Biolegis – Research on vaccines liability exceptions in EU

Overview of mechanisms (existing regulations or emergency measures) allowing national governments to a create compensation shield for COVID 19 vaccine, given the exceptional circumstances (such as a pandemic).

Biolegis
European Life Sciences Lawyers

Article 5 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Member States shall lay down provisions in order to ensure that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not national or Community authorisation has been granted.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Austria	**EU**	**Dorda Brugger Jordis Rechtsanwälte GmbH**	https://www.dorda.at/en/news/dorda-corona-task-force	NO

DETAILED RESPONSE

DORDA

No such liability exemption arrangements are applicable in Austria.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Belgium	**EU**	**ALTIUS Lawyers**	https://www.altius.com/coronavirus-updates	YES

DETAILED RESPONSE

ALTIUS advocaten avocats lawyers

Articles 5(2) to (4) of the Medicinal Products Directive (2001/83) have been implemented without any substantial modification in Belgium in Article 6quater, §1, 5° of the Medicines Act of 25 March 1964 and Article 110 of the implementing Royal Decree on Medicines of 14 December 2006. It belongs to the Minister of Public Health to determine the conditions under which such unauthorised medicines can be distributed. This mechanism is reserved for unregistered medicines. It is without prejudice to other exceptional schemes such as Medical Need Programs.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Czech Republic	**EU**	**HAVEL & PARTNERS**	https://www.havelpartners.cz/en/comprehensive-information-service-on-the-covid-19-crisis/	NO

DETAILED RESPONSE

HAVEL & PARTNERS
CONNECTED THROUGH SUCCESS

There is a relevant legal framework to be found in Art. 5(2) to (4) of the Medicinal Products Directive (2001/83). This provision was implemented into the Czech legal framework. Also, if the vaccine for COVID were registered and vaccination was obligatory, the state could be obliged to compensate material or immaterial damage suffered as a result of mandatory vaccinations by the vaccinated person themself or by their close relatives according to a very new Act No. 116/2020 Coll., on Compensation for Damage Caused by Mandatory Vaccination. The mechanism based on implementation of Art. 5(2) of the Medicinal Products Directive is applicable to unregistered medicines only.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Denmark	**EU**	**Gorrissen Federspiel**	https://gorrissenfederspiel.com/en/coronavirus-covid-19	NO

DETAILED RESPONSE

Gorrissen Federspiel

While certain measures have been put in place in Denmark with regard to vaccines against COVID-19 (e.g. the Danish Medicines Agency's accelerated the procedure for clinical trials related to medicines for the treatment of COVID-19), we are not aware of any special mechanisms that would allow the Danish government to create compensation limitations for vaccines used for the treatment of COVID-19.

In Denmark, the Patient Compensation Association handles claims for damages e.g. caused by medicinal products, the acts of authorized healthcare professionals, or damages otherwise occurring in public or private hospitals, in accordance with the provisions of the Danish Act on the Right to Complain and Receive Compensation with the Danish Health Service (Act no. 995 of 14 June 2018).

As a starting point all patients, including COVID-19 patients, have a right to seek compensation under the Danish patient insurance scheme. However, we note that the abovementioned act does include a number of requirements that must be met in order for compensation to be provided. For example, Section 43 of the Act provides that a "pharmaceutical injury" that is caused as a side effect of a pharmaceutical drug is only compensated if the nature or scope of the side effects exceed what the injured party can reasonably be expected to accept.

When making a decision in relation to an alleged pharmaceutical injury, emphasis will be placed on the following:
- The nature and severity of the disease/illness for which the treatment was intended;
- The injured party's state of health;
- The scope of the injury; and
- Whether there where possibilities of taking into account the risk of injury.

Furthermore, we note that the Danish Patient Compensation Association has proclaimed that in case an injury (e.g. an injury caused by a medicinal product) is due to lacking resources as a result of the COVID-19 situation (e.g. due to a lack of personnel, equipment or the like), then the patient's right to insurance/compensation may be limited. This limitation is yet to be tested.

Compensation under the Act is only paid if the medicinal products has been dispensed in Denmark for consumption or clinical trials with pharmaceutical drugs. It is also a prerequisite that the medicinal product has been dispensed through a pharmacy, hospital, doctor, dentist or approved non-pharmacy sales outlet for over the counter pharmaceutical drugs in accordance with the Danish Medicines Act.

Also, the medicinal product must be approved for marketing in Denmark in accordance with applicable rules (unless the medicinal product is for use in clinical trials).

