Notification form for anaphylaxis following administration of contraceptives.

(To be completed by any physician administering the method and should be sent within 24 hours of the onset of the event to D.MCH,MO.MCH,MOH)

If you suspect an anaphylaxis (see definition of anaphylaxis at the end of page 2) related to a contraceptive, please complete this form. Do not put off reporting because some details are not known. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the anaphylactic reaction.

PATIENT IDENTIFICATION DETAILS			
Name:	Address:		Tel.no:
Date of birth: Age:	BHT number:	MOH Area	RDHS Area:
Past allergic history: Has patient had previous allergic reactions? ☐ Yes ☐ No If 'Yes', Allergen is a ☐Drug ☐Vaccine (specify) ☐ Food ☐ Other Specify details,			

Part I: Clinical features						
Onset of first symptom: Date (dd/mm/yy) Time: am/pm ☐ Unknown						
Skin & Mucosa	☐ Urticaria ☐ Erythema ☐ Pruritus ☐ Prickle sensation				Specify the site of skin reaction:	
	Eye	☐ Red bilateral ☐ Red unilateral ☐ Itchy				
	Angioedema	☐ Tongue ☐ Throat ☐ Uvula ☐ Larynx ☐ Lip ☐ Face ☐ Limbs ☐ Other				
Respiratory system	☐ Sneezing ☐ Rhinorrhea ☐ Sore throat	☐ Hoarse voice ☐ Stridor	☐ Sensation of throat closure ☐ Cough	☐ Tachypnea ☐ Difficulty in swallowing	☐ Wheezing ☐ In drawing / retractions ☐ Chest tightness	☐ Grunting ☐ Cyanosis ☐ Difficulty in Breathing
Circulatory System	☐ Measured hypotension (specify BP)		☐ Decreased central venous pulse		☐ Capillary refill time >3secs	☐ Tachycardia (specify rate)
CNS	☐ Loss of consciousness		☐ Distress	☐ Other(specify):		
GIT	☐ Diarrhea	☐ Nausea		☐ Abdominal pain/cramp		☐ Vomiting
Diagnostic Criteria for anaphylaxis	**☐ Rapid onset of occurrence of above sign & symptoms**			**☐ Two or more systems are affected**		

PART 2: SUSPECTED PRODUCT AND EXPOSURE INFORMATION		
Date & Time of contraceptive administration: Date(dd/mm/yy) Time : am/pm		
Drug : Oral ☐ Parenteral ☐		☐1st dose ☐2nd dose ☐3rd dose ☐4th dose ☐Other
Generic name :	Trade name :	Dose (specify units, mg, ml, mg/kg) and regimen
Batch/Lot number :	Expiry date :	
If parenteral contraceptive : ☐ Single dose ☐ Multi dose		
Route of administration: ☐ Oral ☐ IM ☐ SC ☐ Other(specify)		
Site of Administration: ☐ Deltoid ☐ Thigh ☐ Buttock ☐ Other (specify)		
Person who administered: ☐VOG ☐MO ☐ MOH ☐ PHNS/NS/ NO ☐ PHM ☐ Other (specify)		
Place of administration: ☐ Hospital Clinic ☐ Field Clinic ☐ Private Hospital ☐ GP ☐ Other(specify)		

Part 3: Management

Was Adrenaline administered? □ Yes □ No

If 'Yes', Route : □ IM □ SC □ IV □ Other (Specify)

Dose:.....ml

Place: □ Field Clinic □ Hospital Clinic □ Other (specify)

Time:.....am/pm

Person who administered adrenaline: □ VOG □ MO □ MOH □ PHNS/NS/NO

□ Other (specify)

Was a repeat dose of adrenaline given? □ Yes □ No	If 'Yes', describe
Were other medicines administered? □ Yes □ No	

Any other details concerning medicines/management (Including CPR)?

Part 4 Investigations (All relevant reports)

Blood for mast cell tryptase: □Yes □ No If 'Yes' specify the time interval after event:

(Note: Serum Tryptase levels peak 60-90 min after the onset of anaphylaxis and persist to 6h. 1st blood sample should be taken at ½ hour to 3 hours and second sample at 24 hours from the onset of the event.

Part 5: Outcome

Outcome: □ Full recovery □ Not fully recovered □ Recovered with sequelae
□ Death (date) .....
Specify details:

Part 6: Method administration errors: Did this adverse event occur following an incorrect administration of drug? □Yes □No □Unknown
If yes choose all that apply: □ Product expired □ Wrong dose □ Wrong drug □ Incorrect route
□ Other (Give details)

Part 7: Reporter Information

Name:	Designation:	Institute:
Signature	Date:	Telephone:

Send the filled form to Secretary, Safety of Medicines and Risk Evaluation Subcommittee (SAFRESC), Office of the Director MT&S 120, Norris Canal Road Colombo 10. Email: cdda@health.gov.lk.
Tel: +940112698896/7, Fax: +940112689704
Director/MCH- Family Health Bureau, De Saram Place, Colombo 10. Tel:+940112696677 Fax: +940112690790

Definition: Anaphylaxis is defined as rapidly developing, severe, life-threatening signs and symptoms of two or more of the following systems:
1. Skin and mucosa (including eyes and angio-edema of any site) 2. Respiratory system
3. Circulatory system 4.CNS 5.GIT