MEDICAL PRODUCTS AGENCY
[*LÄKEMEDELSVERKET*]

Market surveillance Programme 2016

Cosmetics

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Background

The Member States are required to apply Community legislation. In accordance with Article 10 of the EC Treaty, Member States shall take all appropriate measures to ensure fulfilment of the obligations arising out of the Treaty. Market surveillance is an important tool for monitoring compliance with the Directive.

The concept of market surveillance is defined in Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance:

''market surveillance' shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.'

The definition therefore covers all of the different activities carried out by an authority to verify whether a good/product is safe and complies with the requirements of the regulations when it is placed/put on the market. Such surveillance may take place at any time during a product's life cycle but is designed to verify whether the product meets the requirements stipulated in the regulations when it is placed on the market. Market surveillance also includes the measures that the authority may need to take in order to ensure that the regulations continue to be applied correctly. The aim of market surveillance is to safeguard the interests of users and to prevent unfair competition from rogue operators in the market.

The requirement for market surveillance by the Member States appears in Article 16(2) of Chapter III of Regulation (EC) No 765/2008:

1. Member States shall organise and carry out market surveillance as provided for in this Chapter.

2. Market surveillance shall ensure that products covered by Community harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly.

3. National market surveillance infrastructures and programmes shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation.

By virtue of its responsibility for market surveillance, the Medical Products Agency must also establish a market surveillance programme under the EC Regulation setting out the requirements for accreditation and market surveillance (765/2008) Article 18(5). This programme is submitted to the Government Offices of Sweden [*Regeringskansliet*] every year and must be made available to the public in electronic format or in another appropriate way.

Organisation

Market surveillance is carried out within the three product areas falling within the Medical Products

Agency's jurisdiction: Medicines, Medical Devices and Cosmetics. Most of the surveillance activities fall under the umbrella of Supervision.

Supervision strategy

Supervision by the Medical Products Agency is based on user safety by virtue of requirements that are laid down by the Swedish Parliament and the European Parliament, any needs and alerts from parties such as consumers, patients, the industry, the care sector, and other authorities, and the fact that quality and safety requirements for products and systems are being developed continuously. By working with risk-based selections, supervision is carried out where it is most effective and yields the greatest benefit for patients and consumers. The implementation of supervision must be communicated clearly and create trust. The observations that the Medical Products Agency makes during supervision are acted upon and form the basis for lessons and feedback through our communication with businesses and trade organisations and our information to patients and consumers.

1 General goals of market surveillance

The regulations for cosmetics have been developed in the EU since the 1970s, and the provisions were transposed into Swedish law when Sweden acceded to the EU. The form of the legislation changed from Directive to Regulation in 2013. The underlying principle of the legislation on cosmetic products is that these must be safe to use with regard to human health.

2 Specific goals of market surveillance

2.1 General conditions

The Cosmetic Products Ordinance states that the primary responsibility for ensuring that products are not harmful lies with the manufacturer or the manufacturer's representative, or with the 'responsible person'. The provisions impose special requirements in the following areas:

- certain substances are prohibited entirely, or restricted;
- only substances which have been tested and approved may be used as dyes, preservatives or UV filters;
- comprehensive product documentation must be available from the responsible person (manufacturer or importer);
- the labelling on packages must include certain specified details;
- notification of operations and products must be submitted to the central European register (CPNP) (Cosmetic Products Notification Portal).

In order for the legislation to have the desired effect, the Member States must take all necessary measures via the competent supervisory authority to ensure that the products placed on the market pose no risk to human health.

2.2 The concept of market surveillance

This implies an obligation for Member States to organise and conduct market surveillance in a way that is effective and sufficiently extensive to identify non-compliant products.

The Medical Products Agency, as the competent authority for cosmetic products, is responsible for organising and carrying out the necessary market surveillance and for providing supervisory guidance to the country's local authorities, which act as the local supervisory authorities.

3 Legal basis

3.1 The role of the Medical Products Agency within the sector

The Medical Products Agency and the local authorities are responsible, on the basis of the Environmental Supervision Ordinance (2011:13) and the Ordinance on Cosmetic Products (2013:413), for the supervision of cosmetic products and compliance with the regulations issued by the Agency. Much of this supervisory work consists of activities which also fall under the concept of market surveillance.

