| **Report Form for Product Complaints and suspected Adverse Effects / Reactions** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Medicinal Product | Cosmetic Product | | Biocide | | Technical Product | | Others |
| Initial  Follow-up information to case No.: | | | | | | | |
| **Reporter / Customer information:** | | | | | | | |
| ***Reporter name (mandatory):*** | |  | | | | | |
| Customer name / number / contact | |  | | | | | |
| Customer address:  (street, ZIP code, town, country) | |  | | | | | |
| Customer phone / fax / e-mail: | |  | | | | | |
| **Product information:** | | | | | | | |
| ***Product name (mandatory)*** / the article no. / size / amount: | |  | | | | | |
| ***Batch-no. or Serial-no.*** ***(mandatory in case of product complaint)*** / Expiry date: | |  | | | | | |
| ***Description of the complaint / adverse effect / drug reaction (mandatory)*** Date of onset / occurrence: | | | | | | | |
| Product applied / used from – till: | |  | | | | | |
| Another product used previously / before?  (If yes, which product?) | |  | | | | | |
| Product / Sample | will be returned  is available  is not (anymore) available | | | | | | |
|  | | | | | | | |
| **Patient information in case of suspected adverse effect (AE) / drug reaction (ADR):** | | | | | | | |
| ***Gender (mandatory):*** | male  female | | | Initials: | |  | |
| Age / Date of birth: |  | | | Weight / Height: | | kg       cm | |
| Reason for use: |  | | | Route of application: | |  | |
| Further persons affected? | yes  no | | | If yes, how many? | |  | |
|  | | | | | | | |
| **Suspected adverse effect (AE) / drug reaction (ADR) information:** | | | | | | | |
| Contact details of involved physician / pharmacist (name / address / e-mail / phone / fax): | | | | | | | |

|  |  |  |
| --- | --- | --- |
| Progress of adverse effect / drug reaction and therapy: (if applicable, use attachment) Life threatening?  yes  no | | |
| **Following action was taken:**  surgical intervention   hospitalisation  prolongation of hospitalisation  none of them | **Final outcome of the AE /ADR:**  unknown  recovered   not yet recovered   irreversible damage   death (date): | **Reaction relation to product:**  definitely  probable  possible  unlikely  not assessable |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Further information relevant for case evaluation:** | | | | |
| e.g. underlying diseases (e.g. allergy, skin diseases), pregnancy, concomitant medication, laboratory data, test results (if applicable, use attachment) | | | | |
| Who was informed :  manufacturer /  MAH /  local authority /  others: | | | | |
| **Received by schülke / contractual partner (name, date, signature) *(mandatory)*:** | |  | | |
| **Transfer to:** | **E-mail:** bezpieczenstwo.sm@schuelke.com | | **Phone:** +48 661 333 385 | **Fax:** +48 22 1160701 |
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