ansm
Agence nationale de sécurité du médicament et des produits de santé

Saint-Denis, le 22 JAN. 2016

Direction de l'inspection

Pôle inspection des essais et des vigilances

Personne chargée du dossier :
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Code : Q13P_DOC_058_v03
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Plant Quality Manager
MENTOR MEDICAL SYSTEMS B.V
Zernikedreef 2
2333 CL Leiden
THE NETHERLANDS.

Company	Address	Period	ANSM Staff
MENTOR MEDICAL SYSTEMS B.V.	Zernikedreef 2 2333 CL Leiden THE NETHERLANDS.	From Tuesday 20th to Thursday 22nd October 2015.	ANSM Inspector.

Dear Madam,

The French National Drug and Health Products Safety Agency (ANSM) proceeded to an inspection, from Tuesday 20th to Thursday 22nd October 2015, of MENTOR MEDICAL SYSTEMS B.V site located Zernikedreef 2, 2333 CL Leiden, The Netherlands, of which you are the Plant Quality Manager

This inspection concerned the compliance of the materiovigilance activities performed by this company, persuant to article 10 and Annex II section 3.1 of the Directive 93/42/EEC applicable to medical devices, as far as MENTOR MEDICAL SYSTEMS B.V. Company holds the EC certification of breast implants marketed in Europe, particularly on the French market.

Persuant to article R. 5313-3 of the French Public Health Code, you will find enclosed the final inspection report as a result of this mission.

I draw your attention on the fact that the following findings raised in the preliminary inspection report did not receive satisfactory responses from you :

Regarding the Quality Management System (QMS) :

D1 The processing of the MV cases, as described in the corresponding procedure used by MENTOR MEDICAL SYSTEMS B.V, is not completely compliant with the European legislation in force (MDD Annex II point 3.1), which implies to update this procedure so that :

1. Any serious incident or risk of serious incident, whether expected/foreseeable or not, shall be reported to the concerned competent authority ;
2. Any serious incident or risk of serious incident, regardless of its likelihood of occurrence, shall be reported to the concerned competent authority (as an example, this shall apply to ALCL cases) ;
3. In case of doubt on the causality of the medical devices and thus on the reportability of an event, there should be a pre-disposition to report.

R4 The description of the corrective and preventive actions (CAPAs/FSCAs) management, in MENTOR MEDICAL SYSTEMS B.V documentation system, should be completed so that it mentions provisions regarding the communications to the notified body of the CAPAs/FSCAs :

- Implemented on medical devices design and/or manufacturing processes and/or labelling, further to each serious incident (to prevent its recurrence) (Meddev 2.12/1 point 5.4.4) ;
- Likely to induce substantial changes to all the medical devices concerned, not only on class III medical devices (MDD Annex II point 3.4).

R5 The product recall process description, in MENTOR MEDICAL SYSTEMS B.V documentation system, should be clarified and completed, at least regarding the medical devices marketed in France, so that it :

1. Mentions that any medical device recall motivated by a technical or medical reason related to a serious incident shall be reported immediately to the European competent authorities on the territory of which the recall is to be conducted (MDD Annex II item 3.1) or that any message intended to the concerned competent authorities and to the patients and/or users, within the framework of such a situation, should be communicated in advance (48 h for example) to the concerned competent authorities ;
2. Precises the reconciliation intended to document the efficency of the recall, with a systematic recall full balance sheet recapitulating the quantities of product units :
   - produced and/or in production ;
   - present in stocks ;
   - likely to be outside stocks (samples sent for analysis, samples given to the staff for demonstration... for examples) ;
   - marketed and recallable (unused) ;
   - marketed and not recallable (used).
3. Plans the evaluation of the efficiency of the recall process by simulations of recall involving the distribution stakeholders until the final clients.

R6 The Post Market Surveillance (PMS) process described in MENTOR documentation system and related to experience gained from devices in the post-production phase should be completed, so that it lays down provisions related to the construction and update of a consolidated survey report for each category of BIs since their first marketing, with a presentation of :

1. The incidents outcomes broken down by :
   - Years of occurrence ;
   - Years of sales and/or implantation ;
   - Sales volumes or numbers of BIs implanted per year.
2. A methodology of identification of the key points, issues and stakes stemming from these data.

Regarding the organization of the staff involved or likely to be involved in materiovigilance :

R7 MENTOR LLC and MENTOR MEDICAL SYSTEMS B.V should complete the documentation related to the delegations of its staff, insofar the delegation form related to activities under the responsibility of the Head of the Product Evaluation Department is not signed by the delegates themselves, which does not certify that they know and accept these delegations.

D3 The continuity of the materiovigilance activity within MENTOR organization is not enough documented, which induces a risk that MV cases may not all be processed and reported with the required due diligence (MDD Annex II items 3.1 and 3.2 b), in the absence of records demonstrating the continuous presence of the *Product Evaluation Department* Head's or of his delegates.

Regarding the audits :

R8 MENTOR should complete the audits covering its complaints and materiovigilance management, so that their scope cover the assessment of the quality and timeliness of :

- the MV serious incidents communications to the concerned European competent authorities ;
- the responses to the requests of the competent authorities.

Regarding the product recall process :

R11 MENTOR MEDICAL SYSTEMS B.V should assess the efficiency of its recall process and the proactivity of its partners (customers and distributors) in this matter by conducting periodic recall simulations, documented with :

1. Reconciliations that shall summarize the quantities of product units :
   - produced and/or in production ;
   - present in stocks ;
   - likely to be outside stocks (samples sent for analysis, samples given to the staff for demonstration... for examples) ;
   - marketed and recallable (unused) ;
   - marketed and not recallable (used).
2. Conclusions and potential areas of improvements that may be deemed necessary, following such simulations.

Regarding the systematic review of experience gained from devices in the post-production phase (PMS) :

R12 MENTOR should complete its BIs post-market survey, so that the PMS reports present an in depth analysis of the key points, issues and stakes stemming from the data related to ALCL cases, including the demonstration of the preservation of the BIs' benefit/risk ratio.

Further corrective and preventive actions should be taken as soon as possible.

Yours sincerely.

Chef de Pôle
Inspection des Essais
et
des Vigilances

Attached : Final inspection report.