afssaps
Agence française de sécurité sanitaire des produits de santé

Market surveillance 2004- 2005 of instruction for use of growth hormone (GH) in vitro diagnostic medical devices

The results of national quality control show very high coefficients of inter-reagent variation of the growth hormone (GH) test systems whatever the concentration of the samples tested. Moreover, for a number of years, it has been noted that significant variations can be observed according to the device used. For this reason, several european and international studies have been undertaken and the recommendations disseminated to improve the diagnosis and the treatment of deficit in GH (GHD) in particular concerning a harmonization of the devices around the latest international standard 98/574 obtained by molecular recombination. Taking into account the possible clinical impact of an erroneous result (treatment or not of GHD by recombining GH according to a single fixed threshold whatever the technique used), Afssaps decided in 2004, as part of its assignments, to set up a market surveillance of the nine GH test systems. This study consisted in evaluating the devices compared to standard 98/574 and their conformity compared to the essential requirements of european directive 98/79/CE by studying the performance data of the technical documentation provided by the manufacturers as well as the instructions for use (IFU) and labels of the devices concerned.

It appeared that, out of the 9 reagents on the market, only 5 were standardized to 98/574. The other devices remained standardized compared to standard 80/505, GH purified from cadaveric pituitary glands. The study also highlighted the fact that certain notices of reagents announced as standardized to 98/574 recommended ng/ml-mUI/l conversion factors different from those indicated by the WHO, i.e. 1ng=3μUI. In fact, the cases had not been restandardized with 98/574. Mathematical corrections only permitted the extrapolation of the results obtained with the preceding standard into 98/574. Moreover, other nonconformities with directive 98/79/CE were observed raised in the IFU.

Afssaps therefore addressed letters to the manufacturers drawing attention to the remarks and/or nonconformities relating to their device. In the end, following a great deal of correspondence between the manufacturers and Afssaps and taking into account the international context, the manufacturers of the devices not standardized to 98/574 admitted that it was necessary to modify their reagents. It is expected that the whole of the devices on the market be standardized to 98/574 by the end of March 2006. The other remarks and/or nonconformities were justified or taken into account by all the manufacturers.

In conclusion, the devices present on the market should be harmonized soon in terms of standardization and their IFU be in conformity with the essential requirements of directive 98/79/CE. Afssaps intends to follow up the evolution of the harmonization of the devices thanks to upcoming operations of the national quality control.

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