IRISH MEDICINES BOARD

Regulation 1223/2009

Impact on Distributors

Camden Court Hotel, 29.03.12

Orla Barry

Contents

1. Definition of a Distributor

2. Articles within Regulation 1223/2009 which specifically apply to Distributors

3. Best practices for Distributors in implementing the legislation

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Distributor

‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market

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Regulation (EC) No. 1223/2009

Article 4	Responsible Person	- Modify - Under distributor name
Article 6	Obligations of Distributors	- Due care - Labelling checks - Storage & Transport - Communicate non-compliances - Take corrective measures
Article 7	Identification within the supply chain	- Identify from whom products were received - Identify to whom products are sold
Article 13	Notification	- Modify labelling - Introduce product to market which is no longer notified by RP
Article 19	Labelling	- Language requirements - Expiry date
Article 23	Communication of serious undesirable effects	- Notify IMB & Responsible Person
Article 26	Non-compliance by distributors	- Corrective measures - Withdrawal / recall

Article 4 - Responsible Person

- Modify product
- Sell product under own name

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Article 5 - Responsible Person Obligations

Consumer information

Sampling & Analysis

SAFETY ASSESSMENT

GMP

PIF

Animal testing

NOTIFICATION

Communication of Serious Undesirable effects

Product claims

Labelling

Restrictions on substances

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Obligations of Distributors

Check labelling

Transport & Storage

Co-operation

Due Care

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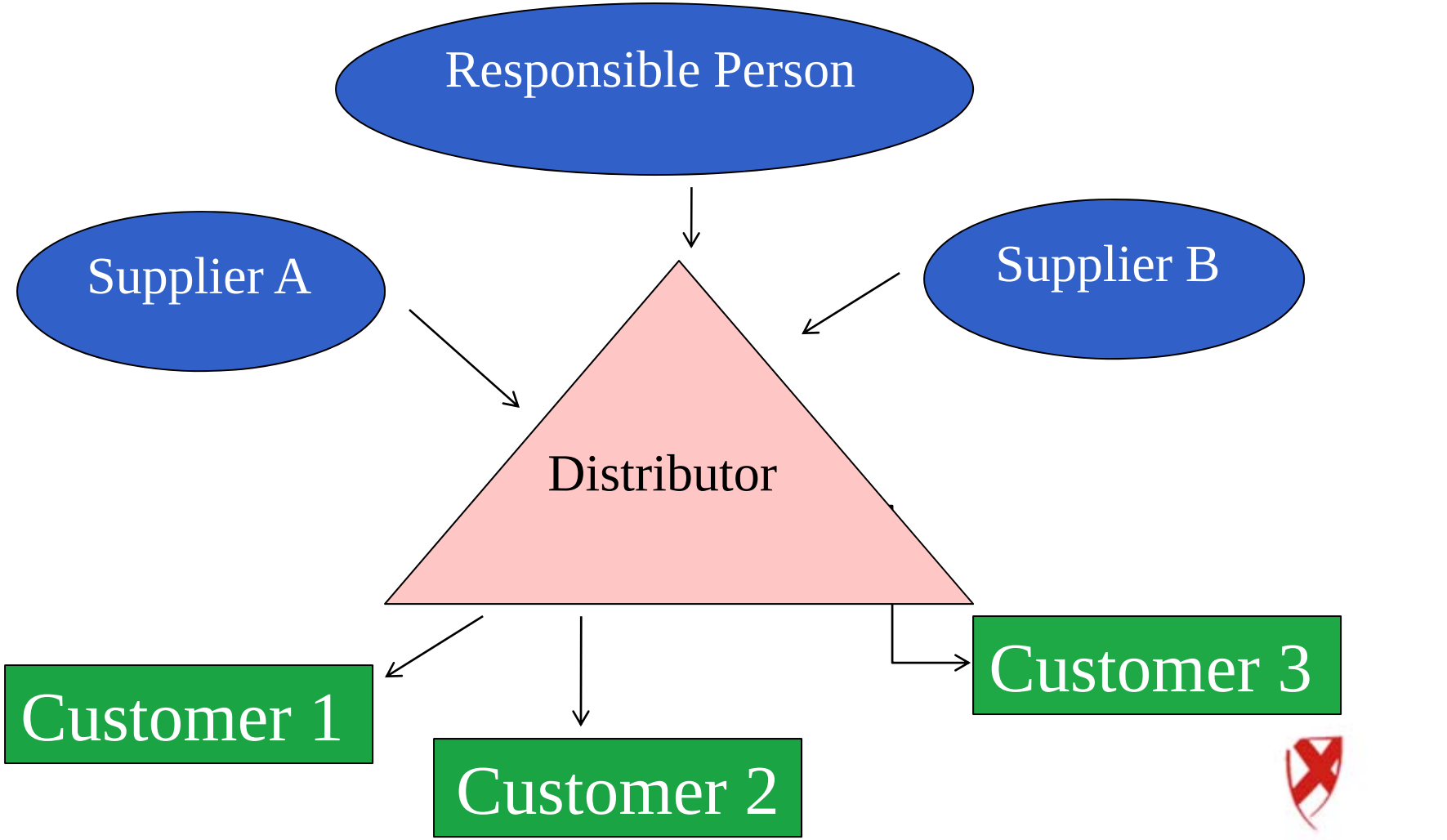
Article 7 - Identification within the supply chain