The Agency is also responsible, under the Product Safety Ordinance (2004:469), for monitoring compliance with the Product Safety Act (2004:451) and the regulations enacted on the basis of the Product Safety Act. The market surveillance that must be carried out pursuant to the Product Safety Ordinance applies to products that are intended for or likely to be used by consumers. Cosmetic products are also covered by the provisions of the Swedish Environmental Code [*Miljöbalken*]

(1998:808), for example Chapter 14 on chemical products, Chapter 26 on supervision and Chapter 29 on penalty provisions.
In accordance with Section 8 of the Environmental Supervision Ordinance, the Agency draws up and adopts annual supervision plans within its sphere of competence under the Swedish Environmental Code.

On the basis of its responsibility for market surveillance in this sector, the Agency is also required to establish a market surveillance programme in accordance with Article 18(5) of the EC Regulation setting out the requirements for accreditation and market surveillance (765/2008). This programme is to be submitted annually to the Government Offices of Sweden.

The requirement on the Member States is derived from Article 22 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council, according to which 'Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market'. Regulation (EC) No 1223/2009 of the European Parliament and of the Council, which entered into force on 11 July 2013, gives the Medical Products Agency greater responsibility with regard to, for instance, monitoring that cosmetics are manufactured in accordance with GMP, that any nanomaterials included in cosmetic products are registered in advance with the EU Commission and that this is declared on the label, that the safety report contains certain elements and that any serious undesirable effects are further reported.

3.2 Legislation in force

Legislation in force:

- EC Regulation on accreditation and market surveillance (765/2008)
- Regulation (EC) No 1223/2009 on cosmetic products
- Environmental Code [*Miljöbalken*] 1998:808
- Environmental Supervision Ordinance (2011:13) [*Miljötillsynsförordningen*]
- Ordinance (1998:941) on chemical products and biotechnical organisms [*Förordning om kemiska produkter och biotekniska organismer*]
- Ordinance (2013:413) on cosmetic products [*Förordning om kosmetiska produkter*]
- Ordinance (2005:893) on market surveillance [*Förordningen om marknadskontroll]*
- Product Safety Act (2004:451) [*Produktsäkerhetslagen*]
- Product Safety Ordinance (2004:469) [*Produktsäkerhetsförordningen*]
- Ordinance (1998:940) on fees for examination and supervision under the Environmental Code [*Förordning om avgifter för prövning och tillsyn enligt miljöbalken*]
- Medical Products Agency regulations (LVFS 2013:10) on cosmetic products [*Läkemedelsverkets föreskrifter om kosmetiska produkter*].

In addition to the above statutory instruments, other important documents for the purposes of market surveillance are harmonised standards, where these exist, and the guidelines published on the European Commission’s website.

4 Principles for selecting products subject to surveillance

4.1 Market structure

The Medical Products Agency is responsible for supervising the products that are manufactured for or made available on the Swedish market. The organisations or undertakings that manufacture cosmetic products in Sweden and/or import products from a country outside the EU are obliged to

report this to the CPNP register. The data from that register provide a significant basis for decisions as to which companies and products to monitor. Thanks to its register the Medical Products Agency is aware of many companies and products on the Swedish market.
The Medical Products Agency receives an annual supervision fee from these undertakings and has access to information on the products reported and details of the responsible person, serving as a basis for continuous supervision.

Since the entry into force of the Cosmetics Regulation 1223/2009, notifications have been sent directly to the European Register (CPNP). Data transmitted from the CPNP to the Medical Products Agency provide the basis for surveillance and invoicing. At present, 607 undertakings and 15 404 products registered in the CPNP are active in Sweden.

A very large proportion of the cosmetic products are imported into Sweden from other EU Member States, and there are around 100 manufacturers in Sweden.

Cosmetic and hygiene products are used by practically the entire population, but to varying degrees. They are used professionally by, for example, hairdressers and skin therapists. They are sold in a huge number of outlets, not only specialist shops but also in principle in all general stores, and nowadays are also obtainable on the internet.

4.2 Intelligence and experience from previous years

RAPEX (RAPid EXchange of information for dangerous non-food products) is a network that is managed by the European Commission and used by the supervisory authorities of the Member States to notify and warn each other of dangerous products and goods. The Agency continuously receives information regarding non-compliant cosmetic products via RAPEX. RAPEX also involves an obligation for the Member States to check whether any notified products are available in their own markets, and, if this is the case, reach a decision as to whether any action must be taken. In 2015 to date 35 RAPEX notifications have been issued for cosmetic products, and six of these were issued by Sweden.

