



A formal relationship between the EU Blood Directives and the Council of Europe Guide - Summary

Context

The EU Blood Directives contain mandatory requirements which at the time of their drafting largely followed recommendations of the Council of Europe Guide to the preparation, use and quality assurance of blood components (8th edition). Since that time, there have been a limited number of amendments to these Directives, though the Council of Europe Guide has been updated several times. The EU Blood Directives therefore are not up-to-date on medical advances or scientific progress.

The Directive should only provide the regulatory framework and minimum requirements. For specific technical requirements that are likely to change over time due to medical and technical advances, the European Directives should refer to specific parts of the Council of Europe Guide.

The parts of the Guide that we consider should become mandatory are those specified in the Guide as 'standards'.

This system has several advantages:

- It is in line with the "better regulation" agenda of the European Commission, as it will be more flexibly updated, in a timely fashion, and incorporate new information and research
- It will reduce the administrative burden of revising EU standards on blood products,
- It is in line with the pharmaceutical sector, where the EDQM is in charge of the European Pharmacopoeia Commission

EBA recommendation: establish the CoE Guide as a standard for blood and blood components, recognized as such in future European Directives

In order to safeguard the EU institutions oversight and capacity to provide input in the revision of the Council of Europe Guide, EBA would propose to foresee a mandatory representation of the European Commission expert group in charge of drafting revisions of the Guide, and to establish a formal consultation mechanism of the European Parliament and Member States representatives.