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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 | |  | | | | | |
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| 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 |
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| **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) | | | | | | | | | | | | |
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| **Additional information – concerning the adverse event(s) – e.g., course of event(s) including a description of signs and symptoms.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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Signature of the reporter Date of the report