MEDICAL PRODUCTS AGENCY

Market Surveillance Programme 2015
Medical Devices

Medical Products Agency
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Background

The Member States are required to apply Community legislation. According to 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users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed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 Article 18(5) of

Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance. This programme is submitted to the Government Offices of Sweden 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 Medical Products Agency's three product areas falling within the Agency's jurisdiction: Medicines, Medical Devices and Cosmetics. Most of the surveillance activities fall under the umbrella of Supervision.

Supervision strategy

In 2013, the Medical Products Agency developed a strategy for its overall supervisory duties, and developed and reinforced the strategy during 2014. 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 on 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 Medical Devices Directive and Regulation (EC) No 765/2008 set out fundamental views on patient and user safety. On the basis of this and the general requirements laid down in the Act and Ordinance on Medical Devices, the aim of the Medical Products Agency's market surveillance in the medical devices sector has been formulated as follows:

Market surveillance by the Medical Products Agency must ensure that medical devices that are placed on the market meet the requirements of the regulations and that they are safe and appropriate for their intended uses.

2. Specific goals of market surveillance

2.1 General conditions

The regulations for medical devices were established in the 1990s and are based on three European Directives developed using the 'new method'. These Directives form a common basis for the legislation that applies within the EU/EEA.

The aim of the regulations is to ensure that medical devices that are placed on the market are safe and appropriate for their intended uses. Manufacturers have direct responsibility for ensuring that the products are assembled and manufactured so that they do not jeopardise the health and safety of patients, users or other people where relevant.

In order for the regulations governing medical devices to have the desired effect, the Member States must, through the supervisory authorities responsible, adopt all measures necessary to ensure that the medical devices placed on the market do not entail any risks to human health and safety and that they meet the requirements of the regulations.

Member States must carry out surveillance to ensure that manufacturers and other economic operators are acting in accordance with the legislation in force. This means that Member States are obliged to organise and carry out effective market surveillance in order to detect any products that do not meet the requirements of the regulations relating to medical devices.

Market surveillance must not only consider the interests of patients, consumers, employees and other users, but also protect economic operators from unfair competition.

By virtue of the Ordinance (1993:876) on Medical Devices, the Medical Products Agency is the authority responsible for examining medical devices that are placed on the Swedish market to ensure that they meet the requirements of the regulations.

2.2 The concept of market surveillance

Market surveillance in the medical devices sector means all of the various activities carried out by the Medical Products Agency in order to ensure that medical devices placed on the Swedish market meet the requirements of the Act (1993:584) on Medical Devices and the statutes promulgated pursuant to it.

The Medical Products Agency may also carry out market surveillance on the basis of the requirements regulated by the Product Safety Act (2004:451). This applies to the surveillance of medical devices intended for consumers or which may be assumed to be used by consumers.

Market surveillance by the Medical Products Agency may also cover cooperation with authorities in other Member States. The need for common market surveillance may be deemed necessary in certain situations in order to take effective action against operators supplying medical devices that do not meet the requirements of the regulations.

Under the existing rules, the Medical Products Agency may prohibit the placing on the market of a medical device that does not meet the requirements of the Acts and relevant statutes. The Medical Products Agency may also decide to order a manufacturer to withdraw the product from the Swedish market, or request that remedial measures be taken to rectify any shortcomings detected during market surveillance.

3. Legal basis

3.1 Duties of the Medical Products Agency within the sector

By virtue of the Ordinance (1993:876) on Medical Devices, the Medical Products Agency is responsible for supervising compliance with the Act (1993:584) on Medical Devices and the statutes produced by the Agency pursuant to that Act. This means that the Medical Products Agency is responsible for supervising manufacturers and the medical devices placed on the market, including custom-made devices. A large part of this supervision consists of activities falling under the concept of market surveillance.

By virtue of its responsibility for supervising the medical devices sector, the Medical Products Agency must establish a market surveillance programme in accordance with Article 18(5) of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance.

In Sweden, the inspection and supervision of medical devices is divided among the Medical Products Agency, the National Board of Health and Welfare and the Health and Social Care Inspectorate. This means that in many situations the authorities need to cooperate in sharing the information necessary for being able to carry out effective market surveillance.

