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Precedential List of Statutes, Regulations, and Decrees to Implement COVID-19 Related Indemnity and Compensation

Set forth below is a list of concrete legislation and executive actions from other countries that the AMC92 countries could potentially use as precedents when implementing compensation programs and/or taking necessary steps (if necessary) to implement a plan for indemnification for manufacturers, distributors, and healthcare providers in the vaccine supply chain.

Authorizations for compensation for adverse events following immunization (AEFI) and for indemnity to vaccine manufacturers, distributors, and administrators has been enacted through three primary legal channels: public procurement laws, public health emergency laws, and laws specific to immunization. Legal precedents from 20 jurisdictions are included below. Nine were adopted pursuant to COVID-19 specifically: Argentina, Brazil, Colombia, Costa Rica, Guatemala, EU, Malawi, Philippines, UK. Eleven were enacted previously: Ghana, Lao DPR, Liberia, Malaysia, Nepal, New Zealand, Sierra Leone, Uganda, Vietnam, and Zambia.

The relevant clauses are listed on pages 3 through 10 of this memorandum. The full text of these legislative, executive, and ministerial enactments are provided by name of jurisdiction as separate attachments.

1. Relevant Text of Statutes, Legislative and Executive Enactments

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List of Legislation and Executive Actions

1. **Argentina**

   Law on Vaccines Intended to Generate Acquired Immunity against Covid-19

   Executive Decree 260/20, its amendment and administrative decision 1,721 / 20

   Relevant clause:

   Article 4 - The national Executive, through the Ministry of Health, is empowered to include in the contracts . . . for the acquisition of vaccines intended to generate acquired immunity against COVID-19, according to the special procedure regulated by decree 260/20, its amendment and administrative decision 1,721/20, clauses that establish conditions of . . . indemnity regarding . . . pecuniary claims related to and in favor of those who participate in research, development, manufacture, provision and supply of vaccines, with the exception of those resulting from fraud, malicious intent, or negligence on the part of the aforementioned subjects.

2. **Brazil**

   Law 14.125 of March 10, 2021

   Relevant clause:

   Article 1 - As long as the Public Health Emergency of National Importance is declared due to human infection with the new coronavirus (SARS-CoV-2), remains, the Union, the States, the Federal District and the Municipalities are authorized to acquire vaccines and to assume the risks related to civil liability, under the terms of the instrument for the acquisition or supply of vaccines, in relation to adverse events after vaccination, provided that the National Health Surveillance Agency (Anvisa) has granted the respective registration or authorization temporary use.

3. **Colombia:**

   Strategy for the Immunization of the Colombian population: Ley 2064 de 2020

   Relevant clause:

   Article 5. Responsibility of the manufacturers. The manufacturers of vaccines against COVID-19 acquired and supplied by the National Government will only be responsible for malicious or seriously culpable actions or omissions, or for the breach of their obligations of good manufacturing practices or of any other obligation that has been imposed on them in the approval process.

The liability regime described in this article will only be applicable to vaccines against COVID-19 and those generated in the event of other pandemics, as long as they are under an emergency approval regime or a temporary special approval by the competent entities in the national territory. After this period, the ordinary liability rules shall apply.

4. Costa Rica

Declaration of State of Emergency throughout the Republic of Costa Rica

N° 42227 - MP – S

Relevant Clause:

As part of the actions set forth in subsection c) of article 2 of this Decree, the regime provided in Law number 8488 may be used for the acquisition of vaccines against the disease caused by the SARS-Cov2 virus and for this, the Costa Rican Social Security Fund will act as the Executing Unit. For their part, the Ministry of Health and the National Commission for Vaccination and Epidemiology will act as supervisory authorities and will provide support to the National Commission for Risk Prevention and Emergency Attention in the selection of the product, the suppliers and the necessary conditions for the protection of people's health and life.

5. European Union

Decision C(2020) 4192 final of 18 June 2020, approving the agreement with Member States on procuring Covid-19 vaccines, based on Article 4, paragraph 5, point (b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union.

Relevant Clauses [from purchase agreement entered into pursuant to law]:

1.17. "Defect" means the characteristic of a product that does not provide the safety which a person is entitled to expect taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation, in each case as such term is interpreted consistently with the term "defective" under Article 6 of the EU Product Liability Directive 85/374/EEC.

