TRIM: R10/300852 - Rép. : Re: New information related to NCAR FR-2010-03-30-007 - POLY IMPLANT PROTHESE [SEC=UNCLASS

Cecile VAUGELADE to: DEDIM UGSV, Larry.kelly, GHTF.NCAR, Shelley.tang 11/06/2010 11:02 PM

Cc: [redacted]

History: This message has been forwarded.

Dear colleague,

Regarding PIP prosthesis tests, we just launched the experiments. Actually, the legal process was complex and the samples were kept under seal.

First one is mechanical characterisation of end product prosthesis according to EN 14607:2009 Standard. Some tests were selected to assess mechanical reaction (fatigue test, Static rupture resistance test, Elongation and tensile strength).

Second axis is to determine biocompatibility of the "unofficial" filling gel based on MEDDEV 2-5-7 and 10993 standard series.

So, in a first step, a laboratory will determine genotoxicity level (ISO 10993-3:OCDE 971, OCDE 476,OCDE 474) and intradermal reactivity test (ISO 10993-10 - Annex B-2)

In addition, a cytotoxicity will be made according ISO 10993-5 standard.

All these tests have just been launched. If first mechanical results will be expected within one month, first biological results will be available not before one month and a half or two month at least.

Regarding the composition of the products, tests are although in progress. The approved gel was Nusyl and the raw materials used to manufacture the silicone included in PIP implants are issued from known european industrial suppliers.

We will give you information as soon as we can.

Best regards

[redacted]
Adjointe au Chef de Département Surveillance du Marché
Direction de l'Evaluation de Dispositifs Médicaux
afssaps