appointed Health Authority, and **the supply of vaccines is the responsibility of the Support Structure to the Extraordinary Commissioner for the COVID-19 emergency** through the competent Regional Health Services.

Given the role of public health control actually attributed to the member company, in this context it is expected that the company vaccination venues can also be made available for the vaccination of workers of other companies (e.g., workers employed by the principal's company working at the user company, workers of other companies in the same territory).

Furthermore, the company vaccination plans do not take into account the age of workers, subject to the availability of vaccines.

The **costs** are borne by the employer or traders associations, with the exception of those for vaccines, the relevant devices (e.g., syringes, needles) and the training and recording tools for vaccination. This, together with the exception whereby the employer makes use of the INAIL health facilities, where the charges are entirely borne by the Institute.

It will also be necessary to refer to **any specific indications issued by the Regions and the Autonomous Provinces** for the territories of their respective competence.

It is also specified that, if the vaccination is performed during working hours, the **time** taken by the worker to undergo the vaccine is considered **as working time for all purposes**.

Side effects: Injury or Illness?

With regards to worker's leave due to side effects because of the vaccine administered at the company, the issue is currently controversial and the subject of a specific query proposed to INAIL. In the absence of indications on this issue, it is believed that the leave can be qualified either as due to illness or to an accident at work (on the basis of the indications previously issued by the same Institute regarding the confirmed cases of Covid-19 infection contracted at work)⁶.

Similarly, there are no specifications with respect to the hypothesis of worker's absence due to injury occurring during the vaccination procedures at the company attributable to the employer. In this case, the ordinary rules must be considered applicable.

⁶ Circular by INAIL no. 13 of April 3, 2020; Circular by INAIL no. 22 of May 20, 2020.

2. Procedure to launch the vaccination campaign **at** the company. What to do?

Pursuant to the Protocol, **the employer, without prejudice to the existence of the preliminary requirements** provided by INAIL indications (see following table):

- **draws up** a business vaccination plan (ensuring discussion with the Committee for the application and verification of the rules set forth under the shared Protocol of April 24);
- **proposes** the business vaccination plan to **the competent Health Authority** (also through the employer representatives' organization), **specifying the number of vaccines required** to allow the Health Authority to schedule distribution.

Workers' subscriptions must be **voluntary** and managed with respect for **confidentiality, avoiding any form of discrimination** linked to the workers' individual choices.

The employer, for the vaccination operations, can profit of:

- **the occupational physician;**
- **private health facilities;**
- **INAIL health facilities.**

It is also necessary to **provide all information to workers by involving the occupational physician** and safety parties, also by promoting specific communication and vaccination information initiatives.

The **occupational physician**:

- provides **information** on vaccines, on the benefits and risks of vaccination;
- ensures the **acquisition of consent**;
- ensures the **preventive health status triage**;
- ensures the **recording of vaccines**;
- guarantees **confidentiality**.

Based on the detailed information provided by INAIL, the vaccination process at the workplace can theoretically be structured in several stages.

Phase 1	
Preliminary requirements	The company must be in possession of: <ul style="list-style-type: none">• sufficiently large working population (for smaller companies, also organizational methods promoted by trade associations, or by entities composed of both employees and employers' representatives, are possible, if intended to involve workers of several companies);• headquarters in the territory of the Health Authority that provides the vaccines

