Biolegis – Research on vaccines liability compensation schemes

Overview of existing regulations or emergency measures governing liability for harm caused by COVID 19 vaccine (liability for result of vaccine application, assuming there are no vaccine defects, i.e. general rules on liability for defective medicinal products excluded)

a) Liability for vaccines which only have a temporary authorisation, either at EMA level or national level;
b) Liability for vaccines which have been finally authorised (not yet the case for any vaccine, but we should take this into account);
c) Liability for off-label use of such vaccines (e.g. mixing of vaccines, administration to unauthorised categories such as children…).

October, 2021

COUNTRY	LAW FIRM	COVID INFO
Belgium	**ALTIUS Lawyers**	https://www.altius.com/coronavirus-updates

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	General legislation on product liability (Belgian Act of 25 February 1991 on liability for defective products) and product safety (Book IX CEL) may apply, as well as liability under common civil law (e.g. Articles 1641 and 1382-1383 CC) and possibly common criminal law. In some cases (e.g. if the damage is sufficiently severe), the patient may also rely on the Act of 31 March 2020 on compensation for damage caused by healthcare.	No special scheme for vaccines, general rules on liability would apply.	Under Belgian common liability law, damages are compensated in full.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	Pursuant to Article 6quater, §1, 5° Belgian Medicines Act, the Minister or his delegate may, in order to prevent the suspected or actual spread of pathogens, toxins, chemical agents or nuclear radiation that could cause harm, temporarily authorise the distribution of unauthorised medicines. In that case, MA holders, manufacturers and healthcare professionals are not responsible for the decision of using a medicine outside its licensed indication areas or for the use of an unlicensed medicine (Art. 110 RD of 14 December 2006). This applies whether or not MA has been granted in another Member State, by the European Commission or at national level. The foregoing does not apply to liability for defective products as laid down in the Act of 25 February 1991 on liability for defective products.	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	The Belgian State (e.g. in case of compulsory vaccination), the MA holder, the HCP, the HCO.	**The Belgian State:** procedure before the civil courts. A procedure before the Council of State is possible on a residual basis (Article 11 of the coordinated laws of 12 January 1973 on the Council of State). Others: procedure before the civil courts. - Burden of proof: a causal relationship between the vaccine and the adverse effect caused must be proved.	**For procedures based on the Belgian Act of 25 February 1991** on liability for defective products: any legal action brought under this Act shall lapse three years from the day on which he should reasonably have become aware of it. **For procedures based on common civil law (Article 2262bis CC**): "Par.1 All personal legal actions shall be time-barred after ten years. Par.2 Notwithstanding paragraph 1, all actions for damages based on non-contractual liability shall be time-barred after five years from the day following the day on which the injured party became aware of the damage or the aggravation thereof and of the identity of the person responsible for it. Par.3 The claims referred to in paragraph 2 shall in any event be time-barred after twenty years from the day following that on which the event causing the damage occurred."
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

COUNTRY	LAW FIRM	COVID INFO
Czech Republic	**HAVEL & PARTNERS**	https://www.havelpartners.cz/en/comprehensive-information-service-on-the-covid-19-crisis/

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Act No. 569/2020 Sb.; Act No. 116/2020 Sb.	Yes. Applicable laws do not distinguish between temporary authorisation and full authorisation. At the moment, the law grants compensation for harm caused by COVID-19 vaccines. The scope is limited only to vaccines purchased based on the Commission Decision C(2020) 4192) (i.e. vaccines authorised by EMA).	A causal link between the vaccination and the harm caused needs to be demonstrated by the injured person. An implementing decree will determine the specific likely consequences for which the demonstration of the causal link will not be required. However, the decree has not yet been adopted.
b)	Amendment to Act No. 569/2020 Sb., Act No. 116/2020 Sb.	Amendment to Act No. 569/2020 is discussed in the Chamber of Deputies. The Government proposed that the state's indemnification for harm caused by COVID-19 vaccination shall also include all fully authorised vaccines and vaccines that have the same active substance as a vaccine that was already authorised.	See answer a).
c)	Directive 2001/83/EC (Act No. 378/2007 Sb., on Pharmaceuticals); Act No. 569/2020 Sb.	The compensation pursuant to Act No. 569/2020 Sb. is rather broad as is not explicitly limited to the use of vaccines in accordance with the SmPC. Therefore, it could be argued that the compensation applies to off-label use as well.	If Act No. 569/2020 Sb. applies to off-label use as well, the same as in letter A) above would apply.

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	State	The application for the compensation needs to be filed at the Ministry of Health. The injured person bears the burden of proof.	The application for compensation needs to be filed at the Ministry of Health within a three-year limitation period.
b)	State	See answer a).	See answer a).
c)	State. If Act No. 569/2020 Sb. does not apply to off-label use, then the responsibility would be borne by the HCO/HCP.	Same as above. If the compensation is claimed from the HCO/HCP, the injured person needs to apply at the respective HCO/HCP.	Same as above. For compensation claimed from HCO/HCP, the same three-year limitation period applies.

