Blood and plasma donors: suitability and screening. Recommendation

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OBJECTIVE : to lay down common rules concerning the suitability of blood and plasma donors in the European Union and practical tests for blood donation within the Community. CONTENT : In order to help ensure a high level of health protection of European citizens and achieve self-sufficiency in blood and plasma supplies, and given the differences in both the legislation and the practices of the Member States in this field, the Commission proposes to set out joint requirements concerning blood donations. The proposed recommendations aim to promote good practices in this field and to achieve a coherent blood donor policy throughout the Community. The recommendations principally concern the suitability (or unsuitability) of blood donors, the volumes of blood donated and the practical screening of blood donation samples, as well as the proper protection of data on prospective donors. More specifically, the recommendations: 1) propose a common terminology for blood and blood products, donors and the suitability of donors; 2) provide a list of information to be given to prospective donors (for example, measures to raise awareness of donors, confidentiality of information on their health, etc.); 3) stipulate certain items of standard information to be obtained from the prospective donor (including identification of donor, medical history by way of a written questionnaire, an example of which is appended to this proposal, donor's written consent to donate blood and, possibly, to export the blood donated); 4) provide for a registration of donors in order to make it easier to check regular donors and the source of the donation at a later date (Member States should establish a mutually compatible system of donor identification/ registration); 5) lay down exclusion criteria governing the suitability of blood and plasma donors (the physical criteria which donors must meet are given in the Annex: these criteria are common to all and relate to factors such as age, weight, donor's blood pressure, etc.) ; 6) lay down criteria governing the unsuitability of donors, including criteria governing the permanent or temporary exclusion of donors with the complaints listed in the Annex. Provision is made for exclusion files for registering excluded prospective donors; 7) ensure proper protection of data on prospective donors (in particular, in application of Directive 95/46/EC on the protection of personal data); 8) provide for measures concerning the volumes of blood donated (joint standards for maximum volumes of blood and maximum intervals between donations); 9) provide for "harmonised" tests on blood samples (joint requirements for testing blood samples, together with common rules for the interpretation of reactions to initial screening tests, are proposed in the Annex). The text also proposes measures to encourage voluntary, as opposed to paid, blood donation.