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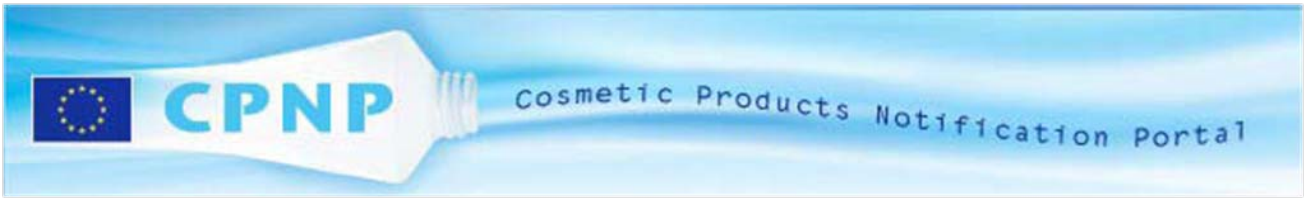
Article 13 – Notification

Cosmetics Product Notification Portal (CPNP).

- http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp_new_en.pdf



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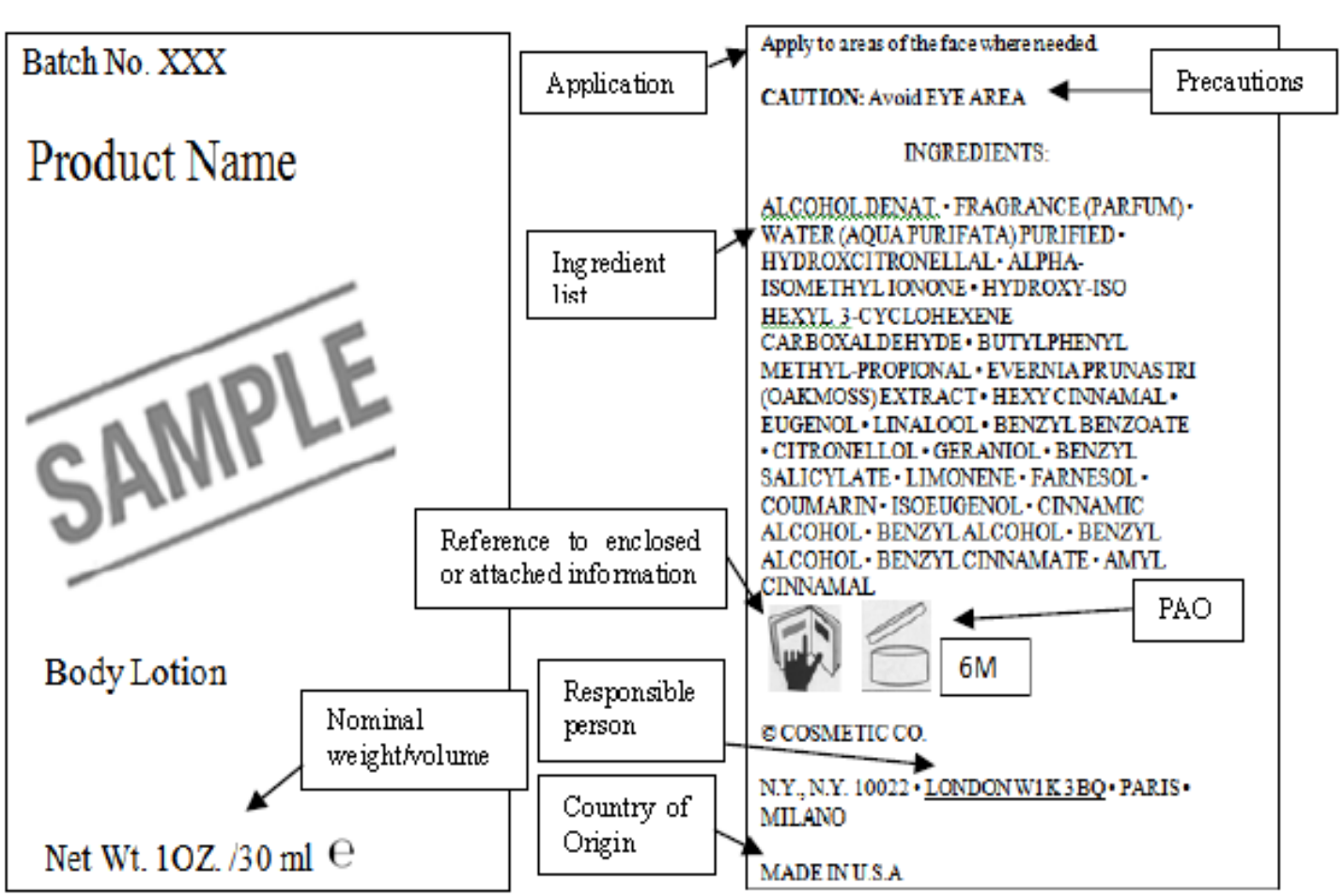
Article 19 - Labelling