In some cases, the selection is made directly from among products on the market, since the CPNP does not provide information on distributors on the Swedish market.
Trends whereby products that were previously only for commercial use are also being profiled for use by private individuals have been noted. There is also a trend for products intended to be used by private individuals becoming much more complicated to use, with all the safety risks that entails. The Medical Products Agency also constantly receives information from outside sources such as consumers and companies, on the basis of which it will investigate whether particular products comply with the statutory requirements in force.

The Medical Products Agency receives serious adverse-reaction reports primarily from the health service, in cases where cosmetics are suspected of having caused the reaction. Reports of undesirable effects are also received, i.e. cases that are not considered as being as serious. The reports received are investigated and assessed by the Medical Products Agency in the same way as reports on adverse reactions to pharmaceuticals. Since the system was introduced in 1989, the number of reports per year has ranged from 30 to 72. The Medical Products Agency received more reports than usual during 2014 with a total of 140 reports. In 2015, 61 reports have to date been received.

4.3 Risk assessments

Information received from consumers, companies or other parties claiming that products do not comply with the current legislative requirements is assessed and ranked in order of priority as to whether and when the Medical Products Agency should take measures. The assessment covers various criteria, including whether the alleged shortcoming poses a risk to health.

The adverse-reaction reports received from the health service are investigated and assessed in the same way as for pharmaceuticals. Adverse-reaction reports received from consumers are investigated in the same way wherever possible.

The Agency also receives information via RAPEX on non-compliant products within the EU. The number of cosmetic products implicated annually has been between 60 and 100 over recent years. The Agency investigates whether the products are on the Swedish market and, if so, takes appropriate measures.

Methods for risk-based surveillance are continuously being developed for the cosmetics sector. The available methods for market surveillance are primarily incident based. The need for directed market surveillance is currently primarily based on risk assessments from reported incidents and based on experience acquired through the Medical Products Agency's system supervision.

5 Surveillance methods

Surveillance by the Medical Products Agency targets both responsible persons (manufacturers and importers into the EU/EEA) and distributors (those importing in from the EU/EEA). Responsible persons and distributors have differing responsibilities, which is why the surveillance for these operators is different.
An inspection of the responsible person may mean that the Medical Products Agency checks that GMP (good manufacturing practice) is being followed in connection with manufacture and that the production information document is available and contains the correct elements, for example a safety report, proof of concept and information concerning reported undesirable and serious undesirable effects.
An inspection of distributors normally means that the labelling or ingredients are checked.
In the various cases, the surveillance may take place via an on-site inspection, a request for and an examination of tests through chemical analysis or through a request for and examination of the documentation. The surveillance may be carried out in the framework of both targeted projects and individual supervision cases.

The background for the various projects may be that the Medical Products Agency receives alerts regarding shortcomings for a particular product type, that a new requirement has been introduced requiring surveillance or because limited surveillance has been carried out previously for a particular area.

Local authorities are responsible for the surveillance of cosmetic products in their local region and may perform supervision in all areas, i.e. for the responsible person, distributors and professionals using cosmetic products in their undertakings. The Medical Products Agency provides guidance for the local authorities, usually both in the planning and during the performance of the checks. During 2014, the Medical Products Agency performed a major collaboration project with 86 local authorities with the goal of checking whether hair dyeing products on the Swedish market fulfil the applicable rules. In 2016 a new collaboration project is planned with the local authorities focusing on products for children.

6 Cooperation

6.1 National

At national level the Medical Products Agency must cooperate with other national authorities engaged in market surveillance and, in this context, participate in the work of the Market Surveillance Council.

The Medical Product Agency participates in the Market Surveillance Council, and in particular cooperates with the Swedish Consumer Agency [*Konsumentverket*] on RAPEX and consumer information, the Swedish Radiation Safety Authority regarding sun enhancing agents and the Swedish Chemicals Agency regarding REACH (Regulation on Registration, Evaluation, Authorisation and restriction of Chemicals) and CMR (carcinogenic, mutagenic and reprotoxic substances).

6.1.1 Public authorities

On specific issues the Agency must seek to cooperate with stakeholder authorities. On the basis of the division of responsibilities established between the Medical Products Agency and the local authorities, cooperation with the latter is a prerequisite for effective supervision work. Cooperation is undertaken on the basis of the guidance notes on supervision issued regularly by the Agency. During 2014, a national supervision project was commenced together with the country's local authorities with a strong response during introductory days and in connection with the surveillance of hair dyes in shops and in hairdressing salons across the entire country. This was performed by environmental inspectors from 86 of the country's 290 local authorities.

