In vitro diagnostic medical devices: security requirements

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Reporting for the Committee Mr Alain POMPIDOU (UFE, F) recommends that Parliament makes a few changes to the Council Common Position on a Directive on safety requirements for in vitro medical devices. Unlike medicines which are administered to the human body, in vitro diagnostics is carried out outside the human body on samples taken form patients. This include methods for the diagnosis of illnesses and screening of blood. The rapporteur notes that Council has accepted most of those amendments adopted by Parliament at first reading which were supported by the Commission. He therefore proposes only a small number of amendments seeking to strengthen the Common Position. In particular, while it is up to each Member State to decide whether instructions for use must be translated into its language or not, the rapporteur considers that this must be mandatory for self-testing devices such as pregnancy tests.