OTHER IMPORTANT NOTE
a) In case of COVID-19 vaccination, only the vaccinated person is entitled to the compensation. In case of compulsory vaccines, in some cases, a close person or a person who incurred costs in relation to the care of the unjured person are entitled to compensation.

COUNTRY	LAW FIRM	COVID INFO
Denmark	**Gorrissen Federspiel**	https://gorrissenfederspiel.com/en/coronavirus-covid-19

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	▪ The Danish Act on the Right to Complain and Receive Compensation within the Danish Health Service (Act no. 995 of 14 June 2018, "the Act"). ▪ The Danish Product Liability Act (Act no. 261 of 20 March 2007).	There is no special scheme governing COVID-19 vaccines. The general rules on product liability as well as the rules on the Danish Patient Compensation Scheme (the "Scheme") apply.	▪ Under the Scheme, the Danish Patient Compensation Association ("Association") handles claims for injuries caused, i.a., i) by side effects of medicinal products; ii) the acts of authorized healthcare professionals; and/or iii) damages otherwise occurring in public or private hospitals. ▪ All citizens/patients do as a starting point have the right to seek compensation under the Scheme for injuries caused by side effects from COVID-19 vaccines. The Scheme is also available to survivors of patients. ▪ When making a decision in relation to an alleged pharmaceutical injury, emphasis will be placed on the following: i) the nature and severity of the disease/illness for which the treatment was intended; ii) the injured party's state of health; iii) the scope of the injury; and iv) whether there where possibilities of taking into account the risk of injury. Furthermore, compensation is only paid if the injury was most probably caused by taking or using the pharmaceutical drug. ▪ Side effects caused by medicinal products are only compensated if the nature or scope of the side effects exceed what the injured party could reasonably be expected to accept. Further, pursuant to the guidance published by the Association with respect to COVID-19 vaccines, compensation will as a starting point not be granted for mild side effects or for side effects that disappear. ▪ The extent of the compensation and damages to be awarded will be determined in accordance with the provisions of the Danish Liability for Damages Act. In principle, compensation can be paid for permanent injuries, loss of earnings, pain and suffering, health expenses, as well as breadwinner loss compensation.
b)	See answer a). Pursuant to the Act, compensation for pharmaceutical injuries is only paid if the medicinal products have been commercially dispensed in Denmark for consumption or for clinical trials with pharmaceutical drugs. Also, it is a prerequisite that the medicinal product has been approved for marketing in Denmark in accordance with applicable rules, i.e. either by the Danish Medicines Agency or by the European Medicines Agency (unless the medicinal product is for use in clinical trials).	See answer a).	See answer a).

c)	See answer a). above concerning the Act and the Scheme, assuming the off label use is ordinated by an authorised healthcare professional or has taken place as part of treatment in public or private hospitals.	There is no special scheme for COVID-19 vaccines.	■ Under the Scheme, patients (and survivors of patients) may complain and receive compensation when suffering injuries in Denmark in connection with examinations, treatment, etc., carried out, i.a., in a hospital or by authorised healthcare professionals. The Scheme is also available in case of medication errors. ■ Compensation for injuries suffered in connection with examinations, treatments, etc. is paid, e.g., if the injury was most probably caused in one of the following situations: i) when it can be assumed that an experienced specialist in the relevant field of expertise and under the given circumstances would have acted differently during the examination, treatment, etc., and the injury could have been avoided; or ii) when a subsequent assessment finds that the injury could have been avoided if a different available treatment technique or method had been used, which from a medical perspective, would have treated the patient's disease or illness just as effectively.

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	■ As a starting point, manufacturers of COVID-19 vaccines have the same liability for their COVID-19 vaccines as for other types of medicines and the general rules on product liability apply. Therefore, patients may choose to direct their claim against the manufacturer of the vaccines. However, this option is rarely used by individual patients as they also have the right to submit complaints and seek compensation under the Scheme, and compensation may be granted under the Scheme regardless of whether the manufacturer can be held liable under the product liability rules. ■ Under the Scheme, the state will be paying the compensation to the citizens. Afterwards, the Ministry of Health will become a party to the citizen's claim against the manufacturer of the pharmaceutical product and may file a product liability claim against the manufacturer to cover the costs of the compensation granted to the citizen.	Please see question on scope of liability.	Three years after the person entitled to compensation became aware or should have become aware of the injury. A maximum statutory limitation period of 10 years applies.
b)	See answer a).	See answer a).	See answer a).
c)	Depends on who/which entity conducts the examination, treatment, etc., e.g. the Region in which the patient resides or the Region in which a non-privately practicing doctor administers vaccinations.	Claims for compensation can be submitted to the Association.	Three years after the person entitled to compensation became aware or should have become aware of the injury. A maximum statutory limitation period of 10 years applies.