6.1.2 Stakeholders

The Medical Products Agency engages in continuous dialogue with several meetings per year with the Association of Chemical and Technical Suppliers (KTF), a trade organisation, with the aim of cooperating on common problems, exchanging information and discussing the legislation and its application. The trade organisation KTF represents companies, primarily larger companies and multinationals, and is represented at EU level by its parent organisation Cosmetics Europe.

The Medical Products Agency provides information by publishing a newsletter approximately four times a year and by uploading information onto the Agency's website on an ongoing basis.

6.2 International

The Medical Products Agency takes part in the European cooperation forum between the authorities responsible nationally for market surveillance of the cosmetics sector, the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC), in the European Commission's working group on cosmetics and, where appropriate, in certain of the working group's subgroups created to address particular issues. Within PEMSAC, plans for joint projects are discussed along with aids for surveillance and for surveillance reporting, and experience is exchanged.

Information is also exchanged informally at meetings, by telephone and via e-mail with colleagues at other equivalent authorities in other countries, particularly the other Nordic countries.

7 Costs

The overall cost to the Medical Products Agency for 2016 is calculated as corresponding to at least four full-time employees plus an additional SEK 450 000, primarily for laboratory analyses. The staffing costs represent SEK 4.5 million.

8 Future outlook

8.1 Market surveillance 2016

Surveillance must be well planned and largely be risk-based. The planning must be done in such a way as to allow scope for surveillance based on incoming alerts concerning significant shortcomings in compliance with the rules.

The plans for 2016 comprise a new comprehensive supervision project in collaboration with the local authorities concerning objects for children. This is a project that will run throughout 2016.

Smaller supervision projects involving the surveillance of product information documents and following up on undertakings with products with a reporting obligation to CPNP to ensure they are genuinely registered there are also planned.

In addition, continuous supervision will be implemented in conjunction with incoming reports on undesirable effects.

The supervision of cosmetic products will also be carried out by the local authorities, which will independently plan their supervision. The Medical Products Agency will provide general supervisory guidance to all local authorities, e.g. via the Medical Products Agency's website and will provide supplementary supervisory guidance to certain local authorities, e.g. in connection with local authority supervision projects.

8.2 Market surveillance over the next three years

Over the 2016-2018 period, the long-term plan for market surveillance should be developed further, among other things in relation to the outcome of the ongoing and planned projects at the Medical Products Agency, intelligence, including reports on undesirable effects, the work being done within PEMSAC as well as discussions being initiated at EU level.

9 Follow-up

Scope of market surveillance

The Medical Products Agency's market surveillance of cosmetics is based to a large degree on the Agency's own experience but also on information received from consumers, companies and the health service and from authorities in other Member States. Surveillance which is of importance to human health is prioritised. During 2015, approximately 200 Swedish companies (manufacturers/importers) were subject to surveillance by the Agency. The high number for 2015 is due to surveillance cases involving checks on the notification obligation to the CPNP. The results of these projects will be set out in surveillance reports once the projects have been completed.

Surveillance-related measures

Pursuant to the Environmental Code, the Medical Products Agency is entitled to issue any prohibitions and injunctions deemed necessary to ensure compliance with the current legislation. The instruments regularly employed by the Agency in connection with its market supervision are:

- injunctions accompanied by imposition of a requirement, e.g. to supply additional information or to alter labelling. An injunction may be coupled with a fine.
- Decisions on imposing a sales ban.

Documentary basis for follow-up and reporting
The time and costs expended on market surveillance are recorded.

Cases are recorded in the Agency's case management system and comments on the supervision are noted in the Cosmetics Register where possible. The outcome of supervision in the individual cases is documented in the case management system.

10 Reporting

The Agency's activities are reported to the Government (the Ministry of Health and Social Affairs) in the Agency's annual report.

The Agency publishes information on its surveillance activities in the cosmetics sector in its newsletters and on its website. Surveillance projects are often the subject of special reports.

At present, there is no coordinated reporting of the surveillance activities carried out by local authorities. However, in certain cases supervision activities are mentioned for information purposes in project reports. If the Agency receives information about the local authorities' supervision of any companies or products listed in the Agency's register, this is noted in the register. However, as of this year, the municipal authorities are responsible for annual reporting on the follow-up and evaluation of surveillance performed in the cosmetics sector (Section 15, Ordinance 2013:413).