CONSULTATION LETTER: MLX 287

EUROPEAN UNION DIRECTIVE 2001/20/EC ON GOOD CLINICAL PRACTICE IN CLINICAL TRIALS – CONSULTATION ON THE UK’s PROPOSED IMPLEMENTING REGULATIONS

Summary

1. This consultation document seeks your views on the UK’s proposed implementing regulations which are required to transpose the Clinical Trials Directive into national law. The full title is Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.


3. The proposed implementing regulations will apply to the whole of the United Kingdom, as is the case with existing legislation relating to medicines control. We welcome views on all aspects of the proposed regulations. Significant changes to current arrangements in the UK and our proposals to comply with the Directive are set out in the attached consultation document. A partial Regulatory Impact Assessment (RIA) is also included and your views on this and the level of proposed regulatory fees are also invited.
4. The scope of the Directive is wide. It covers all aspects of the conduct within the European Union (EU) of clinical trials on medicinal products involving human subjects. There will be implications for a wide range of stakeholders, including researchers, industry, universities and the NHS as well as those that fund clinical trials involving medicines. MCA is committed to involving views from as wide a group of interested parties as possible. Copies of the document have been circulated widely and are available on MCA’s and the Department of Health websites (www.mca.gov.uk and www.doh.gov.uk respectively). A consultation list is attached at Annex A.

5. Please send comments to the address below to arrive at the Medicines Control Agency (MCA) by no later than 16 May 2003:

Mathew Garland
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Medicines Control Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Email: ctmlx@mca.gsi.gov.uk
Tel: 020 7273 0401
Fax: 020 7273 0387

Publications of comments

6. To help informed debate on the issues raised by this consultation exercise, and within the terms of the Code of Practice on Access to Government Information, the Agency intends to make publicly available responses received to this consultation. Copies will be available shortly after the public consultation has ended.

7. The Agency’s Information Centre at Market Towers will supply additional copies of the results of the consultation on request. It will be assumed that your comments can be made publicly available in this way unless you indicate that you wish all or part of them to be treated as confidential and excluded from this arrangement. Under the Code of Practice on Access to Government Information, the Agency will not release confidential replies or replies containing personal confidential information.
8. Should you have any questions regarding the proposals outlined in the consultation document or the conduct of the consultation exercise, please contact Matthew Garland at the address provided. The consultation document is also available on the websites of the MCA and the Department of Health and further paper copies are available on request.

Yours faithfully

Dr Brian Davis  
Clinical Trials Unit  
Medicines Control Agency