(nano)

Label Check

- RP address?
- Is there a batch number?
- List of ingredients?
- Is a label, tag, tape or card required?
- Any other point of sale requirements?
- Language?
- Has the product expired?

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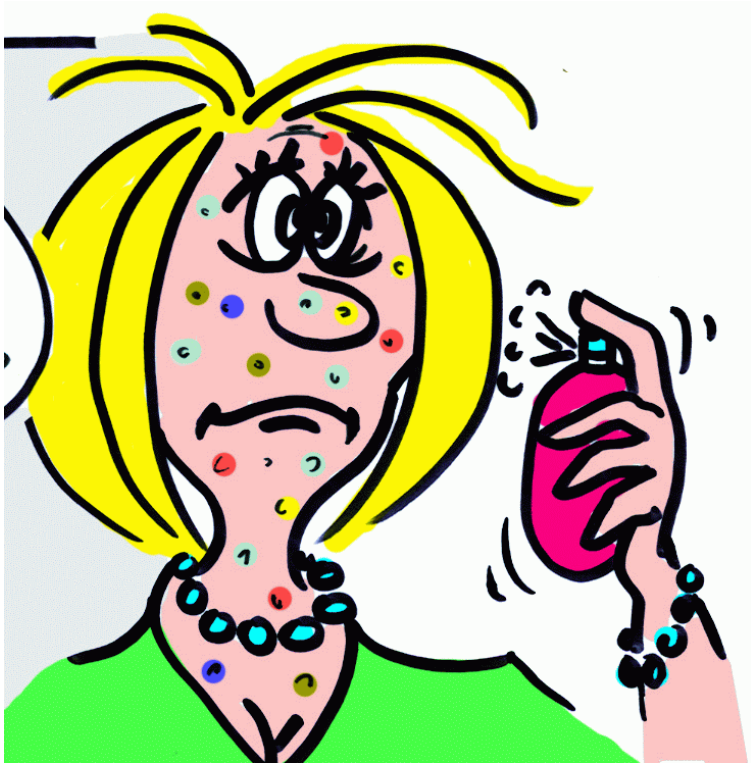
Article 23 - Serious Undesirable Effects