COUNTRY	LAW FIRM		COVID INFO
Finland	BORENIUS	**Borenius Attorneys Ltd**	https://www.borenius.com/category/legal-alerts/

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	■ The Tort Liability law and The Product Liability Act lay down provisions on liability for defective products. ■ The pharmaceutical insurance is a parallel system. All of the vaccines included in the national vaccination programme are covered by the insurance.	No special scheme for vaccines, general rules on liability would apply and the Pharmaceutical insurance policy.	■ The insurance covers personal injuries caused by a vaccine. There must be a probable causal link between use of the vaccine and the damaging consequences. Pharmaceutical product or vaccine damage refers to a physical illness or injury that was probably caused by a drug or vaccine. A probable causal link means that the damaging consequences were either the certain or probable outcome of taking the vaccine. ■ Pharmaceutical insurance does not cover consequential pharmaceutical product damage. ■ An illness or injury caused by the failure of a vaccine to have the intended effect is not regarded as pharmaceutical
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	**Claim for compensation for the vaccine manufacturer:** ■ A claim for compensation can be made to the vaccine manufacturer, importer or marketer if it is not possible to obtain insurance compensation, for reasons such as the case becoming outdated. **Pharmaceutical insurance:** ■ Pharmaceutical insurance compensation may be claimed for harm caused by a COVID-19 vaccine administered in Finland. The Finnish government has granted an insurance guarantee to the Finnish Mutual Insurance Company for Pharmaceutical Injury Indemnities.	■ The injured party must complete a claim notification and send it to the Finnish Mutual Insurance Company For Pharmaceutical Injury Indemnities. ■ The medical records of the injured party related to the injury will be required for assessing any pharmaceutical product and vaccine damage.	■ Any claim for compensation in accordance with these Terms and Conditions shall be submitted to the Insurer within a year of the date on which the person claiming compensation became aware of the validity of the Insurance, the injury caused by the pharmaceutical or blood product involved and the injured event. ■ The claim form for compensation must be submitted no later than within 10 years from the occurrence of the injured event.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

COUNTRY	LAW FIRM		COVID INFO
France	HARLAY AVOCATS	**Harlay Avocats**	http://www.harlaylaw.com/?lang=en

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Article L.3131-4 of the French Public Health Code; Article 18 of the law of the 5th of August 2021 No 2021-1040 and article L.3111-9 of the French Public Health Code; Article L.3131-3 of the French Public Health Code.	**No specific "Covid-19" scheme at this time but:** ■ specific liability scheme for all non mandatory vaccines; ■ general liability scheme for all mandatory vaccine; ■ specific liability scheme in the event of health threat.	■ Full compensation of the damage under national solidarity with assessment of the damage during the procedure before the ONIAM ("National Office for Compensation of Medical Accidents, Iatrogenic Disorders and Nosocomial Infections"). ■ Full compensation for the damage resulting from any action brought against the health professional or the public or private health establishment.
b)	■ In the event the health threat continues: Article L.3131-4 of the French Public Health Code; Article 18 of the law of August 5, 2021 No 2021-1040 and article L.3111-9 of the French Public Health Code; Article L.3131-3 of the French Public Health Code. ■ In the event of normal situation (excluding health threat and health emergency): Article L.3111-9 of the French Public Health Code; Article L.1142-1 of the French Public Health Code (liability of health professionals).	**No specific "Covid-19" scheme at this time but:** 1) In the event the health threat continues ■ specific liability scheme for all non mandatory vaccines; ■ general liability scheme for all mandatory vaccine; ■ specific liability scheme in the event of a health threat. 2) In the event of a normal situation (excluding health threat and health emergency): ■ general liability scheme for all mandatory vaccines; ■ common medical liability.	■ Full compensation of the damage under national solidarity with assessment of the damage during the procedure before the ONIAM ("National Office for Compensation of Medical Accidents, Iatrogenic Disorders and Nosocomial Infections"). ■ Full compensation for the damage resulting from any action brought against the health professional or the public or private health establishment.
c)	■ In the event the health threat continues: Article L.3131-3 of the French Public Health Code. ■ In the event of normal situation: Article L1142-1 of the French Public Health Code.	1) In the event the health threat continues: Special liability scheme in the event of a health threat. 2) In the event of normal situation: Common medical liability.	■ Full compensation for the damage resulting from any action brought against the health professional or the public or private health establishment.

