

# Immunization Act, 2072 (2016)

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(26 January 2016)

## An Act enacted to manage Immunization Services

**Preamble:** Whereas, it is expedient to necessary arrangement for providing quality immunization services with development, expansion and strengthening of immunization services in the country with a view to prevention, control, elimination or eradication of vaccine preventable disease and thereby to reduce infant, child, maternal and other individual mortality rate;

Now, therefore, the Legislature-Parliament has enacted this Act pursuant to Sub-Article (1) of Article 296 of the Constitution of Nepal.

### Chapter-1

#### Preliminary

1. **Short Title and Commencement:**(1) This Act may be cited as “Immunization Act, 2072 (2016)”.

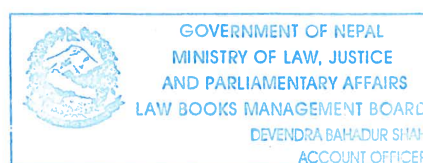
(2) This Act shall come into force from ninety-one days of its authentication.

2. **Definition:**Unless the subject or context otherwise requires, in this Act;

a) “License” means a license issued to conduct immunization services pursuant to Section 11.



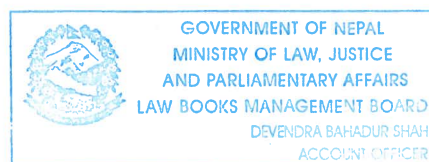
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- b) “Investigation Committee” means a committee formed to conduct investigation on adverse event pursuant to Section 19.
- c) “Fund” means an Immunization Fund established pursuant to Section 21.
- d) “Vaccine” means the vaccine administered to control, prevent, eliminate or eradicate any disease.
- e) “Immunization Card” means a immunization card issued pursuant to Section 12.
- f) “Immunization Program” means National Immunization Program to be conducted by the Government of Nepal as regular immunization program or campaign with a view to prevent, control, eliminate or eradicate vaccine preventable diseases and the term also includes surveillance of vaccine preventable diseases.
- g) “Vaccinator” means a health worker or doctor who administers the vaccine and the term also includes any person deputed by the Ministry to administer special type of vaccine.
- h) “Immunization Service” means administration of vaccine under this Act and the term also includes management, supply, storage and distribution of vaccine, materials to conduct immunization services.
- i) “Doctor” means a person registered as a doctor under prevailing law.



  
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- j) “Prescribed” or “as Prescribed” means prescribed or as prescribed in the rules framed under this Act.
- k) “Ministry” means Ministry of Health.
- m) “Committee” means National Immunization Committee formed pursuant to Section 15.
- n) “Advisory Committee” means National Immunization Advisory Committee formed pursuant to Section 18.
- o) “Department” means Department of Health Services.
- p) “Health Worker” means a person registered as a health worker under prevailing law.

## Chapter-2

### Provisions Relating to Immunization Service

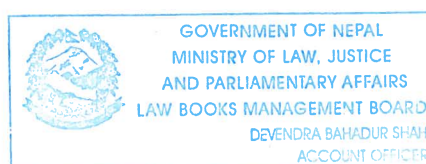
3. **Right to Have Vaccine by Target Group:** (1) The target group shall have right to have vaccines, included into immunization program, at free of cost.

**Clarification:** For the purpose of this Section, “Target Group” means a person belonging to a class, community or region predetermined in immunization program as obliged to have vaccine for prevention, control, elimination or eradication of particular disease.

(2) The Ministry shall make arrangement for administration of vaccine at specific date and time mentioned in sub-section (1) in any hospital, health institution, immunization center, mobile immunization clinic or other prescribed place.



  
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- (3) In order to provide immunization services under this Section, the Ministry may seek support of the concerned local level, police administration and volunteers.
4. **To Have Vaccination Mandatory:** (1) The Ministry may prescribe mandatory vaccination to all for prevention, control, elimination or eradication of defined diseases.
- (2) The concerned person shall be obliged to vaccinate as mentioned in sub-section (1).
5. **Obligation of Patron or Guardian:** Patron or Guardian or person shall be responsible to make arrangement for providing vaccine included in immunization program to the infant, children or other person living under his/her protection, guardianship, or custody.
6. **Not to Administer Vaccine:** Notwithstanding anything contained in this Chapter vaccinator shall not administer vaccine to such person who is not found fit to have that vaccination due to his/her health.
7. **To Inform About Vaccination:** (1) Prior to vaccine administration, the vaccinator shall give information concerning the nature of vaccine, benefits and possible risk associated with vaccine to the vaccine receiver.
- (2) Information as mentioned in Sub-section (1) shall be given to the patron or guardian of the vaccine receiver if he/she is infant, disable or suffering from mental disorders.
8. **Vaccine to be as per Standard:** Vaccine to be administered under this Act shall meet the prescribed standards.