Article 2. para. 1. (p)
'serious undesirable effect'

means an undesirable effect which results in temporary or permanent

- ❑ Functional incapacity,
- ❑ Disability,
- ❑ Hospitalisation,
- ❑ Congenital anomalies or
- ❑ An immediate vital risk or
- ❑ Death



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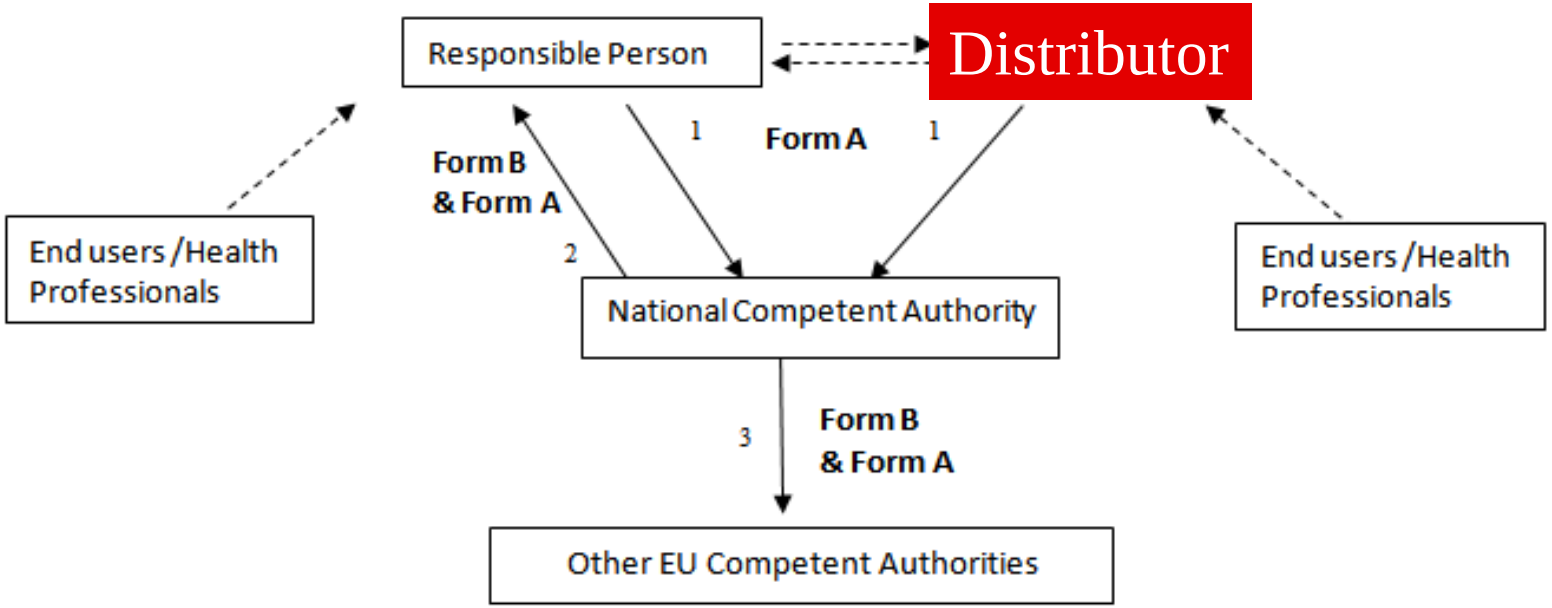
Article 23 - Serious Undesirable Effects