The National Board of Health and Welfare produces regulations on the use of medical devices in healthcare, SOSFS 2008:1. The Health and Social Care Inspectorate supervises activities in the healthcare sector. This includes responsibility for supervising how medical devices are commissioned and used in the Swedish healthcare sector.

Medical devices that are manufactured within the healthcare and dental care sectors and which are only to be used for that specific activity (i.e. what are known as custom-made medical devices) are supervised by the Health and Social Care Inspectorate. This is stipulated in the Ordinance (1993:876) on Medical Devices.

Market surveillance of medical devices intended for consumers
By virtue of the Product Safety Ordinance (2004:469), the Medical Products Agency is also responsible for supervising compliance with the Product Safety Act (2004:451) and the statutes promulgated pursuant to the Product Safety Act.

The market surveillance that must be carried out pursuant to the Product Safety Ordinance concerns medical devices intended for use by consumers or which may be assumed to be used by consumers.

Market surveillance covers the aspects that are specified in the Product Safety Act and which lack equivalence in the regulations on medical devices. This mainly applies to the supervision of:
Importers and distributors dealing in medical products intended for consumers or which may be assumed to be used by consumers;
Certain services that are directly related to medical devices intended for consumers (service, installation, fitting, repair, etc. and similar services);
Trade in (transfer of) second-hand goods that cannot be treated as antiques or as items for restoration;
How medical devices are commissioned (installed, fitted, etc.) when this takes place outside the healthcare sector.

By virtue of the Product Safety Ordinance, the Medical Products Agency also has an obligation to establish, implement and follow up a programme for its supervision of various types of products, services and risks. The programme must be evaluated regularly.

The Product Safety Ordinance also imposes an obligation on the Medical Products Agency in the area of consumer products, namely to establish and maintain a system for receiving and following up complaints relating to product safety and to provide the general public with information about its supervisory activities.

Environmental aspects
With one exception, the regulations on medical devices do not contain any requirements that are directly related to their impact on the environment. The exception is that the Medical Products Agency's regulations (LVFS 2001:7) on medical devices for in vitro diagnostics contain a requirement relating to the safe

management of waste. On the contrary, the regulations do contain requirements that indirectly reduce the environmental impact of medical devices. Examples of this include requirements relating to biocompatibility and restrictions on the use of substances that could be mutagenic, genotoxic or otherwise harmful to the human body. In addition to the regulations on medical devices, environmental requirements for medical devices are also regulated by, for example, REACH and RoHS, which fall under the supervisory responsibility of the Swedish Chemicals Agency.

3.2 Provisions in force

- Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance;
- Act (1993:584) on Medical Devices;
- Ordinance (1993:876) on Medical Devices;
- Ordinance (2005:893) on Market Surveillance;
- Ordinance (2009:392) on the Obligations of the Medical Products Agency in Relation to Medical Devices;
- Product Safety Act (2004:451);
- Product Safety Ordinance (2004:469);
- Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices;
- Commission Regulation (EU) No 722/2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin;
- Ordinance (2011:811) on Accreditation and Technical Surveillance.

Medical Products Agency regulations on:

- Medical products (LVFS 2003:11);
- Active medical devices for implantation (LVFS 2001:5);
- Medical products for in vitro diagnostics (LVFS 2001:7);
- National Medical Information System (NMI) (LVFS 2014:7).

By virtue of the requirement to report any accidents and incidents involving medical devices, the following regulations, which are issued by the National Board of Health and Welfare, contribute to the basis for the market surveillance carried out by the Board:

- National Board of Health and Welfare regulations on the use of medical devices in the healthcare sector (SOSFS 2008:1).

In addition to the statutes enumerated above, the harmonised standards and the guidelines (MEDDEV documents) published on the European Commission's website also constitute an important basis for market surveillance.

4. Principles for selecting products subject to surveillance

4.1 Market structure

There are a limited number of large, multinational medical device companies in the market. The majority of medical device companies are small businesses. The Swedish trade organisations estimate that approximately 80 % of medical device companies in Sweden fall into the category of small businesses (most of which have ≤ 4 employees).