We continuously post COVID-19 related updates and newsletters, including with regard to regulatory matters, on our website.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Finland	**EU**	**Borenius Attorneys Ltd**	https://www.borenius.com/category/legal-alerts/	NO

DETAILED RESPONSE

BORENIUS

No liability shields for vaccines (or investigative treatments or diagnostics) have been proposed in Finland. However, in the swine-flu epidemic a decade ago the then used vaccine caused narcolepsy. To cover parts of the liability related to these cases and in order to ensure solvency of the mutual insurance system in place for drug marketers in Finland, the Finnish government agreed to foot the bill by way of a special law enacted specifically for this ex-post.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
France	**EU**	**Harlay Avocats**	http://www.harlaylaw.com/?lang=en	YES

DETAILED RESPONSE

HARLAY AVOCATS

There are two systems of exemption of liability for health professionals, manufacturers of medicines and holders of a marketing authorization ("MA"), a temporary use authorization ("TUA") or an authorization to import medicines ("AI") in the event of (i) a health emergency or (ii) a serious threat to health.

1. Exemption system in the event of a health emergency

On 23 March 2020, France adopted law n°2020-209 in light of the Covid-19 epidemic, creating a special legal framework in the French Public Health Code in the event of a health emergency (articles L.3131-12 to 3131-20). In the event of a health emergency the French Prime Minister is empowered to adopt measures by decree to guarantee public health. In particular, he may "take any measure to ensure that patients have access to appropriate medicines to eradicate the health disaster".

Damage resulting from measures taken by the French Prime Minister as part of the health emergency benefit from the exemption system applicable in the event of a serious threat to health (art. L. 3131-20 of the French Public Health Code).

Under this exemption system, health professionals (doctors, nurses, etc.), manufacturers of medicines and holders of MA, TUA and AI cannot be held liable in the event of the prescription, administration or use of (i) a medicine outside the therapeutic indications or normal conditions of use described in the MA or TUA; or (ii) a medicine not covered by an authorization, as a result of measures taken by the French Prime Minister as part of the health emergency.

To date, this exemption system applies to (i) the prescription and administration of hydroxychloroquine and a lopinavir/ritonavir combination, (ii) the prescription by pharmacies of injectable paracetamol-based pharmaceutical specialties, (iii) the prescription of the injectable pharmaceutical specialty Ritrovil, and (iv) the prescription and administration of medicines for veterinary use having the same therapeutic purpose, benefiting from a MA for the same active substance, the same strength and the same route of administration, in cases where it is impossible to obtain supplies of medicine for human use.

Only damage resulting from the prescription, administration and use of the above-mentioned medicines is exempt from liability during the health emergency.

In spite of this system of exemption, manufacturers of medicines and holders of MA, TUA and AI may still incur liability in relation to the conditions of manufacture or the placing of the medicine on the market.

2. Applicable system in the event of a serious health threat

In any event, in the event of a serious health threat requiring emergency measures, the French Minister for Health may take any proportionate measure in order to prevent and limit the consequences of any possible threats to the health of the population (article L. 3131-1 of the French Public Health Code).

As part of the measures taken by the Minister for Health, the exemption system (conditions of which have been described above) apply:
(i) - to health professionals when their intervention is made necessary by the existence of a serious health threat and the prescription or administration of medicine has been recommended or required by the French Minister of Health;
(ii) - to manufacturers, holders of MA, TUA and AI, when the use of medicine has been recommended or required by the French Minister for Health.

As indicated above, this exemption from liability does not exclude manufacturers and holders of MA, TUA and AI being held liable for damage resulting from the conditions of manufacture or the placing on the market of the medicine.

The mechanism is applicable to both registered and unregistered vaccines, but only those identified in the measures taken by the French Prime Minister as part of the health emergency or in the event of serious threat to health by the French Minister of Health.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Germany	**EU**	**SKW Schwarz Rechtsanwälte**	https://www.skwschwarz.de/en/expertise/fields-of-law-departments/branche/special-corona/show/do/	NO

DETAILED RESPONSE

SKW Schwarz

Liability limitations for vaccine manufacturers are planned. Research on Covid-19 vaccines is already underway. Different companies are pursuing different approaches. The Paul Ehrlich Institute (PEI), the responsible drug authority for vaccines, has already provided scientific advice to seven academic and industrial vaccine developers on the regulatory support of COVID-19 vaccine development. According to the German Federal Ministry of Health (BMG), the advice focused on RNA-, phage-based, vector-based and whole virus-inactivated vaccine platforms.

The PEI expects to receive the first application for approval for clinical testing of a preventive COVID-19 RNA vaccine candidate within the next few weeks and further applications for RNA and vector vaccine candidates by autumn 2020.

If the first clinical trial results of COVID-19 vaccines are positive, at least several thousand, and depending on the situation, tens of thousands of probands could be vaccinated in further subsequent clinical trials.