14.1. Member States. Each Participating Member State shall indemnify and hold harmless AstraZeneca, its Affiliates, subcontractors, licensors, and sub-licensees, and officers, directors, employees and other agents and representatives of each (collectively, the "Indemnified

Persons") from and against any and all damages and liabilities, including settlements for which the Indemnifying party has given its consent pursuant to Section 14.2, and necessary legal costs relating to, resulting from or associated with claims for death, physical, mental, or emotional injury, illness, disability, or condition, fear of the foregoing, property loss or damage, and business interruption of the injured party or a Related Person of such injured person (together, "Losses") relating to or arising from the use or administration of the Vaccine shipped or allocated to its jurisdiction. Such indemnification will be available regardless of where the Vaccine is administered, where the claim is brought, and whether the claim of a Defect originates from the distribution, administration and use, clinical testing or investigation, manufacture, labelling, formulation, packaging, donation, dispensing, prescribing or licensing of the Vaccine in its jurisdiction. [Followed by redacted limitations on indemnity eligibility].

6. Ghana

Ghana: Public Health Act (2012)

Section 31 - Regulations by the Minister

The Minister may by legislative instrument, make Regulations to provide for . . .

(c) the supply of vaccines to public vaccinators;

(d) the methods of vaccination by public vaccinators;

(e) the follow-up of persons for adverse reaction and the appropriate management

(f) the functions of assistant public vaccinators and the limitations and conditions under which those functions are to be performed;

(g) the payment of fees under this Part; and

(h) any other matters necessary for the purpose of vaccination.

7. Guatemala

Acuerdo Ministerial 40-2021, Norma de Excepción de Responsabilidad y Compensación por Reacciones Adversas Serias Atribuibles a las Vacunas Contra el COVID-19.

Relevant Clause:

To guarantee universal and timely access to vaccines against COVID-19, the manufacturers of said vaccines have established as a condition, both in their participation in the COVAX mechanism, of which Guatemala is a part, as well as in any procurement contract and direct distribution, issue the necessary legal instruments that regulate the liability exception, derived from serious adverse reactions attributable to them . . . It is necessary to create a regulation

that establishes the liability exception of vaccine manufacturers against COVID-19 and a compensation system for serious adverse reactions caused by them.

8. **Lao PDR**

DECREE of the PRESIDENT of the LAO PEOPLE'S DEMOCRATIC REPUBLIC On the Promulgation of the Immunization Law No. 211/PO

Relevant clause:

Article 35 Management of Cases of Death or Disability

In case of disability or death resulting from an adverse event following immunization, the Committee for Inspection of Causes of the Adverse Event Related to the Use of Drugs, Vaccines and other Medical Products must follow up and inspect, investigate the cause, analyze for purposes of making a diagnosis and report [their findings] for taking corrective measures in accordance with the law. The state is responsible for compensating disabled or family of dead person, case by case, as stipulated in the separate regulations.[1]

9. **Liberia:**

Public Health Law of Liberia as Revised 2019

Executive Law, Liberian Code of Laws Title 12.

Relevant clauses:

Executive Law § 3.3. During public health emergencies, the President is authorized "(d) To declare in effect curfews or requirements for compulsory vaccination . . ."[2]

Public Health Law § 17.22. Government not liable when properly exercising powers hereunder Whenever this chapter powers are exercised by the Minister or some other officer of the Ministry in accordance therewith or with the regulations and rules made thereunder, and by reason of the exercise of such powers . . . the Government shall not be liable to pay compensation, provided due care and reasonable precautions have been taken to avoid unnecessary delay, or damage or destruction.[3]

[1] Article 45 separately suggests liability for businesses.
[2] Responding to requests for such coverage of Ebola vaccine trials in 2015, a quote was obtained from a commercial carrier already providing EVD research coverage in Sierra Leone. Commercial insurance quotes ranged from USD40,000–300,000 depending on the coverage amount and deductibles. However, the Liberian government suggested a broad scope, self-insurance fund, capitalized by government and pharmaceutical firms, and administered by Liberia's National Social Security and Welfare Corporation. The trial concluded without either formalized system.
[3] This provision appears to contemplate real or personal property, but its wording is broader.