Of the approximately 1 300 undertakings that are registered with the Medical Products Agency, just over 700 focus on manufacturing special solutions for individual patients/users, i.e. manufacturing custom-made products. Many of these undertakings do not engage in continuous mass production. Most manufacturers of custom-made products are care units within the Swedish healthcare sector.

In total, it is estimated that there are approximately 500 000 medical devices that are being marketed on the European market. The majority of products (variants) have a short life cycle, usually of around 18 months, and the products often go through subsequent development with the constant introduction of new versions.

In most cases, the products may be marketed in a Member State without the authorities of that country having to be contacted/informed. This makes it difficult for national authorities to create and maintain a sense of which products are found on their own national market.

The common Eudamed database is being developed further, thus providing new opportunities to follow up the products that are being made available in the internal market.

4.2 Intelligence and experience from previous years

The guidelines in the Market Surveillance Ordinance for assessing the scope of market surveillance form the basis for planning and implementing market surveillance in the medical devices sector.

The need for market surveillance shall be assessed separately for each product category. Unless otherwise prescribed separately, such assessment shall consider the characteristics of the products and their risks, any reported injuries or damage, the effects of previous market surveillance, prevalence on the market, and the anticipated area of use. Consideration shall also be given to the surveillance initiatives of other authorities and to market surveillance within the European Economic Area.

The Medical Products Agency's intelligence in the medical devices sector is largely based on information and reports from manufacturers, healthcare providers and authorities in other Member States.

New methods have been developed and introduced in 2014 for improving intelligence at the Medical Products Agency. The methods used by the medical devices sector are closely related to this. An intelligence group has the task of coordinating intelligence reported by colleagues and to propose activities and focal points to the unit's management. This task covers both immediate and longer-term activities that are covered by the action plan or market surveillance plan for the coming years.

The accident and incident reports that the Agency receives form a meaningful basis for the priorities made as part of its activities. Through these reports, we identify serious deficiencies in existing products and with their manufacturers, but in some cases we also identify general problems associated with a group of products or treatment method[1].

Experience shows that:

- The need for surveillance initiatives directly related to the accidents/incidents that are reported remains unchanged on the whole;
- The proactive supervisory activities carried out in recent years indicate both documentary and technical failings in the products that have been investigated. There are grounds for continued proactive surveillance/supervision aimed at the manufacturers of custom-made products and products in lower risk categories;
- There may be an increased need to carry out surveillance on software, predominantly free-standing software and so-called mobile apps, with medical functions (e.g. support for decisions relating to diagnosis, medicine administration or analysis).

Information stored in LVIS and EUDAMED

The Medical Products Agency records information about medical devices, manufacturers, and accidents/incidents involving medical devices in an internal database called LVIS. Data that may be of interest to other Member States is transferred to a common European database developed and operated by the Commission, called Eudamed.

LVIS contains (as at 2 November 2014) information on:

- Medical devices for in vitro diagnostics (5 035 Swedish products);
- Medical devices in class I (55 327 Swedish products);
- Manufacturers of custom-made products (716 manufacturers);

[1] The reporting system does have some drawbacks as a basis for planning. There is an uneven distribution between reports from different undertakings and healthcare providers, and some undertakings/healthcare providers do not, on the whole, report all kinds of deficiency. The way in which reporting processes function between healthcare professionals in private practice and the manufacturers responsible is not known, nor is the extent to which undertakings follow up the functioning of the products that are sold directly to consumers. Efforts should therefore be made to achieve a better, more comprehensive basis for planning.

- Certificates issued by Swedish notified bodies (1 422 issued by Intertek AB and SP Technical Research Institute of Sweden AB);
- Accidents and incidents involving medical devices, including measures that have been planned and carried out (28 410 cases).

In 2014, just over 6 000 new medical devices were registered, as well as just over 4 000 reports of accidents and incidents.

A breakdown according to product category of the accident and incident reports received in 2014 shows that approximately one-sixth of all reports relate to aids that are intended to compensate for impaired functions.