In such a constellation, the German government plans to assume liability risks under certain circumstances if an unauthorized vaccine is used. This was announced by the German Minister of Health, Mr. Spahn, at a press conference. Further details or a draft bill are not yet available.

COUNTRY	EU	LAW FIRM	COVID INFO	APPLICABILITY OF MECHANISM
Hungary	**EU**	**Szecskay Attorneys at Law**	https://szecskay.hu/en/publications	NO

DETAILED RESPONSE

No liability shields for vaccines (or investigative treatments or diagnostics) have been implemented in Hungary. No drafts rules in this respect to be enacted.

Israel	**nonEU**	**Horn & Co. Law Offices**	http://hornlaw.co.il/	NO

DETAILED RESPONSE

No such liability exemption arrangements are applicable in Israel. However, the Israeli Ministry of Health has published guidelines allowing the use of certain non-registered drugs for the treatment of COVID19.

Russia	**nonEU**	**Lidings**	http://www.lidings.com/eng/legalupdates2?id=431	NO

DETAILED RESPONSE

Though a number of measures have been already proposed/implemented in Russia for COVID19-related drugs and medical devices (exemptions from import duties, fast track registration, shortened clinical trials), no proposals have been made regarding limitation of liability. There have been very few liability cases in Russia regarding drug quality/safety, while the approach of the courts towards the compensation amounts awarded is very conservative. Therefore it might well be that our politicians do not see a point for discussion here.

Slovakia	**EU**	**HAVEL & PARTNERS**	https://www.havelpartners.cz/en/comprehensive-information-service-on-the-covid-19-crisis/	NO

DETAILED RESPONSE

There is no such liability exemption arrangements in Slovakia. Only when it goes to the authorization of medicines, the Slovak State Institute for Drug Control has announced that the process of authorization of medicines used in COVID-19 has been accelerated, such medicines shall be approved as a matter of priority and by accelerated procedure. It will also speed up the approval of clinical trials for patients with this disease.

Spain	**EU**	**Lener**	https://www.lener.es/en/news-covid-19	YES

DETAILED RESPONSE

With the aim to supply healthcare centers with the necessary medical devices to manage the healthcare crisis caused by COVID-19, exceptional measures were adopted to enable the quick manufacturing and operating of medical devices. In this context, several exceptions were approved in the context of (i) the license of installations, the (ii) CE marking and (iii) the mandatory sanitary guarantees. The State would assume any economic liability arising from damages caused under the three abovementioned exceptions provided that (i) said medical device has been delivered to the Health Ministry with the purpose of attending people affected by the pandemic caused by COVID-19 or with the purpose of helping to control it and that (ii) no business benefit has been obtained in the manufacturing and operation. The sanitary products covered by this situation only are, up to 26 May 2020, masks and surgical gowns (Order SND/326/2020, dated 6 April, article 5).

The law regulating medical products and sanitary devices (Royal Decree 1/2015, dated 24 July) already states under article 24.5 the temporary authorization by the Spanish Agency of Medicines and Medical Devices of distribution of not authorized medicines in response to exceptional situations, like the current one with COVID-19. In this circumstance "*if the competent authority recommends or imposes the use of non-authorized medicines, the holders of the authorization and other professionals involved in the process would be exempt from civil or administrative liability for all the consequences derived from the use of the medicine, with the exception of damages caused by defective products.*"

Although no liability limitations for vaccine manufacturers concerning COVID-19 have expressly been approved up to now, in case that the Spanish Agency agrees to the temporary distribution of a vaccine which, due to the extraordinary circumstances, did not observe the standard approval processes and requirements, this liability regime should apply.

It cannot be excluded to have such state liability shield for vaccines approved in Spain within the next months if developments of investigations are successful.

The mechanism is applicable for unauthorized vaccines temporary distributed due to the extraordinary circumstances stated in Law.

Sweden	**EU**	**Advokatfirman Delphi**	https://www.delphi.se/en/coronavirus-covid-19/	NO

DETAILED RESPONSE

There is definitely a lot of interesting legal developments when it comes to both pharma and medical devices at the moment, both from a regulatory, competition law and state aid side.

We are not aware of any compensation shield for COVID 19 vaccine in Sweden. However, it is interesting to make a comparison with how the swine flu narcolepsy situation was treated and the set-up with the pharmaceutical insurance scheme in Sweden.

If a new vaccine against Covid-19 would lead to injuries to an individual that has received a vaccine supplied by a pharmaceutical company in Sweden, the individual would likely be able to seek compensation from the Swedish Pharmaceutical Insurance. (Alternatively, an individual can claim damages in court, but court proceedings tend to be less expedient and the evidentiary requirements may be higher.)

