Distributors Roles and Responsibilities under the new EU Cosmetics Regulations

1. Definition

Article 2 of the Cosmetics Regulation 1223/2009 defines distributors as *"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"*

The definition is very wide and covers any company or person supplying cosmetic products (in return for payment or free of charge) on the community market for:

- Distribution;
- Consumption; or
- Use.

e.g.: Wholesalers, retailers, shops, beauty or hair salons, telesales, outlet, etc.

Distributors may be involved in very different activities; they can be acting in the wholesale trade as well as selling directly to the consumer for example. This has an impact on the way they fulfil their obligations. The recitals of the Regulation make clear that distributors' obligations should reflect the respective roles and particular activities of each of these operators.

The safety of each cosmetic product placed on the market is the duty of the Responsible Person. In most cases, the Responsible Person is the 'manufacturer' or importer

2. General Duty of Care

> *"In the context of their activities, when making a cosmetic product available on the market, distributors shall act with due care in relation to applicable requirements"*
>
> [EU Cosmetics Regulation Article 6]

This requirement applies to:

- Product Safety
- Labelling
- Notification
- Communication
- Transport and storage

Distributors should provide consumers with safe products. To achieve this goal they are required to:

- verify or check some elements of the labelling,
- take appropriate measures in certain situations, and
- communicate with Competent Authorities and the Responsible Persons.

Distributors are **not** required to assess the safety of cosmetics by checking or asking to see the Product Information File (PIF). The Regulation does not change the fact that the Responsible Person is the one that should guarantee that the product is safe. The Responsible Person is the one that ensures the safety of the product and makes the PIF accessible to the Competent Authority. The PIF contains confidential information and is the property of the Responsible person. Distributors are not required to access / verify the PIF.

If Distributors consider or have a reason to believe a cosmetic is not in compliance with the Regulation, they shall not supply the product. If the product has already been supplied, they should make sure that the corrective measures are taken to bring that product into conformity, to withdraw it or recall it, as appropriate.

If a product presents a risk to human health, the distributor has the obligation to inform both the Responsible Person and the Competent Authorities providing them with details of the non-compliance and corrective measures taken.

In such a scenario, best practice would be for the distributor to work in close collaboration with the Responsible Person. The Responsible Person has the necessary qualification and expertise to assess whether a risk exists and to determine the appropriate corrective measures in conjunction with Competent Authorities. Without this expertise it would be very difficult for the distributor alone to fulfil its safety obligation.

Very similar requirements are already in place under the General Product Safety Directive.

Labelling requirements

Distributors have a duty to check that the information below is present on the product label:

- Name & Address of the Responsible Person
- Batch number
- List of Ingredients

and, if applicable, any 'off pack ingredient notice' accompanies the product.

Before supplying the product to any EU country, distributors must ensure that the product complies with the language requirement established by the relevant national law.

Distributors must not supply cosmetic products that have passed their 'Best Before' date.

Upon request by a competent authority, distributors must demonstrate that the product complies with the labelling requirements above, e.g. by providing copies of the labels or other documentation.

The Regulation is very specific on what must be checked by the distributor. The distributor is not required to check other information on pack. Distributors are not responsible for the overall compliance of the product labelling, in particular when it relates to accuracy of the information. This is a sensible approach as the distributor does not have all the necessary data to ensure that all elements of the labelling are correct.

However, if a distributor considers or has a reason to believe that a cosmetic is not in compliance with the Regulation, it has a duty to contact the Responsible Person. In this situation the distributor should not supply the product until the issue has been resolved.

This requirement should be carefully interpreted. The Regulation does not require distributors to routinely request information on the accuracy of the labelling. This should be done **only** if there is reason to believe that the product is non-compliant.

… Practical examples …

S1. The cosmetic product does not have a Batch Number

Distributors should question the Responsible Person. It is worth noting that Batch number may not be required to be labelled in some circumstances.

S2. Warnings are not labelled in the local language where the product will be available.

It is the distributor's responsibility not to supply this product. If he wants to do so, he will need to ensure that corrective measures have been taken to be fully compliant.

S3.The product does not indicate the Country of Origin

There is no obligation for the distributor to check whether this product is made within the EU.

