ansm
French National Agency for Medicines and Health Products Safety

Decision of **20 NOV. 2019**

Laying down the particular conditions of manufacturing and placing on the market of medical devices manufactured at the production site of Laboratoires Anios at Sainghin-en-Mélantois

The director general of the French National Agency for Medicines and Health Products Safety (ANSM);

Given the amended directive 93/42/ECC of the Council of 14 June 1993 relating to medical devices;

Given the fifth section of the public health code, notably articles L.5312-1 et seq;

Given the government order of 15 March 2010, published in the JORF (French Republic Official Journal) of 16 March 2010, laying down the conditions of implementation of the essential requirements applicable to medical devices, introduced in application of article R.5211-24 of the public health code;

Given the information received from Laboratoires ANIOS on 29 October 2019 relating to a contamination of the Sainghin-en-Mélantois production site and the subsequent exchanges between Laboratoires ANIOS and the ANSM;

Given the safety information datasheets circulated by Laboratoires ANIOS;

Given the replies from Laboratoires ANIOS of 19 November 2019 to the draft health policy decision which was sent to it on the same day;

Considering that Laboratoires ANIOS, hereinafter referred to as “the ANIOS company”, manufactures and places on the market surface disinfection products and medical devices; that these products meet the qualification of medical devices as mentioned in article L.5211-1 of the public health code; that these medical devices are notably intended for the disinfection of surgical instruments but also endoscopes and dialysis circuits;

Considering that in application of articles L.5211-3, R.5211-17, R.5211-34 and R.5211-39 of the public health code, the placing on the market of these medical devices notably implies that they comply with the essential safety and health requirements which are applicable to them and that they are designed and manufactured in such a way as to achieve the performances that the manufacturer claims;

Considering that point 1 of article 1 of the government order of 15 March 2010 provides, in respect of these “General requirements” that the devices must be designed and manufactured in such a way that their use does not compromise the clinical condition and the safety of patients nor the safety and health of users and that any risks linked to their use constitute acceptable risks with regard to the benefit provided to the patient and are compatible with a high level of health and safety protection;

Considering furthermore that point 8.1. of article 1 of the above-mentioned government order provides, in respect of the “Requirements relating to the design and construction”, that the devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as much as possible the risk of infection for the patient, the user and third parties. The design must enable easy handling and, where necessary, minimise contamination of the device by the patient or vice-versa during use;

Considering that on 8 October 2019, the ANIOS company strongly suspected a microbiological contamination in the water system of its production site located at Sainghin-en-Mélantois, with notably the presence of gram negative bacteria; that it, subsequently, demonstrated a degradation notably of several batches of the Surfa'safe premium disinfectants and its related products, and of Opaster Anios, which thus renders them non-compliant with the above-mentioned essential requirements;

Considering that the ANIOS company, without success, carried out a decontamination operation from 16 to 19 October 2019, which saw it suspend production as this operation did not enable the medical devices manufactured to be returned to compliance;

Considering that the ANIOS company carried out a second decontamination operation from 9 to 16 November 2019 accompanied by microbiological inspection measures;

Considering that in view of this contamination, it cannot be excluded that all the medical devices manufactured at this site are no longer compliant with the above-mentioned requirements;

Considering that the medical devices manufactured by the ANIOS company are very widely used by healthcare establishments, moreover visited by populations at risk (notably patients with an immune system weakened, for example, by chemotherapy, an immunosuppressant treatment or waiting for a transplant or transplants, undergoing haemodialysis or hospitalised for a prolonged period in intensive care, in neonatology and patients suffering from cystic fibrosis), and that it thus cannot be envisaged that they are confronted by pressure relating to the procurement of these products;

Considering that this circumstance implies, in the interest of public health, having access to data enabling compliance with the above-mentioned essential requirements to be guaranteed by carrying out appropriate microbiological inspections prior to the release of the medical devices;

Considering that the necessary continuity of care implies, in the interest of the patients with regard to the benefit/risk balance, providing for an alternative procedure enabling the establishments to be supplied with the medical devices considered indispensable and without available alternative;

Considering that the ANIOS company implemented microbiological inspection measures on the batches in storage at the ANIOS company site on 16 November 2019 not yet commercialised;

Decides

Article 1 The manufacture and the place on the market of the medical devices manufactured at the ANIOS company site located at Sainghin-en-Mélantois are subject, for a period of six months, to the carrying out of microbiological tests on each batch, according to a sampling scheme defined in reference to the ISO 2859 standard (“Sampling procedures for inspection by attributes”), sanctioned by obtaining compliant results, leading to the conclusion of an absence of negative gram bacteria, maximum threshold of aerobic bacteria less than 100 cfu/mL and of moulds and fungi less than 10 cfu /ml.

Article 2 Concerning the medical devices for which the results of microbiological inspections are not available on release, the ANIOS company could supply the healthcare establishments with medical devices that the latter consider, following an overall evaluation of the benefit compared with the risks of the medical situation, indispensable and without available alternative for the continuity of patient care. In this case, the ANIOS company is obligated to inform the concerned healthcare establishments of both the absence of microbiological results on release and also of the date of obtaining the results.

Article 3 The ANIOS company is obligated to recall, in all locations where they are located, all the medical devices of which the microbiological results prove to be non-compliant.

Article 4 The ANIOS company is obligated to put in place, according to an appropriate sampling scheme, microbiological tests of the efficacy of the decontamination operation on their facilities and regular inspection tests on the water used in production.

Article 5 The provisions of articles 2 and 3 also apply to the medical devices stored at the ANIOS company site on 16 November 2019.

Article 6 The ANIOS company is obligated to disseminate this decision to all natural or legal persons likely to hold the medical devices concerned by the former.

Article 7 The director of medical devices, cosmetics and in vitro diagnostic medical devices and the inspection director are both charged, as is appropriate, with executing this decision which will be published on the website of the French National Agency for Medicines and Health Products Safety.

Drawn up on

20 NOV. 2019

Dr Christelle Ratignier-CARBONNEIL

Assistant Director General

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