The Swedish Pharmaceuticals Insurance

In 2016 new Swedish legislation on state compensation to individuals affected by narcolepsy after receiving a vaccine (Pandemrix) against the swine flu entered into force. If a vaccine against Covid-19 would give rise to serious adverse events for many individuals, it is possible that Sweden would introduce a similar compensation mechanism.

In Sweden there is a special insurance called the Pharmaceutical Insurance, which covers anyone who is treated with prescribed medication or medication purchased from a legitimate dealer in Sweden, who has received medication at a hospital, or who suffers adverse reactions or side effects due to participation in clinical trials that are covered by the insurance. Most pharmaceutical companies on the Swedish market are part of the insurance and 99% of pharmaceuticals sold on the Swedish market are covered by the Pharmaceutical Insurance.

All claims for compensation for medication-related injuries are investigated by a claims adjuster in consultation with independent medical experts. The evidentiary requirements are not as strict as would be the case in a court proceeding, and the case is handled more quickly than in a court. In order to receive reimbursement from the Pharmaceutical Insurance, it is sufficient that there is preponderant probability that the injury was caused by a pharmaceutical product.

The compensation can cover:
- additional expenses incurred as a consequence of the injury;
- compensation for pain and suffering;
- loss of income during the period of illness. In case of a permanent injury, an individual may be entitled to compensation for bodily defect or permanent harm. The degree of invalidity is evaluated based on special norms;
- if an injury results in permanent additional expenses or inconvenience, an individual may be entitled to compensation for these. An individual may also be entitled to receive compensation for loss of income over an extended period of time. This may be in the form of an amount to cover loss of income or an annuity.

More information in English can be found on Svenska Läkemedelsförsäkringen AB's (the Swedish Pharmaceutical Insurance AB) website: https://lff.se/a-unique-type-of-insurance/for-patients/

State compensation for individuals affected by narcolepsy caused by the swine flu vaccine

In 2016 Sweden introduced legislation on state compensation to individuals affected by narcolepsy after receiving the vaccine Pandemrix against the swine flu during the mass vaccination campaign of 2009–2010.

In order to receive state compensation, individuals must first report their injury to the Pharmaceutical Insurance. The Pharmaceutical Insurance has a compensation limit for all claims reported during the same year, and are therefore not able to cover all of those affected. When this limit is reached, individuals that have been affected by narcolepsy after receiving Pandemrix can apply for compensation from the Swedish state.

The act is available on the following website (only in Swedish): https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2016417-om-statlig-ersattning-till_sfs-2016-417

There is a ten year limitation period.

It is possible that the state would introduce a similar compensation mechanism if a vaccine against Covid-19 would give rise to serious adverse events for many individuals. However, for the time being, we are not aware of any such measures that have been announced by the Swedish Government.

The Pharmaceuticals Insurance covers anyone who is treated with prescribed medication or medication purchased from a legitimate dealer in Sweden, who has received medication at a hospital, or who suffer adverse reactions or side effects due to participation in clinical trials that are covered by the insurance.

Switzerland	**nonEU**	**Walder Wyss Ltd.**	https://www.walderwyss.com/en/coronavirus	NO

DETAILED RESPONSE

There are no such liability exemption arrangements in Switzerland. We will address the Government to propose an evaluation.

Turkey	**nonEU**	**Gün + Partners**	https://gun.av.tr/covid-19-hub	NO

DETAILED RESPONSE

There is no regulation regarding limitation of liability or mechanism to create compensation in Turkey.

United Kingdom	**nonEU**	**Clyde & Co. LLP**	https://www.clydeco.com/coronavirus	NO

DETAILED RESPONSE

For the UK, although:
- the Government has provided funding for an accelerated clinical trial of a potential vaccine against Covid-19 and set up a task force to accelerate the production and roll-out of any successful vaccine;
- the UK regulator, the MHRA, gave accelerated approval for that clinical trial (in 7 working days) and will similarly prioritise applications for trials for other potential Covid-19 treatments; and
- the Government has passed the Coronavirus Act 2020, which includes an indemnity for persons within the National Health Service who diagnose, treat or care for patients suffering from Covid-19;

there is no indemnity for the manufacturer of vaccines. However, the Government has given an indemnity to designers and manufacturers of "rapidly manufactured ventilator systems" against intellectual property infringement and so, if a vaccine does get through clinical trials and goes into accelerated production, it seems quite likely that some form of indemnity would be introduced at that stage. Absent that, standard product liability law applies for which there are 2 schemes running in parallel under the EU Directives (particularly the Product Liability Directive 85/374/EC) and national law on consumer protection and negligence.