10. Malawi

Public Health Act (CAP 34:01)

Public Health (Coronavirus and COVID-19) (Prevention, Containment, and Management) Rules 2020

Relevant Clause

Section 137 [Public Health Act] Protection of local authorities and officers from personal liability

No matter or thing done and no contract entered into by any local authority, and no matter or thing done by any member of any such authority or by any officer of or acting on behalf of such authority or other person whomsoever acting under the direction of such authority, shall, if the matter or thing were done or the contract entered into bonafide for the purpose of executing this Act, subject any member, officer or person as aforesaid personally, to any action, liability, claim or demand whatsoever.

Section 21 [COVID-19 Rules] Immunity against liability

Liability or suit shall not lie against an enforcement officer or a medical practitioner for anything done in good faith under these rules.

11. Malaysia:

Contracts Act (1950)

The Malaysia Contracts Act specifically authorizes contracts for indemnity, which have been included in its procurement agreements.

Relevant clause:

Rights of indemnity-holder when sued

78. The promisee in the contract of indemnity, acting within the scope of his authority, is entitled to recover from the promisor-- (a) all damages which he may be compelled to pay in any suit in respect of any matter to which the promise to indemnify applies;

(b) all costs which he may be compelled to pay in any such suit if, in bringing or defending it, he did not contravene the orders of the promisor, and acted as it would have been prudent for him to act in the absence of any contract of indemnity, or if the promisor authorized him to bring or defend the suit . .

12. Nepal:

Immunization Bill 2072 (2016)

Relevant clauses

(4) Mandatory Vaccination: (1) The Ministry may prescribe any vaccination for the prevention, control, prevention or eradication of the disease as prescribed.

(2) It shall be the duty of the person concerned to administer the vaccine pursuant to Sub-section (1) . . .

28. Provisions related to treatment and compensation:

(1) If the investigation committee finds that the health of the person who has been vaccinated has been seriously affected due to any vaccination, the body or institution will have to treat such person and also pay compensation.
(2) If the Committee of Inquiry finds that a person has suffered severe bodily harm or death due to any vaccination, the Committee shall provide compensation to that person and his or her close relatives . . .
(3) The basis for providing compensation pursuant to Sub-sections (1) and (2) shall be as prescribed.

29. Can form expert committee: The committee may form an expert committee under the coordination of the member of the committee to give opinion and suggestion regarding the punishment as per Article 26 or to determine the compensation as per Article 28.

30. Appeal: A person who is dissatisfied with the decision or order made by the Committee pursuant to Article 26 or 28 may appeal to the High Court within thirty five days from the date of such decision or order.

13. New Zealand:

Public Finance Act (1989)

Relevant clause:

65ZDMinister may give guarantee or indemnity if in public interest

(1) The Minister, on behalf of the Crown, may give, in writing, a guarantee or indemnity to a person, organisation, or government if it appears to the Minister to be necessary or expedient in the public interest to do so.

(2) The Minister may—

(a) give the guarantee or indemnity on any terms and conditions that the Minister thinks fit; and

(b) in the case of a guarantee, give the guarantee in respect of the performance or non-performance of any duties or obligations by a person, organisation, or government.

(3) If the contingent liability of the Crown under a guarantee or an indemnity given by the Minister under subsection (1) exceeds $10 million, the Minister must, as soon as practicable after giving the guarantee or indemnity, present a statement to the House of Representatives that the guarantee or indemnity has been given.

(4) The statement may contain any details about the guarantee or indemnity that the Minister considers appropriate.[4]

14. Philippines

Senate Bill 2057: An Act Establishing the Government Vaccine Indemnification Program, Providing Funds Therefor, and Other Purposes[5]

Relevant clause:

SEC. 8. Notwithstanding any law to the contrary, the Secretary of Health shall provide guidelines declaring a covered person to be immune from suit and liability under Philippine laws with respect to all claims arising out of, related to, or resulting from the administration or use of a COVID-19 vaccine under the COVID-19 Vaccination Program, except if the claim is brought about by willful misconduct. Covered person shall include public officers, their employees, contractors, and volunteers who are duly authorized to carry out and actually carrying out the COVID-19 Vaccination Program.