	<p>(workers can subscribe for the vaccination regardless of their residence or decide to be vaccinated in the vaccination venues of the Health Authorities);</p> <ul style="list-style-type: none"> • organizational structure, equipment and personnel resources adequate to the expected volume of activity, to ensure the smooth running of the business and to avoid gatherings; • suitable IT equipment to record vaccinations correctly and promptly; • suitable premises, commensurate with the volume of vaccinations to be performed, for the preparatory phases (acceptance), the actual administration of the vaccines (clinic / infirmary), and the subsequent phases (post-vaccination observation). Dedicated premises can be internal, external or mobile, as long as they are adequately equipped. The Health Authority providing the vaccine assesses the suitability of the premises.
Participation	<p>The company (or the trade association) communicates its participation to the competent Health Authority, according to procedures established by the Region or Autonomous Province, which ascertains the availability of vaccines and the existence of the requirements, agrees on the methods of collection of vaccines by the occupational physician or health personnel identified by the employer. Those who collect the vaccine must ensure that it is managed correctly and that the cold chain is maintained.</p>
Minimum equipment	<p>The occupational physician or the appropriately identified health personnel draws up the list of what is necessary. The employer or the trade association guarantees the supply at its own expense of what is deemed necessary by the identified health personnel.</p> <p>The necessary materials, equipment and medications for the safe carrying out of vaccinations must be guaranteed, also on the basis of the numbers of vaccinations.</p>
Training and information	<p>The Regional Health Service makes available the access to specific training / information materials prepared at national and regional level. The personnel involved in the vaccination operations will carry out the EDUISS FAD course "<i>Covid-19 vaccination campaign: the safe administration of the anti-SARS-CoV-2 / Covid-19 vaccine</i>", integrated with a specific module for vaccination at the workplace</p>

	edited by INAIL in collaboration with Italian Institute of Health.
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Phase 2	
Organization of the vaccination session	<p>The occupational physician, or other properly identified health personnel, collects the (voluntary) subscriptions of the workers and will be able to evaluate their specific health conditions, by respecting their privacy, in order to address the vaccination requests to the competent Health Authority, which will take care of the demand.</p> <p>The Health Authority may divide the total of the requested vaccines into several deliveries according to availability. In any case, the vaccine supplied must be promptly administered without being stored at the company premises, unless in case of specific and justified derogations authorized by the Health Authority, provided that the conditions of correct storage occur.</p>
Organization of the vaccination campaign - principles	<ul style="list-style-type: none"> • Planning of activity well in advance, based on organizational complexity; • Adherence to anti-contagiousness prevention measures; • Adequate information to vaccination recipients (employers, workers) on organizational procedures and vaccine administration; • acceptance of adhering workers ensured by appointed personnel (internal/external); • compliance with the forms prepared at the national level relating to medical history and informed consent; • compliance to technical indications and good practices related to vaccine storage, preparation and administration; • planning and preparation for the management of any adverse events, also in accordance with plans for the management of emergencies in the workplace; • compliance with Regional indications for the supply of information flows.

Phase 3	
Consent management	The doctor who administers the vaccine informs the worker about vaccination, illustrates the contents of the ministerial information notice and acquires valid consent to vaccination, using the unified forms prepared at national level.
Recording of vaccination	It is carried out immediately after administration , directly at the vaccination venue, during the post-vaccination observation period, according to the

	procedures issued in the competent Region / Autonomous Province. For the record of any adverse reaction, the reporting methods provided for by the competent Region / Autonomous Province will be followed, in compliance with current legislation.
Post-vaccination observation	After vaccination, the administering health personnel must invite the vaccinated person to stay for at least 15 minutes at the premises of the vaccination venue, to intervene immediately in the event of adverse reactions, and it is therefore necessary to provide adequate resources for the management of the same. In any case, any subjects at risk must be referred to the relevant Health Authority to proceed with vaccination in a protected environment.

