LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Opinion on Public Consultation

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Comments by the Medical Products Agency, Sweden, on the public consultation paper "Assessment of the functioning of the Clinical Trials Directive 2001/20/EC"

The Medical Products Agency welcomes the opportunity to comment on the above mentioned public consultation and broadly supports the "Consolidated Comments" prepared by the Clinical Trials Facilitation Group (CTFG) at the request of the Heads of Medicinal Agencies (HMA) group. These comments are enclosed, and also referred to in the response from the HMA group.

In particular, since the majority of clinical trials are authorised in a single Member State (MS) only, the Medical Products Agency does not support a centralised clinical trial application (CTA) process, but is open to a decentralised/mutual recognition model.

On a few Consultation items, listed below, the Medical Products Agency wishes to make additional comments.

Consultation item n°1:
Clinical trials in Sweden before the Clinical Trials Directive
In contrast to several other EU Member States, the Medical Products Agency had implemented GCP and GMP in clinical trials before directive 2001/20/EC. Therefore, there have been no major changes to the assessment neither of the safety of clinical trial participants and their insurances nor of the scientific quality of the clinical trials. Inspections of the conduct of clinical trials were also undertaken prior to the directive, and in line with ICH-GCP, non-interventional phase IV clinical trials were not excluded from the definition of a clinical trial.

The Medical Products Agency supports the other points raised by CTFG in the Consolidated Comments on this issue.

Consultation items n°2 and 3:
The Medical Products Agency supports the issues and comments raised by CTFG in the Consolidated Comments on these issues.

In addition, one of the obstacles against harmonization of timelines in the assessment of Clinical Trial applications consists of differences in timelines. Some Member States have introduced a clock-stop during the CTA assessment, leading to deviations from the maximum 60 days assessment time stated in the CT directive.

Consultation item n°4:
The Medical Products Agency supports the conclusion of the CTFG in their Consolidated Comments on this issue, i.e. that a decentralised/mutual recognition procedure similar to the

procedure for marketing authorisations is preferred over a community-wide centralised procedure. Reasons, in addition to those pointed out by the CTFG, are the following:

- A system which allows multiple assessments, at some level, is less vulnerable compared to a centralised system.
- The assessment of the same clinical trial, at some level, by all concerned National Competent Authorities (NCAs) supports harmonisation, collaboration and exchange of best practice between the concerned NCAs.
- It is important to retain the possibility to prohibit a clinical trial in the territory of a Member State.
- Classification of products is not uniform between Member States. E.g. cost-additives in one MS can be a medicinal product in another MS.
- The Medical Products Agency would support a decentralised system for safety surveillance of ongoing trials based on collaboration between Member States where the clinical trial is undertaken.

Consultation item n°5:
The Medical Products Agency agrees with the procedure to enhance collaboration between a National Competent Authority and the Ethics Committee within a Member State, i.e. as a one stop shop at the national level. This point has not been raised by CTFG.
To guarantee maximum patient safety, the Medical Products Agency wishes to emphasize the role of NCA to evaluate an adequate description of the medicinal product and its suspected or known safety profile in the Subject Information Leaflet.
The conclusions by CTFG on options 2 and 3 are fully endorsed by the Medical Product Agency.

Consultation items n°6-18:
Conclusions of CTFG on these matters are endorsed by the Medical Product Agency. However, concerning non-intervention studies, the Medical Products Agency finds the definition in the Clinical Trial Directive unsatisfactory. A definition of a non-intervention study, based on the rationale to exclude GCP as a quality standard, should be added to an updated Clinical Trial Directive.

Concerning subjects not capable of making an informed consent in an emergency situation, the Medical Products Agency wishes to state that an updated Clinical Trial Directive should clearly state a waiver from informed consent by a legal representative consistent with ICH-GCP. The term legal representative with respect to participation in a clinical trial should be clearly defined in the directive.

On behalf of the Medical Products Agency

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Enclosure: Consolidated comments of the Clinical Trials Facilitation Group (CTFG) on the assessment of the functioning of the “Clinical Trials Directive” 2001/20/EC