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	**State:** strict liability. **Health professional:** liability for serious professional misconduct. **Public establishment** (University Hospital, Regional Hospital, Regional Teaching Hospital, Army Training Hospital): liability for service related faults i.e. a fault which is not personal, committed in the service but detachable. **Private establishment** (private health establishment of collective interest, private clinics): liability for faults of the clinic or its employees.	**Action against the State:** Jurisdiction of administrative courts. Strict liability scheme ie the victim only has to prove the causal link between the vaccine and the harm. Compensation before the ONIAM. **Action against the health professional:** Jurisdiction of the judicial courts. Liability only for serious professional misconduct i.e. the victim must prove a serious professional misconduct, the causal link and the harm. **Action against the establishment:** Jurisdiction of public courts if the establishment in question is public and jurisdiction of judicial courts if the establishment in question is private. Liability for fault. The victim must prove the fault, the causal link and the harm. In case of action before criminal courts, the criminal fault is more difficult to prove as it requires an additional criterion of seriousness (Articles 221-6 and 222-19 of the French Criminal Code). The burden of the proof lies in general within the claimant, but there may be alleged faults, e.g. in the case of mandatory vaccination (CE Ass. March 7, 1958 Secretary of State for Public Health v. Sieur Déjous n° 38230), in the case of contamination with hepatitis C following a transfusion (CE Oct. 19, 2011 M. V. n° 339670) failure to supervise the patient (CE Feb. 27, 1935 Tarbes Hospital).	10 years from the date of consolidation of the damage or, if applicable, death (Article L.1142-28 of the French Public Health Code and Article 2226 of the French Civil Code).
b)	**State:** strict liability. **Health professional:** liability for serious professional misconduct / or for fault. **Public establishment** (University Hospital, Regional Hospital, Regional Teaching Hospital, Army Training Hospital): liability for service related faults i.e. a fault which is not personal, committed in the service but detachable. **Private establishment** (private health establishment of collective interest, private clinics): liability for faults of the clinic or its employees.	**Action against the State:** Jurisdiction of administrative courts. Strict liability scheme i.e. the victim only has to prove the causal link between the vaccine and the harm. Compensation before the ONIAM. **Action against the health professional:** Jurisdiction of the judicial courts. Liability for serious professional misconduct/or fault i.e. the victim must prove a serious professional misconduct/ or fault, the causal link and the harm. **Action against the establishment:** Jurisdiction of public courts if the establishment in question is public and jurisdiction of judicial courts if the establishment in question is private. Liability for fault. The victim must prove the fault, the causal link and the harm. In case of action before criminal courts, the criminal fault is more difficult to prove as it requires an additional criterion of seriousness (Articles 221-6 and 222-19 of the French Criminal Code). The burden of the proof lies in general within the claimant, but there may be alleged faults, e.g. in the case of mandatory vaccination (CE Ass. March 7, 1958 Secretary of State for Public Health v. Sieur Déjous n° 38230), in the case of contamination with hepatitis C following a transfusion (CE Oct. 19, 2011 M. V. n° 339670) failure to supervise the patient (CE Feb. 27, 1935 Tarbes Hospital).	10 years from the date of consolidation of the damage or, if applicable, death (Article L.1142-28 of the French Public Health Code; and Article 2226 of the French Civil Code).

c)	**Health professional:** liability for serious professional misconduct / or for fault. **Public establishment** (University Hospital, Regional Hospital, Regional Teaching Hospital, Army Training Hospital): liability for service related faults i.e. a fault which is not personal, committed in the service but detachable. **Private establishment** (private health establishment of collective interest, private clinics): liability for faults of the clinic or its employees.	**Action against the health professional:** Jurisdiction of the judicial courts. Liability for serious professional misconduct/or fault i.e. the victim must prove a serious professional misconduct/ or fault, the causal link and the harm. **Action against the establishment:** Jurisdiction of public courts if the establishment in question is public and jurisdiction of judicial courts if the establishment in question is private. Liability for fault. The victim must prove the fault, the causal link and the harm. In case of action before criminal courts, the criminal fault is more difficult to prove as it requires an additional criterion of seriousness (Articles 221-6 and 222-19 of the French Criminal Code). The burden of the proof lies in general within the claimant, but there may be alleged faults, e.g. in the case of mandatory vaccination (CE Ass. March 7, 1958 Secretary of State for Public Health v. Sieur Déjous n° 38230), in the case of contamination with hepatitis C following a transfusion (CE Oct. 19, 2011 M. V. n° 339670) failure to supervise the patient (CE Feb. 27, 1935 Tarbes Hospital).	10 years from the date of consolidation of the damage or, if applicable, death (Article L.1142-28 of the French Public Health Code; and Article 2226 of the French Civil Code).

