Annex 7 of Procedure of Pharmacovigilance (subitem 4 of item 1 of section IV)

GENERAL REPORT*

about registered cases of infectious disease controlled by specific immunoprophylaxis in vaccinated persons according to epidemiologic investigation form

	Epid. №**	Diagnosis	Date of birth	Sex M F	Name of facility where the patient works, studies or name of preschool institution, which ill child visits	Data about previous infectious diseases	List of chronic diseases	•	cont pa	act with agious tient unknown	Interval between last immunization and date of illness
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** For each $\mathbb{N}_{\mathbb{P}}$ give the list of vaccinations received within the life.

INSTRUCTIONS FOR COMPLETING THE GENERAL REPORT

1. Epid. No (indicate epid. No which is a unique number for each particular case of controlled infection in vaccinated person and shall not be repeated in certain administrative territorial unit within the reporting period. For each No give the list of all vaccinations received within the life (indicate in table information about all vaccinations received within the life with information about vaccine, enterprise-manufacturer, date of vaccination in format of day/month/year, dose in format of ml or drops, batch (if available), shelf-life in format of day/month/year (if available), method of administration in format of i/v, s/c, i/c, per os)).

For example:

Trade name	Name of manufacturer	Date	Dose	Batch	Shelf-life	Method of administration
DTaP	Biolik, Ukraine, Kharkiv	02.01.2007	0.5 ml	25-5	01.01.2008	i/m
OPV	Sanofi Pasteur S.A., France	02.01.2007	4 drops	871	25.10.2007	per os

^{*} It shall be submitted to the Public Enterprise "The State Expert Center of the Ministry of Health of Ukraine" in e-form to e-mail: *vigilance@dec.gov.ua* and to the appropriate healthcare structural unit in e-form to its e-mail.

2. Diagnosis (indicate diagnosis registered in vaccinated person).

3. Date of birth (indicate date of birth in format of day/month/year).

4. Sex (indicate patient's sex).

5. Name of facility where the patient works, studies or name of preschool institution, which ill child visits (indicate name of facility where the patient works, studies or name of preschool institution, which ill child visits. If patient does not visit preschool institution and does not work when becomes ill, indicate "unemployed" or "unorganized").

6. Data about previous infectious diseases (give information about previous infectious diseases in form of table with date of illness in format of day/month/year and diagnosis. If there are no data about infectious diseases, this column shall be empty).

7. List of chronic diseases (indicate date in format of day/month/year and list of any chronic diseases. If there are no information about chronic diseases, this column shall be empty).

8. Contact with contagious patient (indicate information about contact with contagious patients within the month before illness).

9. Interval between last immunization and date of illness (indicate interval between the date of last immunization against infection which developed in patient and date of illness in format of day/month/years).

10. General report according to epidemiologic investigation form shall be submitted to:

Public Enterprise "The State Expert Center of the Ministry of Health of Ukraine" in e-form to e-mail *vigilance@dec.gov.ua*;

Appropriate healthcare structural unit in e-form to e-mail of appropriate healthcare structural unit.