Phase 4	
Scheduling of second injection	<p>The company ensures the scheduling of the second injection is due. Vaccines are not interchangeable and the second injection must be given with the same vaccine used for the first one. The interval must comply with that prescribed for the specific vaccine.</p> <p>Whoever has experienced a severe reaction to the first injection shall NOT undergo the second one at the workplace and should be sent to the competent Health Authority for the necessary evaluations.</p> <p>Those who have experienced a delayed-onset local reaction (e.g., erythema, induration, itching) around the area of the injection site, after the first injection, may receive the second injection at the workplace, preferably on the other arm.</p> <p>A single dose of vaccine may be considered for those already infected, provided that vaccination is given at least 3 months after documented infection and preferably within 6 months of infection.</p> <p>It is possible to consider administering a single injection of vaccine for those who have already contracted the virus, provided that the vaccination is performed at least 3 months after the documented infection and, preferably, within 6 months of the same.</p>
Monitoring and control	<p>The competent Health Authority, through the Prevention Department, can carry out inspections on the status of the premises, on the essential requirements and on the correctness of the procedures adopted.</p> <p>Companies and trade associations promote the adoption of conduct correct and compliant to the organizational methods provided for by INAIL.</p>

3. Safety in workplaces used as venues to administrate vaccines.

With reference to this matter, one cannot fail to observe that, as it will be seen in greater detail below (chapter 5), the so-called criminal shield introduced by Legislative Decree no. 44/2021, operates only in favor of those who administer the vaccine, while no exemption is set forth in favor of the employer.

The employer continues, in fact, to be responsible for the safety at the workplace, even if it is used as a vaccination venue, due to both the general rules on the subject and the obligation to guarantee the suitability of the workplace and of the organization to prevent contagion risks (e.g., by avoiding gatherings). The employer shall also comply with the legislation protecting the personal data of workers (with regards to all processing of personal data other than the recording of the vaccine which, as it will be seen immediately after, is not carried out by the employer).

Moreover, currently the qualification of the absence of the worker who has reported side effects due to the vaccine administered at the company's premises - whether as an accident at work or as an illness - is still controversial, with all that follows in terms of economic - normative treatment and employer's responsibilities.

Because of the uncertainty of the legal framework and in the absence of jurisprudential or administrative precedents that could guide the company, and in order to contain the risks, the employer could opt for the outsourcing of the service to third parties.

The outsourcing of the process entails, from a legal standpoint, a favorable full discharge of responsibility for what concerns the management of the spaces as well as the vaccination process, thus greatly simplifying the burdens and risks for the employer not accustomed to such medical operations.

From a technical standpoint, the entire process could be outsourced to specialized centers where, in compliance with INAIL⁷ indications and the Protocol, employers can send their employees and family members to have the vaccine administered, or to third party legal entities by entering into a contract for the management not only of the vaccine administration process but also of the management of the company spaces.

⁷ I.e., Italian National Institute for Insurance against Accidents at Work.

4.

Privacy issues

The legal framework

4. Employee's health personal data processing. The legal framework.

When it comes to processing these kinds of personal data, it shall be considered not only the general rules related to personal data protection (EU REGULATION (EU) 2016/679, on the protection of natural persons with regard to the processing of personal data, so-called GDPR and the Italian Legislative Decree n. 193/2003, as amended by Legislative Decree 101/2018) but also the more specific laws and regulation in terms of worker's privacy with reference to health data processing.

More specially, as far as it is concerned here, it is important to keep in mind that this aspect is mainly governed by articles 8 and 5 of the so-called *Statuto dei lavoratori* (Law no. 300/1970) and the articulation of health surveillance and the activity of the occupational physician (whose function in the light of the recent Protocol is highly enhanced and pivotal) which results from the provisions of Legislative Decree n. 81/2008.

In summary, it is highlighted as the national legislation:

- imposes a functional link on the processing of workers' health data with respect to the work performed;
- precludes the employer from directly know data related to worker's health, as well as prohibits a direct assessment of the worker's health status; since such an activity is always carried out with by the occupational physician and it is strictly linked to the worker's duties and its performance.

The legislative framework must be integrated also with the provisions and indications contained in the opinions and guidelines of the European Board of data Protection (EDBP) and the Italian National Authority for personal data protection.

5. Processing of personal data related to the worker's vaccinal status.

In managing personal data relating to worker's vaccination status, the FAQ developed by the Italian data protection Authority issued on February 17, 2021⁸ play a significant role.