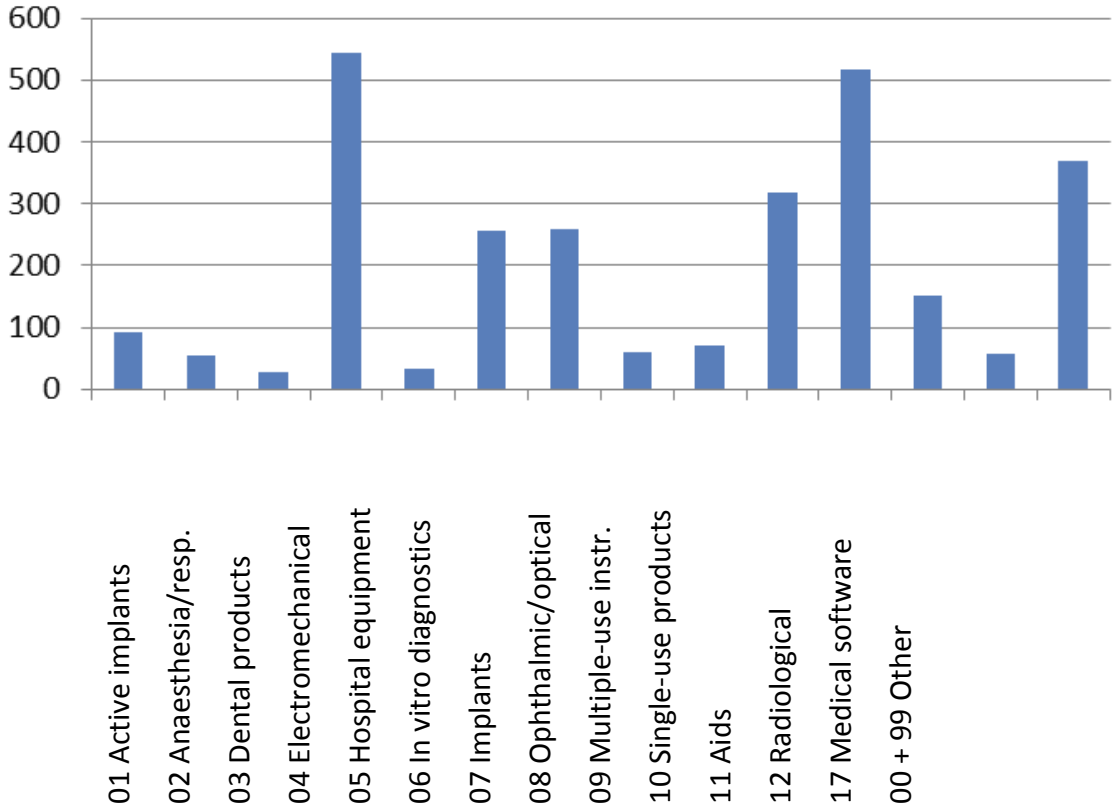

Fig. 1 Reports of accidents and incidents received in 2014 up to and including 31 August, broken down into different product categories.

4.3 Risk assessments

Methods for risk-based surveillance are continuously being developed in the medical devices sector. The selection methods for market surveillance are mainly incident-based. At present, the need for targeted market surveillance is mainly based on risk assessments from information concerning reported incidents and the Medical Products Agency's experience of system supervision.

The risk assessments may lead to separate surveillance of individual products or the surveillance of an alternative, particularly risk-prone group that is over-represented

in the accident reports. For products that feature regularly in the accident and incident reports, a better impression of the risks involved is created than is the case with products that are seldom reported. Market surveillance may therefore also be initiated in a product area with potentially considerable risks, for example where there is deemed to be insufficient knowledge of the risks involved in practical use. Among other things, this applies to consumer products where users do not have any obligation to report accidents and incidents involving medical devices to the Medical Products Agency.

5. Surveillance methods

The Medical Products Agency's supervision of the medical devices sector is process-based. A number of projects have been completed during 2014 to clarify and document processes and sub-processes that are applied. The aim is for the processes to be introduced during 2014.

In general, market surveillance comprises both proactive and reactive activities. All activities start with selection methods that are based on relevance primarily to personal risk but also to significance for the market.
Alerts from the market, operators, the media, etc. are assessed and prioritised based on their relevance. A special intelligence group has been set up to coordinate this prioritisation work.