OTHER IMPORTANT NOTE
a) For the proceedings before the ONIAM, see <https://www.oniam.fr/accidents-medicaux-indemnisés/vaccination-contre-la-covid-19> b) For the proceedings before the ONIAM, see <https://www.oniam.fr/accidents-medicaux-indemnisés/vaccination-contre-la-covid-19> c) If the liability of a health professional, establishment or supplier is not engaged, compensation can be sought on a subsidiary basis before the ONIAM where the permanent physical or psychological damage exceeds a certain rate (Article L.1142-1 II of the French Public Health Code). For the before the ONIAM, see <https://www.oniam.fr/accidents-medicaux-indemnisés/vaccination-contre-la-covid-19>

COUNTRY	LAW FIRM	COVID INFO
Hungary	**Szecskay Attorneys at Law**	https://szecskay.hu/en/publications

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	According to the Act CLIV of 1997 on Healthcare, the claims for damages in connection with health services are governed by the general provisions of non-contractual liability included in the Hungarian Civil Code.	There is no special scheme for COVID-19 vaccine applications.	Any damage incurred by the inappropriate application of the vaccine, including a) any depreciation in value of the property of the injured party; b) any pecuniary advantage lost; and c) the costs necessary for the mitigation or elimination of the financial losses sustained by the injured party. Any person whose capacity to work has been reduced as a result of a harm is entitled to demand payments for loss of income if - for reasons beyond his/her control - his/her earnings after the tort are less than his earnings before. Furthermore, any person whose personal rights had been violated is entitled to compensation for any non-material damage suffered.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	If the harm is not caused by a defective vaccine but professional misconduct (e.g. due to an insufficiently sterile environment), then according to the Act on Healthcare, the healthcare provider is liable for damages caused in the course of the provision of healthcare services. If a healthcare professional has provided healthcare services in his/her own name and on his/her own responsibility, the healthcare professional is liable for any damage and personal injury caused in connection with the healthcare services.	The civil procedural rules apply: the application is filed to a court of general jurisdiction. Burden of proof: the injured party must prove that a) the healthcare provider / healthcare professional carried out unlawful conduct, b) a damage has occurred, c) there was a casual link between the conduct and the damage, and d) the amount of damage sufferred. The casual link may not be established if the damage was not foreseeable and should not have been reasonably foreseen either. The healthcare providor / healthcare professional may exempt from liability if it proves that its conduct was not attributable.	The limitation period is five years. If the conduct constitutes a criminal offense, the statutory limitation period may exceed five years and should be in line with the limitation period of the criminal prosecution.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

COUNTRY	LAW FIRM	COVID INFO
Israel	**Horn & Co. Law Offices**	http://hornlaw.co.il/

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	General tort law	N/A	No specific limitations. Claims are subject to general tort law and may include pain and suffer as well as loss of earnings.
b)	See answer a).	The COVID 19 vaccines have been included in a dedicated law - the Vaccine Insurance Law of 1989, which enables any person who has, as a result of being given certain vaccines, sufferred permanent disability (including secondary victims), to file a claim against the government. The eligibility to receive compensation (capped at approx. EUR 150,000) is determined by a dedicated committee. Such claim is an optional alternative to an ordinary damages claim.	See answer a).
c)	See answer a). provided that if the Vaccine is administered as part of a clinical trial, responsibility may be allocated in accordance with specific regulation governing such trials.	N/A, other than in the case of clinical trials.	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	As provided under general tort law, responsibility is determined based on negligence. If the vaccine is not defective, liability is likely to be imposed on whoever was involved in administering the vaccine - the attending physician, the medical institute or the Ministry of Health.	The injured person bears the burden of proof and must file a claim with the competent court. However, in the case of the special procedure that applies to COVID vaccines, as long as the committee has established a causal link between the vaccine and the injury, there is no need to prove negligence in order to receive compensation.	The general limit is 7 years from the occurrence of the damage. However, a claim may be filed within 7 years from the consolidation of the damage (but no more than 10 years from its occurrence) or within 7 years from the time the injured person became aware of the causal link between the vaccine and the injury. As for the special procedure regarding COVID vaccines - a claim may be submitted to the committee within 3 years.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a). provided that other specific provisions may apply to clinical trials.	See answer a).	See answer a).

COUNTRY	LAW FIRM	COVID INFO
Italy	**Portolano Cavallo**	https://portolano.it/en/blog/life-sciences

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a)	Not specified (there are no specific national provisions in this regard; please see answer below).	Not specified.	Not specified.
b)	Law no. 210/1992 recognizes the patient's right to receive compensation in case of permanent damage as a result of mandatory vaccination. The Italian Constitutional Court has extended this right also to those who have undergone vaccines "strongly" recommended by the State.	Therefore, it could be argued that the same principle may apply to Covid-19 vaccinations as well.	In addition, anyone who suffered damages from vaccination has the possibility to ask for compensation, according to the extra-contractual liability rule, if he/she is able to prove the damage suffered, the intentional or negligent act of the agent and the casual link between the damage and the act.
c)	Not specified (there are no specific provisions regarding vaccines; however, Law no. 94/1998 regulates off-label prescribing of medicines, stating that physicians are liable for any off-label use of medicines on their patients).	Not specified.	Not specified.