  
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9. **Doctors and Health Workers to be responsible:** It shall be the responsibility of the concerned doctors and health workers involved in vaccination under this Act.
10. **Not to Obstruct in Operation of Immunization Program:** Nobody shall create any obstruction in operation of immunization program.
11. **To Obtain License:** (1) Private, non-governmental, community hospital or health institution willing to operate immunization services shall obtain license from the designated body as prescribed.
- (2) Hospital or health institution, obtaining license pursuant to sub-section (1) to operate immunization services, shall submit a report of operation of immunization services to the designated body or health institution on regular basis.
12. **To Maintain Record of Immunization Service:** (1) Vaccinator shall maintain updated record of vaccine receivers.
- (2) Vaccinator shall issue immunization card to vaccine receiver in a format as prescribed.
- (3) Vaccine receiver, his/her patron or guardian shall keep the immunization card safely.

### Chapter-3

#### **Provisions Relating to Supply and Storage of Vaccine**

13. **To Supply Registered Vaccine:** (1) Vaccine supplying institution shall supply only vaccines which are registered in the Department of Drug Administration.
- (2) Vaccines to be supplied pursuant to Sub-section (1) shall have been manufactured in compliance with good

manufacturing practices and shall have been certified by World Health Organization(WHO) as meeting the standards of WHO prequalification.

(3) Notwithstanding anything stated in Sub-section (2) vaccine which is not yet certified by WHO may be imported in following conditions: -

- (a) Manufactured in compliance with good manufacturing practices,
- (b) Already used in manufacturing country or in other countries,
- (c) Registered in national regulatory authority of manufacturing country, and
- (d) Certification of the statement contained in clauses (a), (b) and (c) by the Department of Drug Administration.

14. **Supply, Storage and Distribution of Vaccine:** Supply, storage and distribution of vaccine, equipment required for its use and temperature to be maintained until its use shall be in such standards as prescribed by the Ministry.

## Chapter-4

### **Provisions Relating to various Committees**

15. **Committee:** (1) There shall be a National Immunization Committee to give recommendation to the Ministry on formulation of immunization policy as well

(2) The committee shall be formed as follows: -



  
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- a) Secretary of the Ministry- Chairperson
- b) Director General of the Department- Member
- c) Joint Secretary, Ministry of Finance - Member
- d) Joint Secretary, Ministry of Federal Affairs and Local Development- Member
- e) Joint Secretary, Ministry of Education-Member
- f) Joint Secretary, Ministry of Women, Children and Social Welfare- Member
- g) Two persons, including one woman, nominated by the Ministry among pediatricians, public health experts or health economists -Members
- h) Director, Child Health Division, Department-Member-Secretary

(3) The term of office of the nominated members pursuant to Sub-section (2) shall be four years.

(4) Notwithstanding anything stated in Sub-section (3), the Ministry may remove him/her from the post at any time if the nominated member defaulted to accomplish his/her job responsibility.

(5) The Ministry shall give an opportunity to the concerned member to present his/her clarification prior to remove him/her from the membership pursuant to Sub-section (4).

(6) Child Health Division of the Department shall work as secretariat of the Committee.



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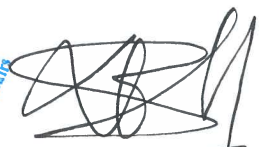
16. **Functions, Duties and Powers of the Committee:** In addition to functions, duties and powers contained in this Act, other functions, duties and powers of the Committee shall be as follows:-

- a) To formulate policy on immunization program and present it to the Ministry,
- b) To give direction to the concerned body for the development, expansion and operation of immunization program,
- c) To collect adequate fund to make immunization program sustainable and trustworthy,
- d) To monitor and supervise or cause to be monitored or supervised the immunization program,
- e) To coordinate with concerned body for the development and expansion of immunization program,
- f) To form sub-committees as per necessity to conduct immunization program effectively.
- g) To give direction to the Department for implementation of the recommendations made by the advisory committee or investigation committee.

