| **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 |
|  |