SEC. 9. The COVID-19 2 National Vaccine Indemnity Fund, which shall be administered by the PhilHealth, is hereby established to compensate any person inoculated through the COVID-19 Vaccination Program, in case of death or for the medical treatment of any SAEs. The amount of Five Hundred Million Pesos (P500,000,000) is hereby authorized to augment the funds of PhilHealth for this purpose which shall be sourced from the Contingent Fund. For this purpose, the lATF shall establish a Special Task Group composed of medical and vaccine experts who will be In charge of monitoring the probable adverse events following immunization from COVID-19. The Special Task Group shall promulgate the necessary guidelines on the monitoring and reporting mechanism to be followed by all LGUs

[4] New Zealand separately provides for compensation of vaccine related injuries through its Accident Compensation Corporation. https://www.legislation.govt.nz/act/public/2001/0049/latest/DLM99494.html
[5] This legislation was adopted as law on

15. Sierra Leone

Sierra Leone: Public Health Act No. 23 (1960):

Section 139. No matter or thing done, and no contract entered into by any Health Authority, and no matter or thing done by any member of such Authority, or by any officer of such authority or other person whomsoever acting under the direction of such authority, shall, if the matter or thing done or the contract were entered into bona fide for the purpose of executing this ordinance, subject them, or any of them personally, to any action, liability, claim or demand whatsoever and any expense incurred by any such Authority, member, officer, or other person acting as last aforesaid, shall be borne and re-paid out of the general revenue of Sierra Leone.

16. Tunisia

Law no. 2021-10 of 2 March 2021

Relevant Clauses

Article 2 – Within the meaning of this law, the following definitions apply: - Use of vaccines and drugs: All operations of research and development, including clinical trials, all stages of manufacture, registration, authorisation, distribution, transport, storage, marketing, sale, donation, description, dispensing, use, and any other legitimate form of use. - Wilful misconduct: Any act, abstention or omission committed in order to achieve an illegitimate aim, whether deliberately, in full knowledge of the facts, in the absence of any reason, or by neglecting a known or obvious risk of the vaccine or drug such that its harm exceeds its expected benefit. - Serious damage: Bodily injury that is life-threatening or has resulted in a permanent physical disability equal to or greater than twenty per cent (20%), total physical incapacity, or injury requiring a medical or surgical procedure to avoid permanent incapacity of any organ of the body or one of its functions.

Article 6 – Subject to the provisions of paragraph 2 of Article 5 of this law, the State is exclusively liable for compensating the damage resulting from the use of vaccines and drugs against the SARSCoV-2 virus having obtained a marketing authorisation.

The assessment and determination of the damages resulting from the use of vaccines and drugs against the SARS-CoV-2 virus having obtained a marketing authorisation shall be undertaken by a multidisciplinary committee, whose remit, composition, terms of operation and referral procedures shall be fixed by governmental decree. The committee mentioned in the second paragraph of this article is responsible for the assessment and determination of the nature of the damage, its causes, and the amount of compensation, if due, within a maximum period of three (3) months from the date of receipt of the compensation claim. If it has not ruled on the compensation claim within the above period, or in case of rejection of the claim,

the injured person may refer the matter to the Administrative Court to claim compensation of the damage from the State.

Article 7 – The amount of compensation in connection with the reparation of the damage resulting from the use of vaccines and drugs against the SARS-CoV-2 virus having obtained a marketing authorisation shall be charged to the general resources of the State budget.

Article 8 – The criteria and terms of compensation in connection with the reparation of the damages resulting from the use of vaccines and drugs against the SARS-CoV-2 virus having obtained a marketing authorisation shall be fixed by governmental decree within a maximum period of three (3) months from the effective date of this law

17. Uganda

Public Health Act Chapter 281

Immunisation Act 2017

Relevant Clauses

Section 48 [Public Health Act]

The Minister may make rules—

(b) conferring powers and imposing duties, in connection with the carrying out or enforcement of vaccination, on magistrates, administrative officers, members of a police force, or other Government officers, local authorities, persons in charge of schools, employers of labour, chiefs, headmen of locations *and others*;

(c) prescribing and defining the duties, in connection with vaccination, of medical practitioners and public vaccinators employed by the Government . . .

(f) providing for the vaccination or revaccination of persons and assigning where deemed desirable the responsibility for carrying out the vaccination or revaccination to local authorities or employers of labour;

(g) as to the application and enforcement of this Part of this Act to persons entering Uganda whether by land, water or air, and for requiring, where deemed necessary, the vaccination or revaccination of any person before entering; and

(h) generally for better carrying out the provisions and attaining the objects and purposes of this Part of this Act.