17. **Meeting and Decision of the Committee:** (1) Meeting of the committee shall be convened at least four times in a year.

(2) Member secretary shall call the meeting of the Committee upon the direction of the Chairperson of the Committee.



  
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(3) Member secretary shall, in advance of twenty four hours of convening the meeting, give notice to all members along with the agenda of the meeting.

(4) Quorum for the meeting shall be deemed to have been attained if more than fifty percent members of the Committee have been presented in the meeting.

(5) The Chairperson shall preside over the meeting and incase of his/her absence a member selected by the committee shall preside over the meeting.

(6) Decision of the majority votes shall be valid in the meeting and incase of a tie; chairperson of the meeting shall caste the decisive vote.

(7) The Committee may invite anybody else who is related to immunization program to participate in the meeting as an invitee if deems necessary.

(8) Other proceedings of the meeting shall be as determined by the Committee itself.


**18. Advisory Committee:** (1) There shall be a National Immunization Advisory Committee for the development, expansion and conduction of immunization program and to give opinion and suggestion to the Committee for immediate operation of immunization program in case of natural calamity or epidemic.

(2) The Advisory Committee shall be formed as follows: -

(a) A person nominated by the Ministry among public health specialist doctors or senior pediatricians-

Chairperson



  
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- (b) Director, Child Health Division, Department-Member
- (c) Chairperson, Nepal Pediatric Society or a designated representative by the chairperson of the society-Member
- (d) Three persons nominated by the Ministry among epidemiologists, public health experts, health economists or senior pediatricians- Members
- (e) Chief, Immunization Section, Department- Member Secretary.

(3) The term of office of the Chairperson and nominated members shall be four years.

(4) Notwithstanding anything stated in sub-section (3), the Ministry may remove him/her from the post at any time if the Chairperson and nominated members of Advisory Committee were defaulted to accomplish his/her job responsibility,.

(5) The Ministry shall give an opportunity to submit his/her clarification prior to remove Chairperson or members from his/her post pursuant to sub-section (4).

(6) Child Health Division of the Department shall work as secretariat of the Advisory Committee.

19. **Investigation Committee:** (1) An Adverse Event Investigation Committee shall be formed to conduct immediate investigation of adverse events following immunization and submit a report to the Committee.



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(2) The Investigation Committee shall be formed as follows: -

- (a) A person nominated by the Ministry from among senior pediatricians – Chairperson
- (b) Representative, Department of Drug Administration- Member
- (c) Representative, Nepal Pediatric Society- Member
- (d) One person among senior pediatricians - Member
- (e) One person among senior public health experts- Member
- (f) One person among senior pathologists- Member
- (g) Chief, Immunization Section, Department- Member Secretary

(3) The Ministry shall nominate the members mentioned in clauses (d), (e) and (f) of sub-section (2).

(4) The term of office of the Chairperson and Nominated members shall be four years.

(5) Notwithstanding anything stated in sub-section (3), the Ministry may remove him/her from the post at any time if the Chairperson and nominated members of Investigation Committee were defaulted to accomplish his/her job responsibility,.

(6) The Ministry shall give an opportunity to submit his/her clarification prior to remove Chairperson or members from his/her post pursuant to sub-section (4).

(7) Child Health Division of the Department shall work as secretariat of the Investigation Committee.



20. **May Provide Direction to Implement Recommendations:** The Chairperson of the Committee may give direction to the Department to implement recommendations if the recommendations of the Advisory Committee or the Investigation Committee require immediate implementation and the meeting of the Committee could not conclude at the same time subject to approve those recommendations in the following meeting of the Committee.

## Chapter-5

### **Fund and Audit**

21. **Fund:**(1) There shall be a Fund named as Immunization Fund for the development of immunization programs as well.

(2) The fund shall comprise following amounts: -

- a) Amount received from the Government of Nepal,
- b) Amount received from Nepali citizen, financial or cooperative organization or other organizations or institutions,
- c) Amount received from foreign individuals, Governments or international organizations,
- d) Amount received from other sources.

(3) The Committee shall get prior approval from the Ministry of Finance before receiving amount mentioned in clause(c) of sub-section 2.

