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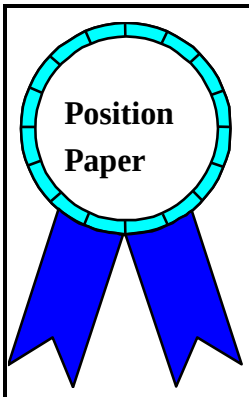

The role of diagnostic tests for the recognition of infection markers for hepatitis B/C and HIV and for ensuring the safety of blood supply

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The forthcoming harmonising directive in the field of In Vitro Diagnostic Medical Devices (IVD-MDs) will specify the requirements and the conformity assessment procedures that are necessary and sufficient to ensure that IVD MDs are of good quality and afford a high level of protection for patients, users and third parties. When the directive becomes effective only IVD MDs complying with the requirements of the directive will be allowed to be placed on the market and to enjoy free movement within the single market. The directive will require Member States not to obstruct the free movement of IVD MDs bearing the CE marking except in circumstances in which a Member State is entitled to use the safeguard clause. Given that the current pre-market and subsequent batch approval requirements differ among the Member States, a single market in relation to IVD-MD for hepatitis B, hepatitis C and HIV testing is not realistically achievable until all the Member States are satisfied that :

a) the safety and performance of the testing products meet agreed criteria and

b) have been found to do so by or under the authority of Notified Bodies competent in that field.

The political pressures for Member States to retain their national pre-market and batch release approval procedures must not be underestimated and, in this context, the difficulty of bringing Medical Devices involving human tissue (including blood) within the scope of 1993 IVD Medical Directive is very relevant.

Pan-European Test Kit Approval

It is essential to achieve pan-European approval of test systems for these infection markers as soon as possible to replace the multitude of standards and regulations that exist now, in order to obtain harmonisation of procedures and criteria for approval of tests for hepatitis B, hepatitis C and HIV.

The following key elements have been identified to be of importance:

1. Availability of reference materials and reference panels for standardised test evaluation

2. Establishment of agreed criteria for evaluation of test performance

Elements 1 and 2 are essential for the implementation of the IVD-MD Directive.

1. REFERENCE MATERIALS AND PANELS

These are currently the major concern to all parties and, since there is no agreement within Europe on these materials, EDMA and its National Associations will exert their influence such that:

a) EC Member states should agree on the same Europe-wide reference materials

and panels as well as on their application and performance criteria. These should be devised by a multi-national group of experts in the field covered by each test;

b) Changes to these reference materials and panels or to expected results from an existing panel must be discussed, agreed and notified in advance by the multi-national expert group;
c) Reference materials and panels must be available to all notified bodies and manufacturers in sufficient quantity to allow appropriate testing in advance of any approval application;

d) Producers of the reference materials and panels must conform to European Quality Norms and provide specifications as well as traceability information.

2. ACCEPTED CRITERIA FOR EVALUATION OF TEST PERFORMANCE

Europe-wide accepted requirements for sensitivity and specificity should be set and agreed by the experts. The extent of any other testing as well as the criteria for evaluation of test performance in order to obtain an approval should also be set and agreed by the experts.
It has to be recognised that the same marker may have different clinical applications, in which case the extent of testing and the criteria for approval may differ.

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