Flowcharts for notification scenarios

1. **SUE initially received by the Responsible Person or the Distributor**



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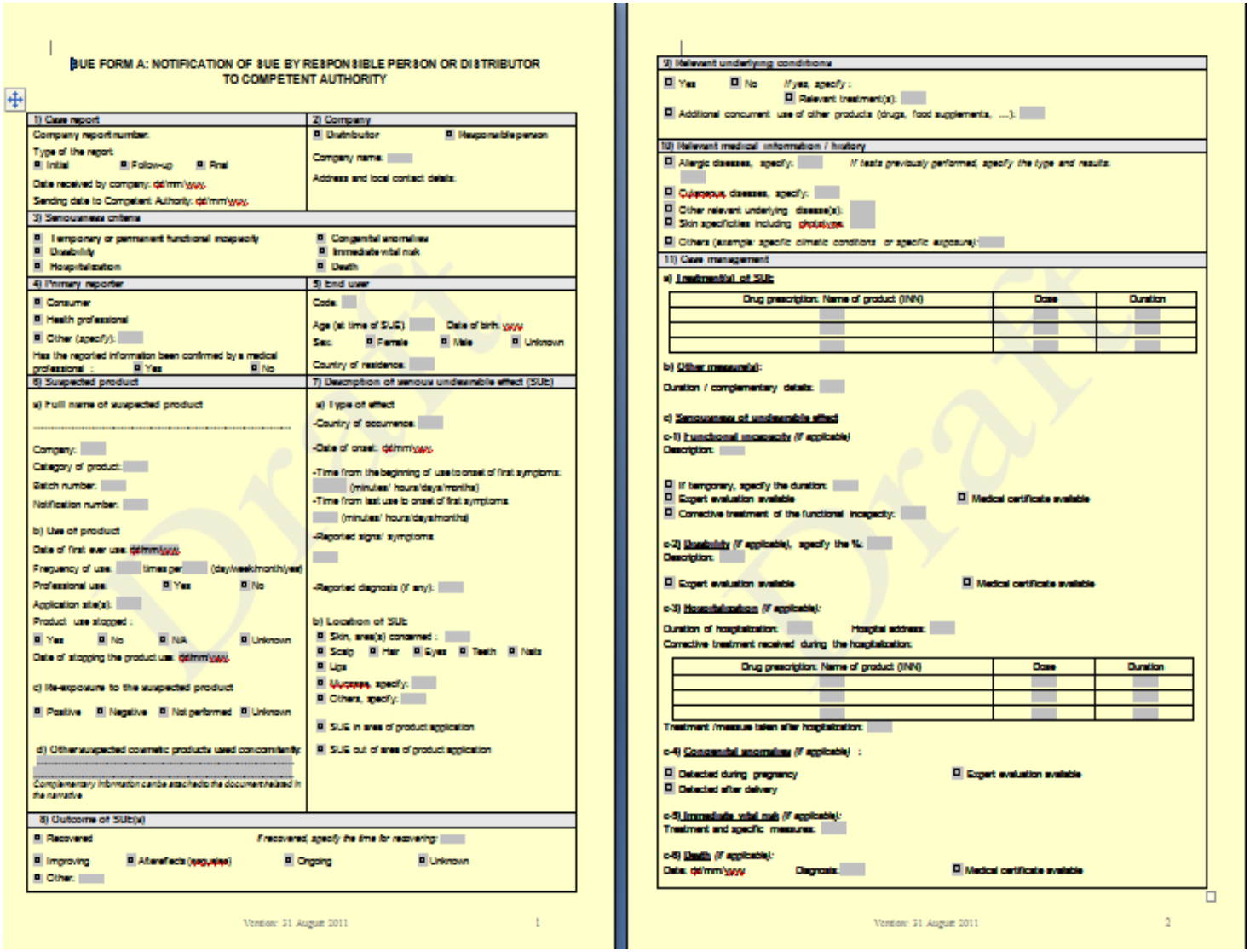
Article 23 - SUE Form A



SUE FORM A: NOTIFICATION OF SUE BY RESPONSIBLE PERSON OR DISTRIBUTOR TO COMPETENT AUTHORITY

1) Case report	2) Company
Company report number: Type of the report: ☐ Initial ☐ Follow-up ☐ Final Date received by company: dd/mm/yyyy Sending date to Competent Authority: dd/mm/yyyy	☐ Distributor ☐ Responsible person Company name: Address and local contact details:

3) Seriousness criteria

- ☐ Temporary or permanent functional incapacity
- ☐ Disability
- ☐ Hospitalisation
- ☐ Congenital anomalies
- ☐ Immediate vital risk
- ☐ Death

