

DECISION

Rescinding the decision of December 17, 2008 temporarily suspending the importation, distribution, transfer and exportation by Ost-Développement of tissues used for therapeutic purposes in humans coming from bone harvests performed in Bulgaria

The Director General of the French Health Products Safety Agency (AFSSaPS),

In view of directive 2006/17/EC of February 8, 2006 implementing directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;

In view of the public health code and particularly articles L. 1211-6, L. 1243-2, L. 1245-1, L. 1245-5, L. 5311-1, L. 5312-3, R. 1211-15, R. 1211-19, R. 1243-10, R. 1243-24, R. 1243-25, R. 1245-5 and R. 1245-8;

In view of the order of the minister responsible for health dated April 1, 1997 approving the rules of best practice related to harvesting tissues and surgical residue for therapeutic purposes;

In view of the AFSSaPS decision referenced as BT/06/R/029 of November 21, 2006, authorizing Ost-Développement to transform, store, distribute and transfer tissues used for therapeutic purposes in humans and renewing authorization BT/01/O/010 of April 10, 2001;

In view of the AFSSaPS decision referenced as IX/1107/R/009 of November 14, 2007 authorizing Ost-Développement to import and export tissues used for therapeutic purposes in humans and renewing authorization IX/01/O/001 of May 9, 2001;

In view of the decision of December 17, 2008 temporarily suspending the importation, distribution, transfer and exportation by Ost-Développement of tissues used for therapeutic purposes in humans coming from bone harvests performed in Bulgaria;

In view of the AFSSaPS letter to Ost-Développement dated July 9, 2009;

In view of the responses from Ost-Développement dated July 16, 2009 and July 22, 2009;

Whereas the inspection conducted by two AFSSaPS inspectors from January 12 to 15, 2009 at Osteotech, Inc. (New Jersey, USA), which prepares bone tissues harvested in Bulgaria, did not reveal any problems;

Whereas the analyses performed by the AFSSaPS on five graft samples collected during the inspection at Osteotech, Inc., prepared using bone grafts harvested in Bulgaria did not show any microbial contamination;

Whereas between March 16 and March 26, 2009, or after the above-mentioned decision dated December 17, 2008, Ost-Développement conducted an in-depth audit of the bone tissue harvesting sites of the four hospitals in the Sofia region currently under contract with OsteoCentre BulGaria (OCBG), including a comparison, based on 120 files, of the data contained in the medical file kept at the hospital with the data contained in the donor file set up by OCBG;

Whereas a follow-up inspection was conducted in Sofia (Bulgaria) from April 21 to April 24, 2009 by AFSSaPS inspectors accompanied by two inspectors from the competent Bulgarian health authorities at the OCBG tissue bank and at the three bone tissue harvesting sites working for this bank, which had already been inspected in November 2008;

Whereas the AFSSaPS inspectors found that the conditions for harvesting bone tissue for OCBG had notably improved and that the procedures now implemented by OST DEVELOPPEMENT allow it to guarantee donor selection and the traceability of donations;

DECIDES

Article 1: The decision of the Director General of the French Health Products Safety Agency dated December 17, 2008 temporarily suspending the importation, distribution, transfer and exportation by Ost-Développement of tissues used for therapeutic purposes in humans coming from bone harvests performed in Bulgaria is rescinded.

Article 2: The Director of Inspections and Establishments is responsible for enforcing this decision.

Saint-Denis, July 24, 2009

The Director General

[signature]

Jean MARIMBERT