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	Not specified.	Not specified.	Not specified.
b)	If the action aimed at getting compensation for damages is filed against the healthcare personnel who administered the vaccine, the injured party will only have to prove a breach of the healthcare professional's obligations, since, according to the Italian case law, healthcare personnel have a contractual liability towards patients raising from the "social contact" with them.	Not specified.	Not specified.
c)	Not specified.	Not specified.	Not specified.

OTHER IMPORTANT NOTE
b) Recently, Law no. 76/2021 has introduced a regime of exemption from criminal liability for those who administer Covid-19 vaccines when the use of the vaccine complies with the indications contained in the marketing authorization and with the notes issued by the Ministry of Health.

COUNTRY	LAW FIRM	COVID INFO
Norway	**Simonsen Vogt Wiig**	https://svw.no/en/covid-19

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Patient Injury Act chapter 1 and the general liability rules for medicinal products in the Product Liability Act. In the rest of our answers in the spreadsheet we will focus on the Patient Injury Act which is the most practical legal instrument.	A combination of special schemes for vaccines and general provisions for patient injuries.	Physical and psycological patient injuries and damage to property caused by an error or omission in the health care treatment.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	The main rule is that the state is strictly liable, cf. Section 2 (1).	The state has the burden of proof, cf. Section 3(2). The application is filed by written notice to the Norwegian System of Patient Injury Compensation (NPE).	Not specified.
b)	See answer a).	See answer a).	Not specified.
c)	See answer a).	See answer a).	Not specified.

OTHER IMPORTANT NOTE

a) The AstraZeneca vaccine has been excluded from the national vaccination program, hence is no longer recommended, nor permitted to use. The Janssen vaccine is not included in the vaccination program. Patient injuries caused by both vaccines are in general covered by the legislation. However, the burden of proof is reversed for vaccines that are not permitted, nor recommended by the state, cf. section 3 (2).

COUNTRY	LAW FIRM		COVID INFO
Russia	Lidings – Leading the Way in Russian Law	**Lidings**	https://www.lidings.com/media/legalupdates/legal-watch/

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Not specified - there is no temporary authorization for vaccines.	Not specified.	Not specified.
b)	A vaccine is considered authorized after its state registration (art. 13 of the Federal law “On circulation of drugs”). General liability provisions apply under the Russian Civil Code.	No special scheme for vacines, general rules on liability for medical drugs would apply.	The general rule is that the injured person can claim compensation for harm and moral damage.
c)	A legal concept of off-label use is not formally introduced in Russian laws. Consequently, there are no specific regulations on off-label use consequences, and general rules apply under the Russian Civil Code or Criminal Code (as the case may be).	No special scheme for vacines, general rules on liability for medical drugs would apply.	The general rule is that the injured person can claim compensation for harm and moral damage (within the civil procedure).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	Not specified.	Not specified.	Not specified.
b)	Vaccine’s Market Authorization Holder.	In disputes with consumers, civil procedural rules apply: the application is filed to a court of general jurisdiction; the burden of proving the circumstances that release from liability for non-performance or improper performance of an obligation, including for causing harm, lies with the manufacturer (its authorized company).	Not specified.
c)	Medical organization if it rendered improper services to the patient HCP if its wrongful acts are proven and have an impact on the seriuous negative consequences to the patient’s health / death.	In disputes with consumers, civil procedural rules apply. Besides, criminal procedural rules can apply due to HCP’s wrongful acts that caused serious harm to the patient’s health / death.	Within the civil procedure: N/A Within the criminal procedure: 2-15 years depending on the circumstances of the case.

OTHER IMPORTANT NOTE

c) The Russian Ministry of Healthcare has prepared a draft order on amendments to the Rules for prescribing medicines that provides for the possibility of prescribing off-label medications to a specific patient for vital indications. However, this draft is still under the consideration.

COUNTRY	LAW FIRM		COVID INFO
Slovakia	HAVEL & PARTNERS – CONNECTED THROUGH SUCCESS	**HAVEL & PARTNERS**	https://www.havelpartners.cz/en/comprehensive-information-service-on-the-covid-19-crisis/

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	No specific legislation has been adopted in relation to vaccines so far. As a result, the general liability, or liability for the damage caused by the circumstances that originate in the nature of a device used in fulfilment of an obligation, as typical liability of HCO/HCP, according to the Act No. 40/1964 Coll. the Civil Code, may apply.	▪ No specific scheme exists, only the general rules on liability would apply. ▪ For the establishment of general liability, all prerequisites of liability must be met. In particular, a causal link between the vaccination and the harm caused needs to be demonstrated by the injured person.	As a result of the side-effects and administration of the vaccines resulting in injury or death, the injured person may be entitled to several claims, such compensation for bodily harm, personal injury, diminished social functioning, etc. (depending on nature of case).
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	▪ There is no specific statutory provision regulating a liable subject. ▪ In the legal theory, there are two possible subject of liability; it may be the state, Slovak Republic, or a HCO, where the vaccines was administered.	The compensation claim needs to be applied at the respective courts. The burden of proof bears an injured person.	There is subjective limitation period of two years in case of harm on health; which starts on the date when the injured persons learns the damage or harm.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

OTHER IMPORTANT NOTE

a) There is lack of regulation governing the liability for vaccination. However, there are long-lasting and repeated efforts to adopt such regulation.

