Medical devices including blood and plasma derivates

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The committee made substantial changes to the report by Mr Alain POMPIDOU (UPE, F) concerning the directive on in vitro diagnostic medical devices. The directive hoped to establish harmonised standards with a view to completing the internal market for these products. Nevertheless, since in vitro diagnostic reagents were derived from the human body, it was important to draw up provisions to provide the maximum guarantees for users. The Committee on Economic and Monetary Affairs did not adopt the amendments tabled by Mr POMPIDOU aimed at defining three types of reagents to enable specific standards to be drawn up in accordance with the risk of error these products might entail. However, the members retained the idea of establishing a European database bringing together all the information provided by manufacturers and agreed on the need for Member States to apply continual surveillance of the quality and safety of these devices after being placed on the market. The other amendments were aimed at: - improving safety, particularly with regard to packaging; - reducing the risk of infection and eliminating the risks for users and patients; - ensuring that when the products were placed on the market, the information accompanying them was in the national language(s) and, if symbols or codes were used, that they were easily understood by non-professional users (self-testing devices); - ensuring extensive information, including the requirement for manufacturers to notify the relevant authorities in each Member State involved when their product was placed on the market.