The National Authority, states that the employer:

- **shall not** ask its employees to provide information about their vaccination status or copies of documents proving that the employee has been vaccinated;
- **consent** to the processing of data relating to vaccination **cannot be enough**, as it cannot constitute a valid condition of lawfulness due to the imbalance of the relationship between the owner and the interested party in the working context (recital 43 of the GDPR);
- **shall not** ask the occupational physician for the names of vaccinated employees;
- **can** acquire, according to the current laws and regulations, only the report concerning the suitability of the worker for the specific task and any prescriptions and/or limitations reported therein by the occupational physician.

Furthermore, the Authority, regarding the possibility of asking for the anti-Covid-19 vaccination of employees as a condition for access to the workplace and for the performance of certain tasks (e.g. in the health sector), specified that the *"special protection measures"* envisaged for certain work environments are applied (Article 279 under Title X of Legislative Decree no. 81/2008) and, adds that, *"only the occupational physician can process the data personal data relating to employee vaccination and, if necessary, take them into account when assessing suitability for the specific job"*.

Since the obligation to get vaccinated for health professions has been introduced, it can be assumed that, limited to such cases, these instructions by the Authority are replaced by the provision referred to in paragraph 6 of the law by decree n. 44/2021, given that the competent local health authority shall communicate to the employer when a professional has been not vaccinated under law by decree n. 44/2021 (chapter 2).

The foreclosures indicated by the Authority, however, apply to all the workers who do not fall within the categories referred to in art. 4 of the law by decree n. 44/2021.

In processing workers' personal data, as part of the implementation of company vaccination campaigns, the employer must comply with the legal provisions and the

⁸<https://www.garanteprivacy.it/documents/10160/0/FAQ++Trattamento+di+dati+relativi+alla+vaccinazione+anti+Covid-19+nel+contesto+lavorativo+-+versione+vademecum.pdf/ba389a97-5cc5-6bd5-fef7-debe613524c6?version=1.0>

indications of the Authority, since he is not entitled to have direct access to detailed worker's personal health information.

The interim indications by INAIL attached to the National Protocol, among the other provisions, allocate to the health personnel involved in the vaccination process the responsibility for the processing of the adhesions to the campaign and the data related to the administration of the vaccine.

6. Personal data processing at the workplace in the context of the health emergency.

Given the specific indications issued by the National Authority, it is also useful to draw attention to the general framework of the limits set about worker's personal data processing within the context of measures to contain the infection.

A summary of the state of the art on this point is useful not only to deal with the specific issue of data processing relating to vaccination status - which in fact constitutes a subset of the broader topic "processing of personal data at work in the pandemic context" -, but also to have some indications when it is required to manage any situations that are located in between the two areas.

Therefore, speaking about the worker's personal data processing in the context of the general measures for the containment Covid - 19, the National Protocol of 6 April 2021 (which updates the protocol issued on April 24, 2020) and the indications by the Italian National Authority for personal data protection are both useful for guiding the management of such process.

Overall, the employee has a specific obligation to report to the employer any situation of danger to health and safety at the workplace. In these specific circumstances, the employee must inform the employer (as well as the family doctor and the competent health authority) of any possible danger (flu symptoms, temperature, coming from risk areas according to WHO indications, contacts with COVID-19-positive individuals over the past 14 days).

Conversely, the employer can process employee's personal data when he is affected by Covid-19 or presents symptoms and can know the condition of positivity to Covid-19:

- when he is **directly informed** about that by the employee itself; or
- when it is necessary for the **mandatory cooperation with the public health authority**; or
- for the purpose of **readmission to the workplace** of the worker who already tested positive for Covid-19 infection.

In any case, the employer shall collect only the **personal data which are necessary, adequate, and relevant** for the purpose of the prevention of the Covid-19 contagion. The employer must **refrain from requesting additional information** regarding the **person who tested positive, the specific locations visited, or other details relating to his/her private sphere** and may process, in compliance with the principles of data protection laws and regulations, the personal data of employees

only if it is legally required or ordered by the competent bodies or upon specific notification of the occupational physician, within his/her health surveillance tasks.