S4. The product does not have a 'best before' date labelled on pack

The obligation to check whether the date has passed is only relevant if the product is labelled with this information.

S5. Cosmetic product supplied with no packaging (soap, bath balls …) subject to a labelling notice at the point of sale.

The labelling material should be provided by the Responsible Person and distributors must ensure this is passed down the supply chain or, if selling to the final consumer, make sure the information is available at the point of sale.

Notification of finished cosmetic products

The new Cosmetic Regulation has put in place a single notification system where Responsible Persons are requested to notify their finished products via the European Cosmetic Product Notification Portal (CPNP) before placing them on the EU market.

In general, distributors are not required to notify cosmetic products prior to making them available to the consumer. However, under Article 13.3, there is one scenario when distributors have the duty to notify their product before making it available. This is the situation when a distributor decides to supply a cosmetic product to another Member State and to do so, translates the labelling.

… In Practice …

1 A UK distributor buys a product to sell it to UK consumers. The product is labelled in English, French and German.

(a) If the distributor decides in the future to sell it to Germany, because they do not have to change the labelling, a notification is not required

(b) An Italian distributor buys this product from the UK distributor to make it available in Italy. To comply with the Regulation the Italian distributor will translate the labelling and notify the product via the CPNP.

2 A UK distributor buys a product to sell it to the UK consumers. The product is not labelled in English. The product is therefore not suitable for the UK market and should not be made available until actions have been taken to make the product compliant with the UK requirements. Two scenarios are possible:

(a) The Distributor may ask the Responsible person to take the appropriate measure to correct the labelling.

(b) If the Responsible Person refuses to do so for any reason, i.e. there is no commercial relationship between the two entities, the distributor should amend the product labelling and notify the product via CPNP.

For notification distributors should provide:

- The category of cosmetic product
- The product name in the Member State of dispatch
- The product name in the Member State in which it is made available - enabling its specific identification
- The Member State in which the cosmetic product is made available
- Distributor's name and address
- The name and address of the Responsible Person where the Product Information File is made readily accessible

CTPA Guidance on registering to use the CPNP is available. (http://www.ctpa.org.uk/content.aspx?pageid=377)

In order to ensure that all products placed on the market are notified under the CPNP, the Regulation has established a specific requirement for distributors, re-introducing a cosmetic product on the EU market under Article 13.4.

This is the scenario when a distributor decides to make a product available which is not being placed on the market by the Responsible Person on 11 July 2013, i.e. a discontinued product.

… In practice …

This situation will not be common. It will be the case if, for instance, a distributor has kept old stock of a product which is no longer placed on the market by the Responsible Person on 11 July 2013 and the distributor decides to supply it again to use up its stock.

This product would not have been notified by the Responsible Person under the CPNP. In order to ensure that this product will be subject to a notification or that information is already accessible to poison centres, distributors are required to communicate with the Responsible Person.

The distributor should inform the Responsible Person of its initiative and should indicate the EU countries where the product will be available. Once the information is received by the Responsible Person, if the product has not previously been notified in those particular countries (under the old Cosmetics Directive) the Responsible Person has the duty to notify this product on the CPNP.

Notification of Nanomaterials

Distributors do not have any role or obligations which relate to the notification of nanomaterials.

Transport and Storage

Distributors should take all the appropriate steps to ensure that the safety of the product cannot be jeopardised during transport and storage. This obligation is a transposition of both:

- The EC guide to the implementation of directives based on the New Approach and the global approach
- The International Practices under the UN Conventions on contracts for the International Sale of Goods

… In Practice …

Finished cosmetic products are exempt from the legislation requiring the provision of a 16-point Safety Data Sheet (SDS), sometimes referred to as Material Safety Data Sheets (MSDS).

For some products, guidance regarding specific storage requirements may be obtained from the information intended for the end users in relation to the product's durability. Distribution agreements concluded with the suppliers may also contain specific references or requirements concerning the appropriate conditions for the storage of cosmetic products.

In the UK

There are legal requirements under Health and Safety legislation. A person to whom a substance is supplied should be provided with adequate information about the substance, so that it can be used and disposed of safely. Also, under the COSHH (Control of Substances Hazardous to Health) Regulations, an employer is required to assess work involving "substances hazardous to health" and to consider the risks. Companies which store or transport cosmetic products may also ask for information.