(4) Amounts of the fund shall be deposited in an account operated in a commercial bank holding "A" class license in accordance with prevailing law.



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**22. Use of Fund:** (1) The committee may use amount of the fund in following activities: -

- a) To purchase vaccine for operation of immunization program,
- b) To purchase vaccine immediately for operation of immunization program in case of natural calamity or epidemic,
- c) To conduct study or research for the development or extension of immunization program,
- d) To make investment on manufacture of vaccine to be used in immunization program in partnership with private sector if it deems feasible from the perspective of cost effectiveness,
- e) To perform administrative works as well as to conduct Committee meetings.

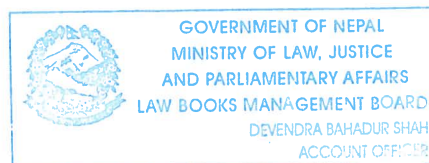
(2) The Committee shall get prior approval from the Ministry to spend the fund to carry out the works stated in clauses (a), (b) and (d) of sub-section (1).

**23. Not to use Fund for other work:** The committee shall not use amount of the fund in any work except as mentioned in Section 22.

**24. Arrangement of Budget:** (1) The Government of Nepal shall make arrangement of adequate budget required for sustainable management of immunization program.



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(2) While disbursing amounts of the fund in other works except mentioned in clause (b) of sub-section (1) of Section 22, the Committee shall have to maintain at least ten crore rupees balance in the fund.

(3) The Government of Nepal shall, as far as possible, reimburse the amounts into the fund that has been disbursed to perform work as mentioned in clause (b) of Sub-section (1) of Section 22.

**25. Account of Fund and Audit:** (1) Income and expenditure accounts of the fund shall be maintained in such a format as adopted by the Government of Nepal.

(2) Office of the Controller of Treasury and Account shall conduct internal audit of the fund.

(3) Final audit of the Fund shall be conducted by the Auditor General of Nepal.

## Chapter-6

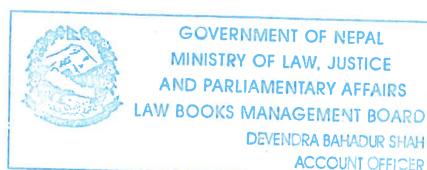
### Punishment, Compensation and Appeal

**26. Punishment:** (1) If anyone operates immunization service without obtaining a license, the committee shall end such operation and impose a fine of three hundred thousand rupees to five hundred thousand rupees to the concerned.

(2) If anyone supplies unregistered vaccine, the committee shall destroy such vaccine and impose a fine of twenty-five thousand to one hundred thousand rupees to the concerned.



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(3) If anyone distributes vaccine in contrary to the standard prescribed pursuant to Section 14, the committee shall destroy such vaccine and impose a fine of fifty thousand rupees.

(4) If anyone commits an act contrary to this Act or Rules framed under this Act other than what is referred to in sub-section (1), (2) or (3), the committee shall impose a fine of ten thousand to twenty-five thousand rupees to the concerned.

(5) If an act punishable under sub-section (4) is committed by an employee of the Government or public institution, the committee may request the concerned authority to take departmental action.

**27. To File a complaint:** (1) If anyone is aware of committing an act punishable under Section 26, such person may file a complaint to the committee within 35 days of such act.

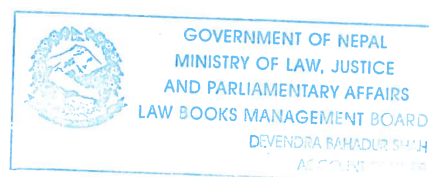
(2) Notwithstanding anything mentioned in sub-section (1), even if no complaint regarding the activities contrary to this Act is filed, the committee may initiate inquiry and impose punishment pursuant to Section 26 if the committee obtains information from any source regarding the commission of such act.

**28. Provision Relating to Treatment and Compensation:**(1) If a person encounters serious health problem following vaccination and Investigation Committee has certified the same, the vaccinating body or organization shall be responsible for the treatment of the victim and provide compensation.

(2) If the Investigation Committee has certified that a person has encountered serious type of physical losses like mutilation or death following vaccination, the Committee shall make arrangement



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of providing compensation from vaccinating body or organization to the victim in the event of mutilation and next of kin in case of death.