4) Primary reporter	5) End user
☐ Consumer ☐ Health professional ☐ Other (specify): Has the reported information been confirmed by a medical professional : ☐ Yes ☐ No	Code: Age (at time of SUE): Date of birth: yyyy Sex: ☐ Female ☐ Male ☐ Unknown Country of residence:

6) Suspected product	7) Description of serious undesirable effect (SUE)
a) Full name of suspected product ..... Company: Category of product: Batch number: Notification number: b) Use of product Date of first ever use: dd/mm/yyyy Frequency of use: times per (day/week/month/year) Professional use: ☐ Yes ☐ No Application site(s): Product use stopped : ☐ Yes ☐ No ☐ NA ☐ Unknown Date of stopping the product use: dd/mm/yyyy c) Re-exposure to the suspected product ☐ Positive ☐ Negative ☐ Not performed ☐ Unknown d) Other suspected cosmetic products used concomitantly: .... *Complementary information can be attached to the document related in the narrative*	a) Type of effect -Country of occurrence: -Date of onset: dd/mm/yyyy -Time from the beginning of use to onset of first symptoms: (minutes/ hours/days/months) -Time from last use to onset of first symptoms: (minutes/ hours/days/months) -Reported signs/ symptoms: -Reported diagnosis (if any): b) Location of SUE: ☐ Skin, area(s) concerned : ☐ Scalp ☐ Hair ☐ Eyes ☐ Teeth ☐ Nails ☐ Lips ☐ Mucosae, specify: ☐ Others, specify: ☐ SUE in area of product application ☐ SUE out of area of product application

8) Outcome of SUE(s)

☐ Recovered — *If recovered, specify the time for recovering:*
☐ Improving ☐ Aftereffects (sequelae) ☐ Ongoing ☐ Unknown
☐ Other:

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9) Relevant underlying conditions

☐ Yes ☐ No *If yes, specify :*
☐ Relevant treatment(s):
☐ Additional concurrent use of other products (drugs, food supplements, ...):

10) Relevant medical information / history

☐ Allergic diseases, specify: *If tests previously performed, specify the type and results:*
☐ Chronic diseases, specify:
☐ Other relevant underlying disease(s):
☐ Skin specificities including photosensitivity
☐ Others (example: specific climatic conditions or specific exposure):

11) Case management

a) Treatment(s) of SUE:

Drug prescription: Name of product (INN)	Dose	Duration

b) Other measure(s):
Duration / complementary details:

c) Seriousness of undesirable effect

c-1) Functional incapacity (if applicable)
Description:

☐ If temporary, specify the duration:
☐ Expert evaluation available ☐ Medical certificate available
☐ Corrective treatment of the functional incapacity:

c-2) Disability (if applicable), specify the %:
Description:

☐ Expert evaluation available ☐ Medical certificate available

c-3) Hospitalisation (if applicable):
Duration of hospitalization: Hospital address:
Corrective treatment received during the hospitalization:

Drug prescription: Name of product (INN)	Dose	Duration

Treatment / measure taken after hospitalization:

c-4) Congenital anomalies (if applicable) :
☐ Detected during pregnancy ☐ Expert evaluation available
☐ Detected after delivery

c-5) Immediate vital risk (if applicable):
Treatment and specific measures:

c-6) Death (if applicable):
Date: dd/mm/yyyy Diagnosis: ☐ Medical certificate available

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Article 26 – Non-compliance by Distributors

Requirement to take appropriate measures

- Corrective measures
- Withdrawal / recall

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Best Practice for Distributors

- Quality Management System
- Assurance of product quality
- Goods in Checks
- Documentation & Record Keeping
- Labelling Checks
- Regular Stock Review & House Keeping
- Maintenance of Appropriate Storage Environment
- Good Out Checks
- Corrective Actions
- Recalls/Withdrawals
- Reporting Serious Undesirable Effects

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Quality Management System

A Quality Management system includes:

- Written procedures (SOPs)
- Documentation & Records
- Product traceability
- Training
- Self-inspection
- Continuous Improvement

