**FORM I**

| | |
|---|---|
| Complication other than anaphylaxis | |
| Contraceptive failure | |
| Poor quality | |

## Notification form for adverse events (other than anaphylaxis) following administration of contraceptives.

**1. Reporting Source**

Institution — Telephone no:

Designation of the reporting officer

**2. Information of the product/procedure**

Name of the product /procedure (OCP/DMPA/Implants/Condoms/LRT/Vasectomy)

Brand (If relevant) — Batch Number (If relevant)

**3. Information regarding the patient (if relevant)**

Name — RDHS area

Age (in years) — MOH division

Telephone number — PHM area

Address

Date of administration of the method — Date of appearance of symptoms

**4. Information regarding the service provider**

Government ☐ Private ☐ Non-Governmental Organization ☐

Name of the Institution/clinic

**5. Tick the event.**

| OCP | IUCD | Condom | DMPA | Implants |
|---|---|---|---|---|
| Allergy ☐ | Allergy ☐ | Allergy ☐ | Allergy ☐ | Allergy ☐ |
| Thromboembilism ☐ | Internal organ damage ☐ | | Abscess ☐ | Local infection ☐ |
| DVT ☐ | Perforation of uterus ☐ | | Minor local reaction/ local infection ☐ | Abscess ☐ |
| | Expulsion ☐ | | Severe local reaction ☐ | Local reaction ☐ |
| | Infection ☐ | | | Thromboembolism ☐ |
| | Vasovagal attacks ☐ | | | Difficult removal or missing rods ☐ |
| | | | | DVT ☐ |
| | | | | Expulsion ☐ |

**Other event:** ( e.g Contraceptive failures, quality failures, any clustering of events, any event occurring in unusual numbers, any hospitalization, any event of public concern and any event the informant thinks necessary to inform)

(Please describe): .....

**6. Outcome of the patient**

..... .....

**Signature & Designation of the Officer** **Date**

**Director/MCH - Family Health Bureau, No 231,De Saram Place,Colombo10**
**Tel;0112696677,0112681309, Fax 0112690790**
**Director/ MT & S - No 120,Norris Canal Road ,Colombo 10, Tel 0112698896/7, Fax 0112689704**
**Director/NDQAL - No 120,Norris Canal Road ,Colombo 10, Tel 0112687744, Fax 0112687742**

**Notification and investigation of an adverse event**

| | Event | Method and form | Time duration | Responsible officer to inform the event | To whom to inform |
|---|---|---|---|---|---|
| 1. | Anaphylaxis | 1) Over the phone | Within 6 hours | Any physician administering the method | D.MCH/FHB<br>MO.MCH<br>MOH |
| | | 2) Notification form for anaphylaxis following administration of contraceptives. | Within 24 hours | | |
| | | 3) Form II | Within 7 days | MO.MCH | D.MCH/FHB |
| 2. | 1.Any serious reaction other than anaphylaxis<br>2.Clustering of events | 1) Form I | Within 3 days | Any physician administering the method | D.MCH/FHB<br>MO.MCH<br>MOH |
| | | 2) Form II (Section 4) | Within 7 days | MOH | D.MCH/FHB<br>MO.MCH |
| 3. | Any minor reaction mentioned under sec. 5 of form I | 1) Form I | Within 14 days of notification | Any physician administering the method | D.MCH/FHB<br>MO.MCH<br>MOH |
| | | 2) Form II | Before the 5th of following month | MOH | D.MCH/FHB<br>MO.MCH |
| 4. | Suspected quality failure | 1) Over the phone | Within 6 hours | Any physician administering the method | D.MCH/FHB<br>D.MT&S<br>D.NDQAL<br>MO.MCH<br>MOH |
| | | 2) Form I | Within 3 days | | |
| | | 3) Drug sample for quality testing(complaint/surveillance) form | Within 7 days | | |
| 5. | Contraceptive failure | 1) Form I | Within 14 days | Any physician administering the method | D.MCH/ FHB<br>MO.MCH<br>MOH |
| | | 2) Form III | Before the 5th of following month | MOH | MO.MCH<br>(To be reviewed at MCH review) |

***Diagnostic criteria of anaphylaxis –**

**Rapid onset of 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**

***Lab confirmation of anaphylaxis -Collect two blood samples (2 cc ). First sample at ½ hour to 3 hours and second sample at 24 hours from the onset of the event. Centrifuge to separate the serum, and store in deep freezer until handed over to MRI. Send to MRI within 48 hours of collection**