In summary, it can be drawn the following operational indications:

Measuring body temperature
<p>Employees:</p> <ul style="list-style-type: none"> • Measuring and recording are allowed just when the body temperature is higher than 37,5°. • Information, also not written, about the personal data processing with the possibility of omitting information already known. • The purpose is the need to prevent contagion from Covid - 19. • The legal basis is the implementation of the implementation of anti-contagion security protocols pursuant to art. 1 n. 7, letter d) D.P.C.M. March 11, 2020. • Data can be stored until the end of the emergency. • Technical and organizational measures for personal data protection shall be adopted. • Appointment and instruction of the persons in charge of data processing. • The data shall be not shared with third parties (unless otherwise provided for by specific regulatory provisions). <p>External subjects:</p> <ul style="list-style-type: none"> • Measurement allowed; • Recording not allowed; <p>compliance with the current legislation on the personal data protection shall be granted in any case.</p>
Dealing with personal data of whom presents symptoms or has been infected
<ul style="list-style-type: none"> • The employer can know the infected or symptomatic state only in the cases provided for by the current legal framework. • Respect for the privacy and dignity of the person. • Dissemination of personal data and of the identity of the subject is strictly forbidden. • The employer shall communicate the identity only to the competent health authorities and must collaborate with them for the identification of “close contacts” for a timely activation of prophylaxis measures. • Where the workers’ representative for safety becomes aware of information in discharging the relevant duties — which information the representative usually processes in aggregate form, e.g., the information included in the risk assessment document —, he or she complies with data protection provisions if it is possible, even indirectly, to identify certain data subjects. • The information provided by the worker are confidential and they must be treated in compliance with the relevant legislation on personal data protection.
Self-declaration
<p>Self-declaration about contact with COVID-19-positive individuals over the past 14 days or to coming from risk areas according to WHO indications can be requested in any case, but the principle of data minimization must be respected and it is</p>

not possible to request information related to the private sphere or the locations visited.

The employee has a specific obligation to **report any situation of danger to health and safety at the workplace to the employer.**

In any case, **only the necessary, adequate, and relevant data must be collected** with respect to the prevention of contagion from Covid-19 and asking for additional information additional information about the COVID-19-positive person, the specific places visited or other details relating to that person's private sphere is forbidden.

Health surveillance

The occupational physician, as usual, **must not inform the employer about the specific diseases affecting employees.**

The obligations related to health surveillance (e.g., possibility of subjecting workers to special visits) must be carried out **in compliance with the principles and rules related to personal data protection.**

The occupational physician **cooperates** with the employer and the workers' representative for safety and reports to the employer *"situations of particular fragility and current or previous pathologies of employees"*.

On the other hand, it is not necessary to communicate to the employer the specific pathology suffered by the worker.

Information relating to **the diagnosis or family history of the worker cannot be processed** by the employer (unless required by law).

The employer **can process the data relating to** report concerning the suitability of the worker for the specific task and any prescriptions or limitations established by the occupational physician and **is prohibited from carrying out diagnostic tests directly; visits and assessments, also for the purpose of evaluating the employee's readmission to work**, which must be carried out by the occupational physician or other health personnel in compliance with the general conditions.

The **certificates** of negativization of the infected worker **are addressed to the occupational physician** (Circular by the Ministry of Health no. 15127/2021).

Serological tests

Admitted if ordered by the occupational physician, in compliance with the indications of the health authorities, also regarding the reliability and appropriateness of these tests.

Workers can freely join the screening campaigns launched by the competent health authorities at the regional level relating to Covid-19 serological tests, which they have also become aware of through the employer.