Purpose: to ensure Quality & Safety

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Assurance of product quality

- Reputable Supplier
- Safety
- Traceability
- Responsibilities

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Technical Agreement

- Relationship of parties & contact details
- Products concerned
- Transportation
- Inspection and Acceptance Criteria
- Traceability Requirements
- Responsibilities in terms of:
  - recall/withdrawal procedures,
  - handling returns,
  - complaints and/or undesirable effects
- Packaging & Storage Requirements

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Goods In Checks

- ✓ Labelling checks
- ✓ Record of batch number
- ✓ Consignment received from an approved supplier
- ✓ Storage conditions
- ✓ Check the purchase order against the invoice and the goods received

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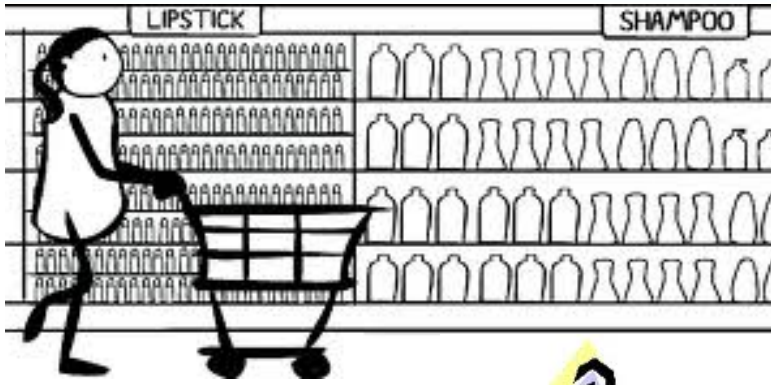
Documentation & Record Keeping



- Invoices /Delivery Dockets
- First In/First Out
- Register of customers
- Records of checks carried out
  - Goods in checks
  - Labelling Checks
  - Approval of product into saleable stock
- Standard Operating Procedures
- Training records

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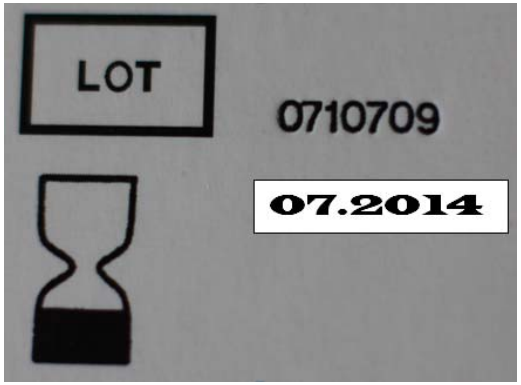
Goods Out Checks



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Corrective Actions

Re-Label

Agree Modifications with RP

Update precautions

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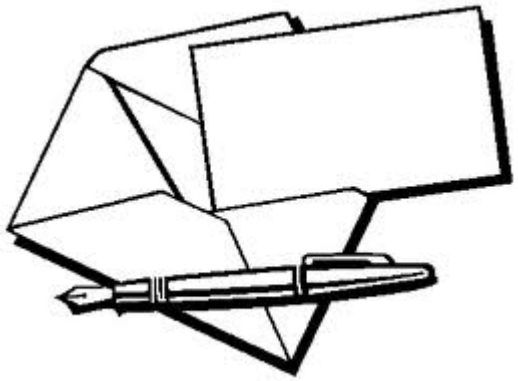
Recall/Withdrawal



- Mechanism of communication
- Agree recall letter with IMB
- Timelines
- Assign person responsible for:
  - Recording, Monitoring and Reconciling stocks
  - Facilitating liaison between the RP, manufacturer, distributor, EHOs and IMB
- Quarantine area

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Recall/Withdrawal Summary Report

- Reason for withdrawal/recall
- Product details
- Basis on which the recall is being made (e.g. voluntary)
- List of customers supplied with the affected product
- Extent of withdrawal/recall (distributor /retail /consumer level)
- Copies of notification letters
- Date of close out of withdrawal/recall
- The total quantity of packs placed on the market
- The total quantity of packs recovered

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