Supervision will take the form of:

- Monitoring and, in some cases, active participation in the investigation of accidents/incidents involving one or more medical devices;
- Inspections of manufacturers/authorised representatives of medical devices. 'Inspections' means activities that involve a visit to the undertaking in question and possibly its sub-contractors;
- Administrative checks aimed at an individual undertaking, an individual product, or a special type of product;
- Laboratory tests on medical devices.

The supervisory activities that are carried out also include system supervision, i.e. a review of the undertaking's procedures for product development, production, final checks and market follow-up. This applies formally to manufacturers of products with a higher risk classification that must therefore apply any of the verification models described in the legislation that are based on an approved quality system. System supervision may also be relevant for other manufacturers where some form of quality system is most often used to meet the requirements of the regulations relating to risk management and product follow-up. Surveillance of the undertaking's quality system includes both the design and use of the system. The aim is to examine what opportunities the undertaking has to ensure/maintain an acceptable level of safety in the products that it places on the market.

For products with a higher risk classification, the regulations include a kind of advance approval. This entails a requirement for the manufacturer to hold

certification from a notified body. The Medical Products Agency acts as a technical evaluator, partly for Swedac and the assessment of notified bodies in Sweden, and partly for European-level cooperation in assessments of notified bodies in other Member States of the Community.

6. Cooperation

6.1 National

6.1.1 Authorities

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

The Agency must seek to cooperate with the relevant authorities on specific matters. Through the division of supervisory responsibility between the Medical Products Agency and the Health and Social Care Inspectorate (IVO), cooperation with the IVO will be a prerequisite for effective supervisory work. There is also a division of responsibility for the medical devices sector between the National Board of Health and Welfare and the Medical Products Agency, and cooperation is necessary for dealing effectively with matters in the area of medical devices.

There are various forms of radiation that are used to examine and treat patients, for example during X-ray tests and cancer treatment. For this type of medical device, the Medical Products Agency works in collaboration with the Swedish Radiation Safety Authority for some parts of its supervisory work.

The Dental and Pharmaceutical Benefits Agency (TLV) is responsible for subsidising consumer goods that are often medical devices. The TLV also has a government mandate to carry out health-economic assessments on medical devices. The Medical Products Agency assists the TLV with facts upon request.

The authority responsible for the supervision of Swedish notified bodies in the area of medical devices is Swedac. The Medical Products Agency collaborates with Swedac on standardisation work relating to notified bodies in the area of medical devices. In its capacity as a technical expert, the Medical Products Agency also provides assistance with Swedac's supervision of notified bodies.

For some medical devices, it can be difficult to determine under what legislation they should be regulated. In such cases, we collaborate with the National Food Agency, the Swedish Chemicals Agency and the Swedish Consumer Agency. We also collaborate with the Swedish Chemicals Agency on environmental matters in the area of medical devices.

The number of medical devices that build on and utilise information technology for their functioning is increasing rapidly. This gives rise to a need for increasing

collaboration with the Swedish eHealth Agency and the Swedish Data Inspection Board with regard to supervision, but also requires collaboration with e.g. the Swedish Civil Contingencies Agency.

The Medical Devices Directive regulates the overarching requirements. More detailed requirements are stipulated in standards. The so-called harmonised standards have a special status in this case, as they have been developed to cover the requirements of the legislation to varying extents. The Medical Products Agency participates in a large number of technical committees that are organised under the auspices of the Swedish Standards Institute (SIS) and the Swedish Electrical Standards (SEK).

Our cooperation with Swedish Customs must take place in accordance with the procedures developed by the Market Surveillance Council.

6.1.2 Interested parties

The Medical Products Agency meets representatives of relevant trade organisations (Swedish Medtech, Swedish Labtech, the Swedish Association of Dental Technicians, etc.) four to five times a year to exchange information and to discuss the regulations and their application.

The Medical Products Agency also meets a new trade organisation for all consultants working in the medical devices sector, called Medea, a few times a year.