Employers can offer their employees, even supporting all or part of the costs, **to carry out serological tests at public and private health facilities** (e.g., through the stipulation or integration of health policies or through special agreements), without being able to know the outcome of the exam.

Contact tracing systems

The **"contact tracing"** function, provided by some applications with the declared purpose of being able to reconstruct, in the event of contagion, the significant

contacts had in a period of time commensurate with that identified by the health authorities in order to reconstruct the chain of infections and alert people who have come into close contact with subjects who have tested positive, is - at present - governed solely by art. 6, law by decree 30.4.2020, n. 28.

The **employer may resort to the use of applications**, currently available on the market, **which do not involve the processing of personal data relating to identified or identifiable subjects (see FAQ no. 9 and 10 Italian National Authority for personal data protection).**

The role of the workers' representative for safety

The **workers' representative for safety must not communicate the names of infected personnel** to the competent health authorities to identify "close contacts".

He must continue to carry out his duties in collaboration with the employer and the occupational physician.

When, in the exercise of his/her functions, he/she becomes aware of information that may be relevant for prevention of Covid-19 contagion, he/she shall comply with the provisions on data protection when it is possible, even indirectly, to identify certain data subjects.

5.

Criminal issues

1. Article 3 of Law by Decree no. 44 of April 1, 2021 - *Criminal liability for administration of the anti-SARS-CoV-2 vaccine.*

The National Protocol, signed by the on April 6, 2021, regulates the possibility for employers to implement company plans for the preparation of extraordinary anti-SARS-CoV-2 (Covid-19) vaccination points in workplaces intended for administration *in favor* of workers who voluntarily request it.

The role of the occupational physician

Indeed, it is an initiative expressly qualified as a public health activity, within the scope of the National Strategic Plan for vaccination prepared by the *Commissario Straordinario* (i.e., an Extraordinary Commissioner for the COVID-19 emergency).

From the analysis of the Protocol, it emerges that the **occupational physician**, whose appointment is mandatory according to article 18, paragraph 1, letter a) of Legislative Decree no. 81/2008, **is called upon not only to inoculate the vaccine, but also to provide workers with adequate information on the advantages and risks related to vaccination, also ensuring the acquisition of informed consent from the interested party**, the necessary preventive triage relating to the state of health, the protection of data confidentiality and, again, the registration of vaccinations carried out according to the channels contemplated by the Regional Health Services. **The doctor must have adequate training for the Covid-19 vaccination and can make use of adequately trained healthcare personnel. However, the employer has the option of turning to private health facilities.**

Thus outlined the key role played by the occupational physician for the purposes of the effective implementation of the vaccination system at the workplace, it is necessary to question the **criminal risks** to which the healthcare professional could expose themselves in administering the vaccine to workers.

Well, there is no doubt that the activity of this professional (and the health personnel who assist him) is now overseen by the so-called criminal shield recently introduced into Italian law by the emergency legislation.

Article 3, law by decree no. 44/2021

As known, **article 3 of law by decree 1 April 2021, no. 44 - «Criminal liability for the administration of the anti-SARS-CoV-2 vaccine»** - prescribes that *«For the facts referred to under articles 589 and 590 of the criminal code that occurred due to the administration of a vaccine for the prevention of SARS-CoV-2 infections, carried out during the extraordinary vaccination campaign in implementation of the plan referred to under article 1, paragraph 457, of law no. 178, punishment is excluded when the use of the vaccine complies with the indications contained in the marketing authorization provision issued by the competent authorities and the circulars published on the institutional website of the Ministry of Health relating to vaccination activities»*.

Such provision **excludes the criminal liability of the health professional who administered the vaccine** if the patient's death or injuries are causally derived from the administration of the vaccine, provided that the healthcare professional has complied with the vaccine compliance indications (or, more correctly, the marketing authorization provision issued by AIFA (*i.e.*, Italian Medicines Agency), with related attachments) and the ministerial circulars. This is because the indications by the competent authorities constitute precautionary rules that fully describe and rule the execution of the medical act of vaccination.