Section 22 [Immunisation Act] – Protection of Medical Practitioners from liability

A person shall not institute legal proceedings against a medical practitioner who does any act in good faith for the purpose of giving effect to this Act.

18. United Kingdom

Regulation 174A The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

Relevant clause:

174A.—(1) Where the sale or supply of a medicinal product is authorised by the licensing authority on a temporary basis under regulation 174, the licensing authority may attach conditions to that authorisation, those being conditions to which the following are subject—

(a)its recommendation or requirement as to the use of that product for the purposes of regulation 345; and

(b)its authorisation of the sale or supply of that product.

(2) The sale or supply of that medicinal product is not authorised by the licensing authority for the purposes of regulation 174 if—

(a)the sale or supply is for the purpose of any use other than the recommended or required use, as mentioned in paragraph (1)(a); or

(b)a condition attached in accordance with paragraph (1) to the authorisation of the sale or supply is breached.

(3) The use of that medicinal product is not in accordance with a recommendation or requirement of the licensing authority for the purposes of regulation 345 if—

(a)a condition attached in accordance with paragraph (1) to the authorisation of its sale or supply is breached; and

(b)any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person with relevant expertise in the subject matter of the breach would regard the breach as sufficiently serious to justify the licensing authority setting aside the recommendation or requirement.

(4) Notwithstanding paragraph (3), the persons mentioned in regulation 345(3) are not subject to any civil liability resulting from a use of that medicinal product that was (but for the operation of that paragraph) in accordance with the recommendation or requirement of the licensing authority, if those persons were not wholly or partly responsible for the breach in question.

any holder of an authorisation for the product;

Regulation 345(3) (excerpted0:

(a) any holder of an authorisation for the product

(b)any manufacturer of the product;

(c)any officer, servant, employee or agent of a person within [F2sub-paragraph (a), (aa) or (b);]

(d)any health care professional[F3; or]

[F4(e)any person, not being a health care professional, who administers the product in accordance with a protocol of the type mentioned in regulation 247A.]

Compensation: 2020 No. 1411 The Vaccine Damage Payments (Specified Disease) Order 2020 Made 2nd December 2020 Laid before Parliament 3rd December 2020 Coming into force 31st December 2020

The Secretary of State makes this Order in exercise of the powers conferred by sections 1(2)(i) and 2(2) of the Vaccine Damage Payments Act 1979(1).

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Vaccine Damage Payments (Specified Disease) Order 2020 and comes into force on 31st December 2020.

(2) In this Order "the Act" means the Vaccine Damage Payments Act 1979.

Addition to the list of diseases to which the Act applies

2. COVID-19 is specified as a disease to which the Act applies.

Modification of condition of entitlement

The condition of entitlement in section 2(1)(b) of the Act (age or time at which vaccination was carried out) is omitted in relation to vaccination against COVID-19.

19. Vietnam:

Decree on Vaccination No. 104/2016/ND-CP

Relevant clause:

Article 15. Cases eligible for compensation

1. The State shall pay compensation for serious injuries or deaths from severe adverse reactions after vaccination implemented under the programs of expanded vaccination and vaccination for epidemiology prevention.

2. The State shall pay compensation for:

a) disabilities resulted from severe adverse reactions after vaccination;

b) Deaths caused by vaccination.

Article 16. Damages, scope and level of compensation

1. Damage caused by leaving sequelae leading to disability shall be compensated for 30 months of base salary and expenses specified in Clauses 3 and 4 of this Article.

2. Compensation in case of death caused by vaccination is paid as follows:

a) Pre-death expenses specified in Clause 3 of this Article;

b) The cost of funeral charge is equal to 10 months' base salary set by the State;

c) Compensation for emotional distress for relatives of the aggrieved person is 100,000,000 VND . . .

20. Zambia

Chapter 295 of the Laws of Zambia, Public Health Act

30. Whenever any part of Zambia appears to be threatened by any formidable epidemic, endemic or infectious disease, the Minister may declare it an "infected area" and may, by statutory instrument, make regulations for all or any of the following purposes, namely

(m) for any other purpose, whether of the same kind or nature as the foregoing or not, having for its object the prevention, control or suppression of infectious diseases;

[114] The Minister shall have power, by statutory instrument, to make regulations generally for the carrying out of the purposes of this Act. (As amended by Act No. 51 of 1963).