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| [ ]  Initial report [ ]  Follow-up no      Date of information : | Country :Name of the LSO : | Local Case No.      Global Case No.       |
| **REPORTER INFORMATION** |
| **Name**      | **Address**      | **Phone no.**      | **Email**      | **Country**      |

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| **PATIENT INFORMATION** |
| **Patient initials**        | **Age**        | [ ]  Male [ ]  Female | Pregnant [ ]  Non [ ]  Yes, in week       |
| **Relevant medical history  / concomitant diseases** *(ex. Herpes, inmunological disease, skin infection, surgery or dental*)*List non extensive*      | Allergies[ ]  No [ ]  Yes | If Yes, please specify       |
| **Concomitant medication.** If applicable, please specify indication for any medication      | **Covid** disease [ ]  Yes [ ]  No Date of the positive results:Covid vaccine [ ]  Yes [ ]  No Date of the first vaccine injection:  Date of the second vaccine injection: Date of the third vaccine injection:Type of vaccine: [ ]  Pfizer [ ]  Moderna [ ]  AstraZeneca [ ]  J&J/Janssen [ ]  Other:………..   |
| **Previous aesthetic procedures**? [ ]  Non [ ]  Yes 🡪 Please specifiy in the columns below |
| **Dermal filler (please precise), botulinium toxine, surgery,…** | **Area treated** | **Date of the treatment** |
|       |       |       |
|       |       |       |
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| TREATMENT with Produc(s) suspected to have caused or contributed to the adverse event |
| Product(s) / Trade name | Lot No. / Exp date | Area(s) treated | Indication/reason for use | Injection technique(s) and needle used  | Amount (ml) | Date of treatment (dd-mm-yyyy) |
|  |  |  |  |  | Left | Right |  |
|       |       |       |       |       |      |      |       |
|       |       |       |       |       |      |      |       |
|       |       |       |       |       |      |      |       |
| ADVERSE EVENT INFORMATION |
| **Adverse Event(s) description** | **Area(s) affected** | **Side****(L**eft**, R**ight) | **Start date(s)**(dd-mmm-yyyy) | **Stop date(s)**(dd-mmm-yyyy) or duration | **Severity** | **Causality to the treatment** | **Outcome** |
|  |  |  |  |  | Mild | Mod | Sev | Pos | Unl | NA | Rec | RwS | Imp | Ong |
|       |       |  |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |  |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       |       |  |       |       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **Please tick appropriate boxes** for Severity (**Mild** – **Mod**erate - **Sev**ere), Causality (**Pos**sible – **Unl**ikely - **N**ot **A**ssessable/not yet assessable) and Outcome. (**Rec**overed – **R**ecovered **w**. **S**equelae – **Imp**roving – **Ong**oing). If recovered with sequelae, please specify: |
| **Did the complaint lead to any of the following below? Please tick all that apply.** | **If not yet assessable tick here:** [ ]  |
| Hospitalisation or significant prolongation of hospitalisation? | [ ]  No | [ ]  Yes, For how long? |  | Was the intervention or hospitalisation required to prevent a life-threatening condition, permanent impairment of a body function or permanent damage to a body structure.  No [ ]  Yes [ ]  |
| Medical or surgical intervention for treatment of the adverse event(s)? | [ ]  No | [ ]  Yes, specify in the table below |  |  |
| Permanent impairment of a body function or permanent damage to a body structure?  | [ ]  No | *[ ]*  Yes |
| Foetal distress, foetal death, congenital abnormality, birth defects?  | [ ]  No | *[ ]*  Yes |
| Death | [ ]  No | *[ ]* Yes, date: |
| Medication(s) / Intervention(s) / Product Removal / Retreatment(s) | Dosage | Start date | Stop date | Treatment ongoing | Results of treatment(s) |
|       |       |       |       | *[ ]*  |       |
|       |       |       |       | *[ ]*  |       |
| **Additional information – concerning the adverse event(s) – e.g., course of event(s) including a description of signs and symptoms.** |
|       |

Signature of the reporter Date of the report