COUNTRY	LAW FIRM		COVID INFO
Spain	lener	**Lener**	https://www.lener.es/en/news-covid-19

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	General regime for a vaccine with definitive authorization (See answer b).	See answer b).	See answer b).
b)	▪ Law 40/2015, dated October 1, 2015, on the Legal Regime of the Public Sector. ▪ Royal Legislative Decree 1/2015, dated July 24, 2015, approving the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Porducts.	**No Specific Covid-19 Scheme. The general regime distinguises:** ▪ Liability for the vaccine being a defective product, (Royal Decree 1/2007, dated November 16, 2007, General Law for the Defense of Consumers, Articles 141 and following). ▪ Liability for negligent medical act in the administration of the vaccine: liability of the State/Autonomous Community, to which may be added the liability of the health center responsible for the damage. ▪ Liability for adverse effects of a vaccine: liability of the producer or of the Administation (State /Autonomous Communities), due to its powers to authorize and monitor health products (Art. 32 of Law 40/2015, or the General Regime on Civil Liability (Art. 1902 Civil Code).	Full compensation for all damages to be claimed.
c)	▪ Royal Decree 1015/2009 dated June 19, 2009, on the Availability of Medicines in Special Situations. ▪ Law 44/2003, dated November 21, 2003, on the Regulation of Healthcare Professions.	Royal Decree 1015/2009 regulates specifically these cases with a particular regulation -although with common aspects- of compassionate use and off-label use of drugs.	Article 46 of Law 44/2003 provides for the need to take out liability insurance to cover these possible damages, referring to the general liability regime for damages described in answer B

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	See answer b).	See answer b).	See answer b).
b)	(a) The Administration (State or Autonomous Communities) can be held liable based on: ▪ Liability for lack of information on the adverse reactions. ▪ Liability for negligent medical act, of a health professional who provides the vaccine in a Public Center or mixed management center. ▪ Liability due to the omissions or limitations of certain vaccines in the vaccination schedule. b) The Pharmaceutical companies can be liable unless these adverse effects are described and foreseen the drug data sheet (Ruling of the Surpeme Court nº 412/2014, dated 10 July 2014)	a) Action before the Administration requires an initial claim for compensation through administrative channels (Law 39/2015, Arts. 91 and 92, and Law 40/2015, Arts. 32 to 35). If such claim is denied, the claimant would claim thought the specific contentious-administrative judicial channel for commpensation provided in Law 29/1998, dated July 13, regulating the Contentious-Administrative Jurisdiction. b) Action against the pharmaceutical companies would have to follow the civil liability claim regime established in the Civil Code through the pertinent judicial procedures. ▪ Burden of proof: a causal relationship between the vaccine and the adverse effect caused must be proved.	1 year, counting from the date when the injured party had knowledge of the caused harm, or 3 years, if the vaccine is considered a defective product.
c)	▪ The Administration in case it does not comply with the inoculation guidelines. Thus, the pharmaceutical companies would not be held liable. ▪ A professional would be exonerated of liability in case it administrates the vaccine following the recommendations of the Spanish Agency on Medicines (AEMPS), or the protocols of the healthcare center (generally).	See answer b).	See answer b).

COUNTRY	LAW FIRM		COVID INFO
Sweden	Delphi	**Advokatfirman Delphi**	https://www.delphi.se/en/coronavirus-covid-19/

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	A Governmental Bill was published 9 September 2021.	Yes for covid vaccines	The state compensation shall be determined in accordance with the Tort Liability Act on compensation for personal injury, which means that personal injury includes compensation for, inter alia, loss of income as well as physical and mental suffering. According to the proposal, the compensation may not exceed SEK 10 million (approximately EUR 1 million) or so-called 200 price base amount.
b)	See answer a).	Not specified.	Not specified.
c)	See answer a).	Not specified.	Not specified.

