Ministry of Health, Welfare and Sport

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Information

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Subject Medical devices action plan

Dear Commissioner Dalli,

Thank you for your letters of the 3rd and 9th of February, in particular your proposal for a joint plan for immediate actions.

Medical devices are used in all parts of health care and are vital for every dependent patient. The recent incidents are severe and I regret that patients have suffered from complications.
Although the revision process to improve the regulatory framework for medical devices has been in progress, incidents like the PIP case, but also recent incidents with other medical devices (for instance with metal-on-metal hip implants and implantable cardioverter defibrillators leads) have shown that appropriate and more immediate actions are necessary.

Therefore I would like to stress that I am pleased with your initiative for this joint EU action plan. I fully support your proposed actions. I am convinced that the current regulatory framework can be improved effectively without losing its specific approach concerning the safety and the possibility to market access of effective medical products.
It is very important that we ensure medical needs of patients both now and in the future. Currently, with this action plan to strengthen controls and in the future, with the revision of the directives and further developments in the regulatory frameworks to facilitate the suitable access of innovative medical products for unmet medical needs.

With regard to the further elaboration of some of the actions, I would like to stress the importance of Member States to act jointly and in a coordinated manner while implementing the proposed actions. The Central Management Committee (CMC) could be of great added value in this process.

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Concerning the specific actions in your action plan, I would like to emphasize the following:

The functioning of the Notified Bodies
'Joint Inspection Teams' of Competent Authorities (CA's) should be composed of inspectors of at least two member states. Inspections of Notified Bodies should take place partly unannounced. It is also crucial that inspection reports are written in English and filed in an EU-database, which has to be accessible to every Competent Authority.

Market Surveillance
Competent Authorities should focus in their market surveillance on manufacturing companies as a whole (the action plan already indicates the need for inspection by the notified body of the specific product which is being assessed). Manufacturing companies that operate internationally should be inspected by Joint Inspection teams of at least two member states. Moreover, EU coordinated market surveillance should be organized according to the complete life cycle of specific 'product lines'. It is crucial that inspection reports by the Competent Authorities, but also the audit reports from Notified Bodies are written in English and accessible to Competent Authorities in an EU-database. This improves transparency and the results can be used in market surveillance by the Competent Authorities.

Registration of implants and its complications
Registration of implants and the registration of adverse events are essential to effective market surveillance including the detection of long-term implications and taking effective corrective actions at European level in case of serious incidents. It is necessary to involve health care professionals and end-users. At short notice the Netherlands intends to set up a working group to investigate the possibilities of such a registration in the Netherlands. The working group will also take into account other existing initiatives in the EU. I am very much prepared to share the outcomes of the different experiences on a EU level. This way the working group will contribute to a European registration.

Stricter Post Market Surveillance (PMS)- obligations of the manufacturer
Current Post Market Surveillance obligations could be stricter; manufacturers could be obliged in a stricter way to notify vigilance reports to Notified Bodies directly. Post Market Surveillance activities and frequent reports to the Competent Authority should be a specific obligation as part of audits of manufacturers by Notified Bodies.

The Netherlands will actively participate in further guidance processes for the implementation of the action plan. I hope the above considerations can be taken into account to the extent possible in the implementation and the revision(s) of the regulatory framework(s).

Yours sincerely,

Ms E. Schippers,
minister of Health, Welfare and Sport