In vitro diagnostic medical devices: security requirements

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In adopting the report by Mr Alain POMPIDOU (RDE, F), the European Parliament amended the directive on in vitro diagnostic medical devices. It calls for the establishment of a European Union databank containing data provided by the manufacturers and stresses the need for continuous assessment, by the Member States, of the quality and safety of such devices after they have been placed on the market. Other amendments seek to enhance the safety of products, particularly as regards packaging, and to reduce to the minimum the risks to users and patients. The EP calls for information on such products to be drawn up in the national language of the final user and, in the case of devices for self-testing, to be comprehensible to non-professional users. The EP also completes Annex II, which lists those reagents requiring a stringent monitoring of quality, by adding self-testing reagents and those of biological origin for the diagnosis of genetic diseases.