In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 12/03/1996

The rapporteur, Mr Pompidou (UPE, F), referred to the problems associated with this proposal, which had to reconcile two essential requirements, namely to ensure the free movement of products while at the same time protecting the health and safety of EU citizens. He thought that the ‘new approach’ was not appropriate for dealing with the problems posed by the stability of biological reactants, which in 35% of cases could lead to serious errors in diagnosis. For this reason he called for a quality control system to be introduced before and after the product was placed on the market, as this was the only way in which public health and safety could be guaranteed. Finally, the rapporteur stressed that a centralised database was needed in order to ensure consistency in the information being supplied to this sector. Commissioner Bangemann said that everyone was in favour of providing better protection for patients and declared that the Commission could accept 47 of the 78 amendments tabled. These were Amendments Nos 1 to 6, 8, 10 to 16, 19 and 21 in part, 22 to 29, 32 to 34, 36 to 39, 41, 42, 44 and 45 to 47 in part, 48 to 52, 56 in part, 58 to 60, 68 in part and 74. However, the Commission could not accept the compulsory use of labels in the national language of the country in which the product was marketed. The Commissioner went on to explain that most of the products were used by professionals who had a knowledge of foreign languages and that the cost of such a measure would be excessive, especially for smaller countries. However, he did not rule out the possibility of Member States introducing this requirement on a national basis. Finally, Mr Bangemann expressed his support for a regulatory committee.