Surveillance programme 2014 to 2017
for the medical devices sector

This document describes the Surveillance programme 2014 to 2017 for the medical devices sector. It serves to implement Article 18(5) of Regulation (EC) No 765/2008 for medical devices.

Scope of the surveillance programme:

The programme is applied in the medical devices sector, governed in Germany by the *Medizinproduktegesetz* (MPG – Medical Devices Act) and the ordinances issued pursuant to it. The Act transposes:

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ EC No L 189 p. 17), as amended by Article 1 of Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ EC No L 247 of 21.09.2007, p. 21),

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ EC No L 169, p. 1), as amended by Article 2 of Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ EC No L 247 of 21.09.2007, p. 21), and

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ EC No L 331, p. 1), as amended by Regulation (EC) No 1882/2003 of 29 September 2003 (OJ EC No L 284 of 31.10.2003, p. 7, 49).

Content of the surveillance:

The harmonised rules on the initial placing on the market of medical devices do not provide for any State authorisation or examination as a condition of market access. Those responsible for the initial placing on the market, within the meaning of §5 of the MPG (the manufacturer, agent or importer) must ensure independently that their products meet all the relevant Community rules. Effective surveillance is necessary as a counterweight to these liberal rules on market access, to ensure that those responsible for the initial placing on the market meet their obligations and that only medical devices which comply with the European and German rules are placed on the market. Only in this way can an EEA-wide uniform high level of safety with homogenous competitive conditions be ensured.

Responsibilities:

The Federal Government is responsible for legislation in the medical devices sector, with the lead ministry being the Ministry of Health.

The *Länder* are responsible in Germany for enforcing the *Medizinproduktegesetz* and the rules based on it. They establish the responsible authorities and make the resources available. The task of surveillance is delegated in all the *Länder* to local monitoring authorities. The Working Group of Supreme Land Health Authorities (AOLG) has set up the Medical Devices Working Group to harmonise and coordinate the activities of the *Länder*. This Working Group has set up a Project Group on Quality Assurance in the

Monitoring of Medical Devices so as to ensure high quality, consistent and equivalent action by the various authorities. The Project Group has drawn up guidelines on the monitoring of:

- medical devices placed on the market for the first time,
- clinical and performance trials,
- operators and users, and
- processors for others,

and made them available to the responsible authorities for use.

Procedure:

The primary objective of the monitoring authorities is to protect the health of patients, users and third parties. A standardised approach means that mutual trust can be developed, administrative resources effectively used and the safety of medical devices for patients, users and third parties enhanced. Quality-assured action means that the monitoring authorities can become a competent partner for businesses.

The surveillance can be implemented

- proactively, in other words on the basis of established, systematic, risk-based monitoring or
- reactively, i.e. as a response to information received.

In both proactive and reactive surveillance, the competent authorities act to ensure that shortcomings by those responsible for the initial placing of goods on the market are removed either voluntarily or – if that does not work – by means of an administrative order. They also advise those involved with regard to the fulfilment of their statutory obligations.

The monitoring of the initial placing on the market can take one of three forms:

- A: monitoring based on the communication of an incident (reactive),
- B: sampling from retailers or along the distribution channel (proactive) or
- C: systematic, risk-based monitoring (proactive).

Collaboration with the customs authorities:

The collaboration with the customs authorities is based on Articles 27 to 29 of Regulation (EC) No 765/2008.

Risk profiles are drawn up with the monitoring authorities on the basis of past experiences with non-compliant medical devices so that the customs authorities can accurately identify products posing a serious risk to health, safety, the environment or any other public interest (see Article 27(3)(a) of Regulation (EC) No 765/2008). These risk profiles make it easier for the customs authorities to decide whether to suspend the release of the products and inform the authorities responsible for the surveillance of medical devices that such action has been taken. This form of collaboration is to be further developed in future.

Key aspects of the proactive surveillance for the period from 2014 to 2017:

The most effective and efficient way for the surveillance authorities to work is to block any non-compliant medical devices as soon as possible, i.e. at source, with the party responsible for first bringing it onto the market, within the meaning of §5 of the MPG. Every year, the *Länder* establish the framework for the proactive surveillance in a risk-based plan (see enclosure).