Plans for the monitoring of medical devices in 2014

Action for the monitoring of medical devices	Aim (possible aims)	Reason	Possible activities
Manufacturers of Class IIb medical devices	Compliance monitoring	Highest risk category	
Monitoring compliance with the requirements for the first-time placing on the market within the meaning of § 5 MPG (*Medizinproduktegesetz*, Act on Medical Devices) in line with the procedural instructions set out by the working group on medical devices at marketers *in situ*. The focus will be on: Sterilised inactive implants, particularly of animal origin or made from organic materials, Surgical suture material .	Priority is to be given to monitoring those areas which are not certified by a notified body. Due consideration must therefore be given during monitoring to audit certificates and certificates of conformity from the "notified bodies" (e.g. TÜV).	(Avoidance of "duplicate monitoring" of areas which have already been covered by conformity assessment by the "notified body"). For sterile medical devices – given the high risk potential in particular for implants, - the reliability of the sterilisation procedure in particular must be covered during monitoring, especially since sterilisation is generally outsourced to other companies (contracts, validation, etc.).	*In situ* monitoring in particular for first marketers within the meaning of § 5 MPG of sterilised, inactive implants of animal origin or made from organic materials and surgical suture material. Scope and depth will be decided at the discretion of the competent authority.
Proactive monitoring of medical devices on the market. Samples taken from inactive medical devices which can be tested at the LGL for quality, performance and safety. As part of routine inspections, or a specific sample from the distribution chain (e.g. pharmaceutical wholesale).	A physical laboratory check which goes beyond the documentary check (§ 7 MPGVwV (general administrative regulation implementing the MPG)) for the proposed product groups at the LGL. Assessment of chemical, microbiological and physico-chemical quality, drawing on the expertise of the LGL for the product groups in question.	This generalised measure is essential for the quality and safety of medical devices during their life span. Furthermore, only samples from the market can detect any counterfeits. The priority plans provided for by the competent monitoring authorities must be adapted to the existing test possibilities of the LGL, in order to then draw up a customised sample plan.	Sampling at wholesalers and retailers of medical devices placed on the market which fall within the scope, and testing for quality, performance and safety. Medical devices (examples, priorities: surgical suture material, inactive implants coated with active substances). If appropriate, product-related check of the conformity assessment procedure using all technical documentation for medical devices or product groups selected by way of example.

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Monitoring on the basis of vigilance reports, complaints from users, competitors, unauthorised advertising etc.	To check in particular risk management for first-time placing on the market in line with the procedural instruction established in the working group on medical devices.	Notifications of first-time placing on the market and vigilance reports frequently call for the monitoring of the essential requirements for placing on the market and for risk management	Depending on the reason and the risk potential, companies are monitored on the basis of incidents or in the case of problems with notifications. It is a good idea, in connection with any incidents, to check the documentation on risk management (processing of complaints, notification of incidents, active market monitoring).
Dental lasers	Monitoring of requirements for the placing on the market of dental lasers	When monitoring operators, a number of dental lasers were found which did not meet the requirements for the placing on the market of medical devices.	
Monitoring of manufacturers of active medical devices pursuant to the MPG.	Placing on the market of medical devices which have been shown to be in conformity	Monitoring of newly notified manufacturers of medical devices or if new/other medical devices than those notified to date are being manufactured	
Monitoring of clinical tests by the control body and the sponsor	To ensure that all framework conditions for the implementation of clinical tests are met	Monitoring in particular of new control bodies	
Inspections of manufacturers	Ensuring compliance with the regulations for the first-time placing on the market of medical devices	Statutory mandatory task pursuant to §26 MPG	Inspection of approx. 10 companies
Inspections of clinical tests	Ensuring compliance with the regulations for the implementation of clinical tests with medical devices	Statutory mandatory task pursuant to §26 MPG	Inspections of approx. 10 clinical tests at sponsors and control centres
Opinions in the context of customs procedures	Ensuring the correct placing on the market of medical devices and in vitro diagnostic medical devices from third countries	Mandatory task (Regulation (EC) No 765/2008)	Check on labelling and/or instructions for use of medical devices, possibly examination of sample.