6.2 International

European cooperation

The Medical Products Agency must participate in European-level cooperation among authorities responsible for product safety in the medical devices sector. This involves participation in the following expert and working groups in the EU:

- Medical Devices Expert Group (MDEG), with the following sub-groups:
  - MDEG Vigilance;
  - MDEG Borderline and Classification;
  - MDEG IVD Technical Group;
  - MDEG Clinical Investigation & Evaluation (CIE);
- European Database on Medical Devices (EUDAMED)

In addition to the groups that have been established by the Commission, the Medical Products Agency also participates in:

- Competent Authority meetings (CAMD) for discussing strategic matters in the area of medical devices. These meetings are arranged by whichever country holds the Presidency;
- Executive group. This group was established during 2014 and is tasked with coordinating issues between the various EU working groups to effectively manage common EU issues;

- Medical Devices Compliance and Enforcement group (COEN);
- Notified Body Operations Group (NBOG);
- New and Emerging Technologies (NET).

The European Council negotiations on the proposed EU Regulations will also continue during 2014-2015. The Medical Products Agency will assist the Ministry of Health and Social Affairs as an expert in these negotiations.

The Medical Products Agency also takes care of priority matters that are discussed by the International Medical Device Regulatory Forum (IMDRF). The IMDRF works to harmonise the regulations worldwide.

Market surveillance in the EU/EEA
The Compliance and Enforcement group (COEN) has the task of coordinating and developing market surveillance in the area of medical devices. This group has developed a system for:

- Notifying other Member States of the results of market surveillance that is/may be of interest to those countries too;
- Requesting assistance where market surveillance indicates failings at an undertaking outside the jurisdiction of the country in question;
- Inviting coordinated market surveillance.

7. Costs

In total, it is estimated that supervision of medical devices and traders, and the associated information initiatives in the field of medical devices, will equate to nine man-years and entail costs equivalent to approximately SEK 10.3 million.

8. Time frame

8.1 Market surveillance 2015

In 2015, the Medical Products Agency's market surveillance in the area of medical devices will cover:

- An estimated 4 200 cases where the Agency will follow up measures taken by manufacturers to establish the causes of accidents/incidents that have occurred, and the measures taken by the undertaking to eliminate any deficiencies in the products;
- Proactive inspections of manufacturers of medical devices that are subject to self-certification;
- Inspections caused by occurrences where there is a suspicion of systemic errors on the part of manufacturers;
- A large amount of market surveillance carried out by means of documentation checks.

Targeted market surveillance will be carried out in the areas of:

- Dressing materials;

- Common EU market surveillance of medical devices that can be re-sterilised, with a focus on the information in user instructions necessary to re-sterilise the product by the user or the hospital (COEN activity);
- Teeth-whitening agents.

During 2015, we will also perform preliminary studies to determine the need for targeted market surveillance in the following areas:

- Apps and mHealth;
- 3D printing;
- Products in the area of diabetes care.

Many of the products that will be covered by proactive initiatives in the form of targeted market surveillance are consumer products in widespread use that have an indeterminate market and a low level of spontaneous experience feedback from the general public, and where a functional fault in the product may have serious consequences for an individual.

Information
The market surveillance that is carried out often indicates a lack of awareness of the regulations in force and, in some cases, an inability to turn the legal text into concrete action. The development and publication of guidelines is therefore often an effective tool for reinforcing the application of the regulations in force. During 2015, guidelines will also be developed concerning the clinical evaluation of information systems. The project initiated during 2013 concerning guidelines for in vitro diagnostic medical devices will be concluded in 2015. As part of this, the Medical Products Agency will participate in relevant training courses and trade fairs in order to provide information about its supervisory activities and to continue developing information for manufacturers on its website.

8.2 Market surveillance over the next three years

The supervision strategy that was developed in 2013 has partially been put into practice in 2014. Among other things, this will involve more structured intelligence. The long-term plan will be developed and refined on the basis of the alerts generated by this intelligence, and it should give a better overview of needs throughout the medical devices sector.

The areas that are currently being discussed for future thematic supervision in addition to those planned for 2015 are:

Product groups:

- Products that are marketed directly to individual consumers, including by means of mapping manufacturers' follow-up on these products;
- Defibrillators;
- Product usability;
- Products with similarities to medicines.