(3) Grounds to provide compensation pursuant to sub-section (1) and (2) shall be as prescribed.

29. **May Form Expert Committee:** The Committee may form an Expert Committee under the convenership of a committee member to present recommendation to impose punishment pursuant to Section 26 or to determine compensation pursuant to Section 28.

30. **Appeal:** Person not satisfied with the decision or order made by the Committee pursuant to Section 26 or 28 may file an appeal to the High court within 35 days of issuing such decision or order.

Provided that there shall not be any difficulty to file an appeal to the Appellate Court until the High Court adopts its jurisdiction.

31. **No Difficulty to File Complaint under Prevailing Law:** If an act punishable under this Act is also punishable under other prevailing laws, this Act shall not be deemed to have created any difficulty to take action or file complaint under other prevailing law.

## Chapter-7

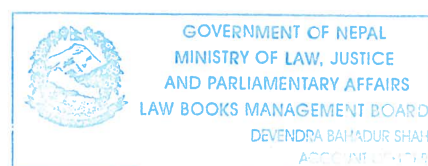
### Miscellaneous

32. **May Provide Encouragement and Reward:** The Ministry may encourage or give reward to such a person or institution having excellent contribution in the area of immunization.

33. **May Require Immunization Card:** (1) Schools may ask immunization card at the time of admission of student from his/her patron or guardian.



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(2) Notwithstanding anything stated in sub-section (1), a child shall not be barred from admitting in the school only on the ground of failure to submit immunization card.

(3) School shall maintain records of the students who have not received such vaccines which are included in immunization program and shall forward a report to the local government health institution.

34. **May Designate Brand Ambassador:** The Government of Nepal may designate a brand ambassador to a person who has high reputation in the country for promotion of immunization program.
35. **To Conduct Awareness Programs:** The Committee shall regularly conduct awareness programs on benefits of vaccine and possible adverse impact arising due to not receiving vaccine in time.
36. **Meeting allowance:** Chairperson, members and invited members of the Committee or sub-committees formed under this Act on account of participating in the meeting shall receive meeting allowance as prescribed by the Ministry of Finance.
37. **To Cooperate:** It shall be the duty of the concerned person or agency to provide necessary support to the immunization service.
38. **Delegation of Authority:** (1) The Ministry may delegate some of its power conferred by this Act to the Committee or body as required.
- (2) The Committee may delegate some of its power conferred by this Act to Chairperson, member or any other officer as required.
39. **To Submit Annual Report:** (1) The Committee shall submit annual report to the Ministry regarding its activities performed during the year within three months of expiration of the fiscal year.



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(2) The Committee may publish its annual report as mentioned in sub-section (1).

**40. To Give Direction:** (1) The Ministry may give necessary direction to the Committee regarding its activities.

(2) It shall be the obligation of the Committee to follow the directions given by the Ministry pursuant to sub-section (1).

**41. May Frame Guidelines:** The Committee may frame and implement essential guidelines subject to this Act and the Rules made under the Act.

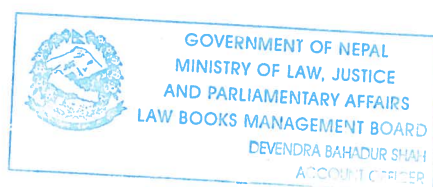
**42. Power to Frame Rules:** (1) The Government of Nepal may frame required Rules to implement this Act.

(2) Without prejudice to the generality of the authority conferred by sub-section (1), the Government of Nepal may frame rules particularly on the following matters :-

- (a) Standard of vaccine,
- (b) License issuing process, fee for license, fee for license renewal, validity of license, revocation of license and terms and conditions to be followed by licensee,
- (c) Monitoring of immunization services,
- (d) Report to be submitted to the health institution,
- (e) Record of immunization services,
- (f) Immunization card,
- (g) Other functions, duties and powers of the Committee,



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- (h) Meetings of Advisory Committee and Investigation Committee,
- (i) Operation of fund's account,
- (j) Use of fund,
- (k) About Compensation given to the vaccine receiver,
- (l) About Other essential matters concerning immunization.

43. **Repeal and Saving:** (1) National Immunization Fund (Operation) Regulation, 2070 (2013) has been repealed.

(2) Works carried out pursuant to National Immunization Fund (Operation) Regulation, 2013 shall be deemed to have done pursuant to this Act.



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