Action for the monitoring of medical devices	Aim (possible aims)	Reason	Possible activities
Manufacturers, dealers	Monitoring on the basis of vigilance reports, complaints	Mandatory task (§ 26 subpara 2 and § 28 subpara 1 MPG)	Monitoring in specific situations of corrective measures or of the placing on the market of medical devices. Where appropriate, inspections, check on labelling, instructions for use, examination of sample.
Manufacturers, authorised representatives	Ensuring the correct placing on the market of medical devices and in vitro diagnostic medical devices	Mandatory task (§ 34 subpara. 1 MPG)	As part of the processing of applications for the issue of export certificates, random samples of notifications by the manufacturer, declarations of conformity, certificates from the notified bodies, labelling models and user instructions are checked.
Monitoring of the lawful placing on the market of medical devices	Safety of products on the market, guaranteeing the protection of patients, users and third parties, and also ensuring fair competition.		Monitoring companies and facilities which place medical devices on the market (first-time placing on the market and trade) through inspections and documentary checks as well as physical product checks.
Monitoring of clinical trials and performance evaluation studies	Safety of medical devices and in vitro diagnostic medical devices for clinical trials and performance evaluation studies.	Due to the high risk linked to the use of medical devices in clinical trials or in vitro diagnostic devices in performance evaluation studies, provision has been made for intensified monitoring.	Notified or approved clinical trials / performance evaluation studies are monitored on a case-by-case basis, or depending on circumstances. Inspections and documentary checks are performed for notifications and serious adverse events (SAE) on a case-by-case basis.
Information and risk management in the event of incidents with medical devices, and the ordering and monitoring of the necessary measures to minimise risks	To improve/guarantee patient protection from unsafe products.		Incoming incident reports are processed in line with the risk incurred. The implementation of corrective measures is monitored in individual cases.

Action for the monitoring of medical devices	Aim (possible aims)	Reason	Possible activities
Checking instructions for the use of medical devices to be reprocessed	Safety of products on the market. To guarantee high patient protection in cooperation with other European authorities.	COEN project	Monitoring of medical devices with respect to the adequacy of information on the reprocessing of medical devices in the instructions for use in accordance with the project documents drawn up at European level (COEN). Monitoring/testing must be performed mainly through documentary checks. The relevant documents are requested from the first marketers in question and checked. The focal point must be on surgically invasive instruments.
Manufacturer monitoring Market monitoring (reactive)	As part of the monitoring measures, compliance with the requirements for first-time placing on the market is checked in accordance with the procedural instructions adopted by the working group on medical devices. The focal point here is clinical assessment and implementation of manufacturers' quality assurance systems and risk management.	In recent years, only a small number of responsible parties have been monitored. The main approach is systematic risk-oriented monitoring of all parties responsible for first-time placing on the market pursuant to § 5 MPG (manufacturers, importers and authorised representatives), taking into account § 2 MPGVwV.	Monitoring in accordance with procedural instructions, sampling and testing in individual cases Manufacturers will be monitored over a number of years.
LWP/14/3 Market monitoring of active medical devices pursuant to the MPGVwV, in this case breathing and breathing support devices	Establishing compliance with requirements for first-time placing on the market.	We endeavour to perform regular market monitoring actions as part of implementing the administrative regulation on the MPG.	The checks are performed on the market and on the manufacturer's premises in accordance with the procedural instructions adopted in the working group on medical devices.
Monitoring of market participants manufacturing products or placing them on the market	To check whether the requirements for the first-time placing on the market of medical devices are met. To improve the safety of medical devices as a contribution to patient protection.	The main approach to monitoring is the systematic, risk-oriented monitoring of the parties responsible for the first-time placing on the market pursuant to § 5 MPG (manufacturers, importers and authorised representatives).	Monitoring and sampling

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Monitoring of compliance with the prerequisites for first-time placing on the market within the meaning of §5 MPG, on the basis of the procedural instructions adopted in the working group on medical devices, at parties based in Saxony-Anhalt to whom §5 MPG applies All manufacturing companies in the *Land* must be monitored within two years Period 2014 and 2015	In addition to the necessary audit certificates from the notified bodies, priority action in the *Land* must focus in particular on checking in-house organisation obligations regarding active market monitoring of businesses and their risk assessment or risk communication with customers.	With respect to the complexity of the performance of tasks linked to active market monitoring by the companies themselves, it is assumed that there is still a lot of scope for improvements to the in-house sales/distribution structure of SMEs.	Consultancy and, where appropriate, a renewed call to optimise in-house organisational duties
Monitoring the instructions for use of medical devices intended for reprocessing under the notification procedure set out in § 25 MPG	Safety of products on the market. To guarantee a high level of patient protection.	In the framework of operator monitoring, a sufficient number of defects were detected in the quality of the manufacturer's information on processing.	Monitoring of medical devices under the notification procedure set out in § 25 MPG regarding the appropriateness of the information on the reprocessing of medical devices in the instructions on the basis of DIN EN ISO 17664
Monitoring the consumer information provided by companies which are indicated as manufacturers/marketers of disinfectants.	Safety of products on the market. To guarantee a high level of patient protection with respect to the safe use of disinfectants.	As part of operator monitoring, a sufficient number of defects were detected in the quality of the manufacturer information.	Checking the information provided by manufacturers for plausibility and content.