The rationale for this provision is clarified by the reading of the Explanatory Report to the aforementioned law by decree, where it highlights that «In a context characterized by margins of scientific uncertainty, and by a constantly evolving framework, the prospect of incurring possible criminal liability, as a consequence of adverse events ascribable, even only hypothetically, to the administration of the vaccine, can generate alarm among those who are called to make their contribution to the success of the national vaccination campaign, which represents a priority for the protection of public health at present.

The provision - with particular reference to that referred to under article 590-sexies of the criminal code - excludes responsibility for the crimes of manslaughter and personal injury committed in the emergency period, when the events are causally attributable to the administration of an anti-SARS-CoV-2 vaccine. [...] The exclusion of liability - and in particular of fault - is anchored to the observance of the precautionary rules that are specifically relevant to the vaccination activity [...] ».

Relation with article 590 – sexies, paragraph 2, Criminal Code

On closer inspection, **the so-called criminal shield for vaccinators is characterized by a broader spectrum of applications than the cause of non-punishment pursuant to art. 590-sexies, paragraph 2, of the Italian Criminal Code**, introduced by Law no. 24 of March 8, 2017, (the so-called Gelli-Bianco Law), according to which the healthcare professional cannot be punished for manslaughter or for culpable injury if the event occurred due to inexperience and the recommendations provided for by the guidelines defined and published in accordance with the law or, in the absence of the latter, good clinical-assistance practices, provided that the recommendations provided for by the aforementioned guidelines are adequate to the peculiarities of the specific case.

In this regard, it should be noted that the Join Chambers of the Court of Cassation, **in the so-called *Mariotti*** proceeding, have ruled that this clause, which precludes liability of the healthcare professional, operates only in cases in which the healthcare professional has identified and adopted guidelines appropriate to the specific case and is subject to slight negligence due to inexperience in the implementation phase of the recommendations provided for by the same. On the other hand, it is not applicable neither to cases of fault due to imprudence and negligence, nor when the medical act is not regulated at all by guidelines or good practices, nor when these have been identified / selected by the doctor in a manner inadequate with respect to the specific concrete case, nor, again, in case of gross negligence due to inexperience in the implementation phase of the recommendations provided (Join Chambers of the Criminal Court of Cassation, 21/12/2017, no. 8770; see also Criminal Court of Cassation, Section IV, 09/24/2020, no. 34983).

It is, therefore, easy to note that article 3 of the mentioned law by decree in its current formulation, is **a special law (and thus prevails over) the provision of the criminal code**. In fact, it is possible identify the following profiles, which are considered as indexes of a special provision by the Supreme Court:

- the most recent regulatory intervention is focused exclusively on the activity of anti-Covid-19 vaccine administration by health professionals;
- the provision referred to under **article 3 has a temporal scope limited to the duration** of the ongoing extraordinary vaccination campaign;
- the **scope of such clause seems to be not limited to the hypothesis of inexperience**, as instead provided for by article 590-sexies of the Italian Criminal Code;
- it does not make reference to a requirement of **adequacy of the compliance indications on the use of vaccines in the specific case**. This differs from what the legislator provided in 2017.

Automatic effectiveness of the exemption from liability clause

On such ground it can be infer that, **where the healthcare professional has observed the indications on the specific use of the vaccine contained in the AIFA provision and the ministerial circulars, the non-punishment will operate automatically**, neutralizing the responsibility of the professional for any adverse outcomes deriving from the drug administration.

Which, in turn, confirms that the unedited criminal shield is characterized by a much broader scope of operation than the precept of article 590-sexies of the criminal code.

With the *caveat*, however, that the considerations made up to now must be considered strictly connected to the current wording of the provision in question, since a change of the scenario during the conversion of the aforementioned Decree cannot be excluded, as well as due to the case law interpretation that will train on the subject.

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