In vitro diagnostic medical devices: security requirements

1995/0013(COD) - 23/03/1998 - Council position

The Council common position is based on the amended Commission proposal and incorporates in full or in part most of the amendments put forward by Parliament and accepted by the Commission. The one significant exception is the amendments concerning the inclusion of certain medical devices manufactured using substances derived from human tissue or cells in the scope of Directive 93/42/EEC. In fact the common position covers only the section on in vitro diagnostic medical devices, including in vitro diagnostic devices manufactured using substances of human origin. It does not incorporate the section of the proposal aiming to modify Directive 93/42/EEC to include medical devices other than those for in vitro diagnosis which have been manufactured from human tissues. This section of the proposal is still at the first reading stage in the Council and is to be the subject of separate legislation. The main changes to the Commission proposal to increase the safety of in vitro diagnostic medical devices are: (a) field of application: the directive does not affect national laws requiring devices to be issued only on a medical prescription; it also covers devices designed to monitor therapeutic treatment; (b) essential requirements: these are also concerned with the packaging of devices in so far as such packaging is related to the safety and performance aspects of the device; (c) devices subject to certification by a third party: Annex II of the common position lists, in addition to the extension already provided by the amended proposal, a number of devices for which certification by a third party will be required; this annex makes a distinction between products used in particular for blood transfusions (list A tests for blood groups, HIV and Hepatitis B, C and D) and products regarded as sensitive which require the intervention of a third party before they are placed on the market (list B); the list at Annex II has been extended to take account in particular of the medical conditions under which they are used, the consequences of false negative or positive results and the experience of the Member States; (d) market monitoring measures: the common position provides for a European databank to be set up containing data relating to registration of manufacturers and devices, certificates and data obtained in accordance with the vigilance procedure; it states that Member States have an obligation to monitor the safety and quality of devices placed on the market. The Council has also introduced new provisions with regard to the following aspects: (a) technical specifications: the common position provides that for devices listed at Annex II list A and if necessary for those on list B, 'common technical specifications' should be drawn up; these specifications would establish appropriate performance evaluation and re-evaluation criteria and replace national documents on these subjects. (b) strengthening evaluation and conformity procedures: in order to ensure an optimal level of safety for devices normally used for blood transfusions, Annex IV (full quality assurance system) requires for devices on list A of Annex II a particular assessment of the products' design; in addition, each batch of manufactured products is subject to additional checks on samples of the manufactured products; (c) rules applicable to the notified bodies: the common position states that the notified bodies have an obligation to suspend or withdraw certificates in given circumstances; the designation criteria for these bodies are also set out in greater detail; (d) particular health monitoring measures: a new provision makes it possible to take transitional national measures or Community measures to prohibit or restrict the availability of certain products or groups of products or to subject them to particular requirements.