CTPA has developed a Position Paper explaining the legal requirements and offers advice on how best to provide the information required for certain establishments to carry out their risk assessments. (http://www.ctpa.org.uk/content.aspx?pageid=435)

Communication along the Supply Chain

Ensuring the traceability of cosmetic products throughout the whole supply chain helps to make surveillance simpler and more efficient.

An efficient traceability system will facilitate the withdrawal of an unsafe products and enable Competent Authorities to be provided with specific and accurate information for identifying the product concerned.

Distributors should be able to identify the company from whom they have bought or obtained the product (either a distributor, manufacturer or importer) and to whom they are supplying the product (other distributors). The obligation does not extend to identifying the final consumers. The information should be kept for a period of 3 years starting after the day of the last delivery of the product made available to other distributors.

Information should be shared with the Competent Authority upon request.

… In practice …

There is no specific format or system prescribed by the Regulation. The only requirement is that the information should be easily found and passed on to the Competent Authority. Companies may for instance:

- Keep invoices
- Provide delivery statements

There is no specific requirement to store this information by batch number or to record batch numbers.

Post Marketing Surveillance

Due to their activity and involvement, distributors are part of the post marketing surveillance system. They have obligations under the General Product Safety Directive and under the Cosmetics Regulation.

Distributors have a duty to take appropriate measures in case of non-conformity with the obligation laid down in article 6 of the Cosmetics Regulation within a given reasonable time limit. The corrective measures should be commensurate with the nature of the risk.

These can be:

- Making the product compliant
- Withdrawing products
- Recalling products

1. Risk to human health

Under Articles 6.3 and 6.5, when a product presents a risk to human health, distributors have the obligation to work in collaboration with the Responsible Person and with the Competent Authority of the EU country where the product is sold.

In this specific situation, the Regulation requires distributors to:

- Immediately inform the Responsible Person
- Immediately inform the Competent Authority
- Cooperate with Competent Authority on any action to eliminate the risk posed by the product.

… In practice …

It may be difficult for distributors to assess whether a product is presenting an actual risk to human health as they do not have all the knowledge relating to the product. In this situation, the distributor should ensure that the Responsible Person is involved in the process. The Responsible Person, as the PIF holder, has the expertise to assess the risk and would be the key person to be able to put in place the necessary corrective measures.

The key principle is that all products made available to consumer should be safe. If a consumer is likely to be exposed to a risk due to the use of a cosmetic product, all stakeholders should work together to resolve the issue.

2. Serious Undesirable Effect

It is very important to differentiate between "risk to human health" and "Serious Undesirable Effect (SUE)". A risk to human health will have an impact on all consumers whereas a SUE will affect one particular consumer (e.g. with allergies to certain substances). Sometimes, a consumer using a cosmetic under the normal and foreseeable use may experience an adverse reaction which results in "temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or immediate vital risk or death" [article (2) – Definitions]

This does not mean that the product is unsafe or poses a risk to human health. In general these unfortunate events are often linked to underlying conditions of the individual.

In the event of Serious Undesirable Effects, Article 23 requires distributors notify the Competent Authority where the SUE took place, without delay. They should provide:

- SUE
- The name of the cosmetic
- The corrective measure taken if any

When a Serious undesirable Effect is reported a specific assessment should be carried out to determine whether the event is serious. Companies should:

- Verify the existence of the undesirable effect and the conditions under which the product was used
- Verify the level of causality between the product and the undesirable effect
- Determine the seriousness of the undesirable effect

Only SUEs within the meaning of Article 23 have to be notified.

… In practice …

Distributors, and in particular retailers, may be contacted by consumers who experience an adverse reaction. If this happens, distributors may find it difficult to assess whether this reaction is serious and is linked to the product. It may therefore be a challenge for them to know whether they should notify this event to the Competent Authority. The most qualified person to carry out the assessment is the Responsible Person. In this situation it is important that distributors and the Responsible Person work together. It will improve the market surveillance system and will ensure a coordination of the notifications.

Guidance on SUE reporting is available from the European Commission's cosmetics website:

http://ec.europa.eu/consumers/sectors/cosmetics/index_en.htm.