Industry:

- Swedish manufacturers of in vitro diagnostic (IVD) products;
- Swedish manufacturers of imported products, probably what are known as Own Brand Labelled (OBL);
- Large distributors with a varied product range.

In accordance with the recommendations submitted concerning the investigation performed by the Swedish National Accident Investigation Board as a result of an accident at the Karolinska University Hospital, the Medical Products Agency will further emphasise the assessment of aspects relating to usability in supervision cases.

9. Follow-up

Requirements and mandates

Articles 12-14 of the Act on Medical Devices and Article 11 of the Ordinance on Medical Devices state that the Medical Products Agency is entitled to issue such bans and injunctions as may be required to ensure compliance with the regulations in force.

> Article 12. The Medical Products Agency shall be entitled to obtain the information and documents required for its supervisory activities and to obtain access to areas, premises and other spaces, with the exception of homes, where medical devices are handled. The authority may conduct investigations and take samples where necessary for the purpose of supervision. No compensation shall be given for costs arising from investigations conducted or samples taken.
>
> A supervisory authority shall be entitled to receive assistance from the Swedish Enforcement Authority to implement the measures envisaged by the present article.
>
> Article 13. A supervisory authority may issue such bans and injunctions as may be required to ensure compliance with the present Act and with the statutes issued pursuant hereto.
>
> Article 14. A request pursuant to Article 12 or injunction pursuant to Article 13 may be associated with a fine.

Follow-up method

The Medical Products Agency follows up market surveillance measures for medical devices in every single case, in the form of statistics on reporting and, where relevant, in the form of project reports.

A large part of the market surveillance is carried out on the basis of occurrences. This could be reports of accidents and incidents, product recalls, or inspections with system supervision. All such cases are followed up, and they are closed when a satisfactory result or response is reported, or alternatively the case is escalated to another form of supervision.

The coercive measures that may arise during follow-up of an individual case are:

- Requests to complete/correct the information available (investigations);
- Injunctions with required measures, for example a demand for supplementary documentation to demonstrate compliance with the requirements in force (e.g. risk-management documentation, clinical evaluations, technical documentation, certificates from notified bodies and/or declarations of conformity). An injunction may be associated with a fine;
- Decisions to ban marketing, sale and supply. The decision may be linked to a penalty.

One control point for cases received is the list produced by the Office of the Chancellor of Justice, known as the 'JK List', which ensures that no cases remain for a long time without any action being taken unless there is a satisfactory reason for this.

Statistics of the cases that are received and closed are one of the tools used to follow up the need for resources for these activities, as well as their productivity.

Screening inspections that are carried out at the initiative of the authority but which are not triggered by any known deviation are followed up with a targeted inspection if any serious errors are found.

Market surveillance in the form of a project follows an established plan that generally includes a follow-up report.

Cases are documented in the Medical Products Agency's case-management system. This system forms a basis for statistics and for planning follow-up market surveillance measures. The system contains information about case events such as the reason for the notification, the risk level, product information, communication in the case, the measures taken, certificates, any connection to similar incidents involving the same type of product, etc. Information about the number of cases, any de-registered products, recalls or remedial measures may be extracted.

Costs
The time spent is followed up by means of time-based reporting.

The times and costs involved for various kinds of market surveillance are followed up once they have been sub-divided.

10. Reporting

Activities are reported to:

- The Swedish Government (the Ministry of Health and Social Affairs) as part of the Agency's annual report;
- The Market Surveillance Council and the Ministry for Foreign Affairs by means of this report;

- Information about decisions made in connection with market surveillance is reported to the European Commission;

The Medical Products Agency also publishes the following information on its website:

- Information about decisions made in connection with market surveillance, where necessary;
- Field Safety Notices that have been completed by manufacturers;
- Other safety information regarded as important to disseminate and resulting from observations made during market surveillance.

The Medical Products Agency continuously exchanges information with sister authorities in the EEA, Canada, USA, Australia, Japan and New Zealand. This exchange takes place electronically in a standardised information format, initially in the form of National Competent Authority Reports (NCARs) and COEN 2 Forms.

The results of the Medical Products Agency's market surveillance are also reproduced on its website.