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	According to the proposal, the state will pay personal injury compensation when the injury is most likely caused by vaccines against COVID-19 provided in Sweden. Since the evidentiary requirement is designed in accordance with the Pharmaceutical Insurance's conditions, the practice of the Pharmaceutical Injury Board should serve as a guideline assessing the causal connection under the proposed legislation.	It is further proposed that the cases should be reported to the Pharmaceutical Insurance and examined by the Legal, Financial and Administrative Services Agency (Sw: "Kammarkollegiet") and that the Agency's decision can be appealed to the National Claims Adjustment Board (Sw: "Statens skaderegleringsnämnd"). The decisions of the Board cannot be appealed. The proposed legislation also contains provisions on limitation periods, oral hearings and the right of contribution.	Ten years from time of vaccination (as main rule).
b)	Not specified.	Not specified.	Not specified.
c)	Not specified.	Not specified.	Not specified.

OTHER IMPORTANT NOTE
a) The suggested legislation is proposed to enter into force 1 December 2021 but needs to be voted in Parliament.

COUNTRY	LAW FIRM		COVID INFO
Switzerland	walderwyss attorneys at law	**Walder Wyss Ltd.**	https://www.walderwyss.com/en/coronavirus

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Articles 64-69 of the Federal Law against Epidemics (SR 818.101) ("EpL").	Special liablitiy provisions are set out in the EpL, according to which anyone who suffers damage as a result of a vaccination ordered or recommended by the authorities is entitled to compensation. Compensation shall only be granted insofar as the damage cannot be covered otherwise with reasonable efforts. Compensation may include also moral damages up to CHF 70'000.	All concrete and proven financial damanges and moral damages (e.g. pain etc.) up to CHF 70'000 if this is justified by the severity of the impariment suffered.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	In the case of recommended vaccinations, the Confederation and the canton in which the vaccination was carried out shall each bear half of the costs of compensation. In the case of compulsory vaccinations, the full cost of the compensation shall be borne by the Confederation, if it has declared the vaccination to be compulsory; otherwise by the canton that has declared the vaccination to be compulsory.	The request must be filed with the Federal Department of Home Affairs; the procedure is governed by administrative law, including appeal in the case of rejection of the request by the Federal Department of Home Affairs.	The claim must be submitted by the age of 21 or within five years of the vaccination.
b)	See answer a).	See answer a).	See answer a).
c)	See answer a).	See answer a).	See answer a).

COUNTRY	LAW FIRM		COVID INFO
Turkey	GÜN + PARTNERS AVUKATLIK BÜROSU	**Gün + Partners**	https://gun.av.tr/covid-19-hub

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Not specified (Temporary authorization is not regulated in Turkey).	Not specified.	Not specified.
b)	Manufacturer liability provisions of Consumer Protection Law no. 6502 and general liability rules of Turkish Code of Obligations no. 6098.	General liability rules would apply, no special scheme for COVID vaccines or vaccines in general.	Damages directly caused by the defective product.
c)	No special scheme for COVID vaccines or vaccines in general.	No special scheme for COVID vaccines or vaccines in general.	In accordance with the Guideline for Off-Label Use For Drugs, patients shall sign an informed consent form that ensures patients understand the risks arising from off-label use of the drug. Therefore, no liability arises from off-label use.

OPTION a/b/c	WHO BEARS THE LIABILITY? (please state the entity, e.g. physician, pharmaceutical company, state etc.)	WHAT PROCEDURAL RULES WOULD APPLY? (e.g. who bears the burden of proof, at which body is the application filed etc.)	WHAT IS THE STATUTORY LIMITATION PERIOD?
a)	Not specified.	Not specified.	Not specified.
b)	Pharmaceutical manufacturer company.	For disputes with a value under TRY 6,000, an application shall be filed before the Consumer Arbitration Tribunal. For disputes with a value over TRY 6,000, a lawsuit shall be filed before the Consumer Courts.	Two years as of the delivery of the product to the patient.
c)	Not specified.	Not specified.	Not specified.

COUNTRY	LAW FIRM		COVID INFO
United Kingdom	CLYDE&CO	**Clyde & Co. LLP**	https://www.clydeco.com/coronavirus

OPTION a/b/c	LEGAL PROVISION	IS THERE A SPECIFIC SCHEME? (e.g: Specific scheme for COVID vaccines / General scheme for all vaccines / No special scheme for vaccines, general rules on liability would apply, etc.)	SCOPE OF LIABILITY AND SCOPE OF REDRESS (e.g. pain, loss of earnings, loss of amenity, secondary victims)
a)	Reg. 174 of the Human Medicines Regulations 2012 was used for the temporary authorisation of Covid-19 vaccines. Reg. 345 gives immunity from civil liability to manufacturers, authorisation holders etc. of Covid-19 vaccines.	There are no specific rules applicable to a fully approved Covid-19 vaccine.	Reg. 345 could be used to give immunity for off-label use of a vaccine if required / recommended by the MHRA.
b)	Not specified.	Not specified.	Not specified.
c)	Not specified.	Not specified.	Not specified.