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# GCP Update

19 October 2010

## Updates (1)

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- New UK SI – SI 2010/1882: The Medicines for Human Use (Advanced Therapy Medicinal Products & Miscellaneous Amendments) Regulations 2010
- Draft consolidated UK Medicines Regulations
- Online trial safety reporting
- MHRA Enforcement Strategy
- MHRA update to Inspection Dossier
- Annex VI - Guidance for the Conduct of Good Clinical Practice inspections

## Updates (2)

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- New GMC guidance for doctors involved in research
- Eudralex Vol 10 Chapter V Q & A updated September 2010 – 4 new questions
- European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) extended confidentiality
- New FDA Guidance on 1572 Form
- EMA Reflection paper on trials in 3<sup>rd</sup> Countries
- New ICH Guidelines E16, E2F, E7 Q&A

## New UK SI – SI 2010/1882: The Medicines for Human Use (Advanced Therapy Medicinal Products & Miscellaneous Amendments) Regulations 2010

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The purpose of this new S.I. is to:

- Enforce Regulation (EC) 1394/2007 on Advanced Therapy Medicinal Products (ATMPs) to make exemptions for ATMPs used under certain conditions from some aspects of existing authorisation and supervision regulation, amending that regulation accordingly to set expectations for authorisation and supervision of these “exempt ATMPs”
- Make amendments to UK SI 2004/1031 to bring procedures for the EC opinion and authorisation for clinical trials for tissue engineered products (TEPs) in line with those for trials involving gene therapy and somatic cell therapy as well as correction of a typographical error in Schedule 2. The change to schedule 2 has no impact on the intent of the Schedule
- **SI makes it an offence to treat a patient with an ATMP where there is not a system for traceability of product <-> patient or provide written assurance that such a system is in place where it is not and provides the penalties for these offences**

# Draft Consolidated UK Medicines Regulations

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- MHRA is undertaking a consolidation and review of medicines legislation.
- Aim of the project is to ensure that the legislative framework for medicines is comprehensive, comprehensible and fit for current purpose.
- Project has two phases: The first phase (the 'consolidation') involves consolidating the existing legislation into one set of regulations while simplifying and clarifying the way it is drafted. The second phase (the 'review') involves identifying areas where MHRA might make substantive policy changes to existing provisions (where there is flexibility to do so under EU legislation) and further amend the draft regulations.
- This draft is being published in order to provide an update on what the consolidation phase of the project has achieved so far.
- This is not a formal consultation. The MHRA will, in consultation with interested parties, be carrying out a significant amount of further work on the review phase of the project. This will be followed by a formal consultation in early 2011 on the draft consolidated legislation and proposals for substantive change.
- They would, however, be grateful for any high-level comments on whether the draft is clear and user-friendly and whether there are any issues that cause particular concern.

# Electronic reporting to the MHRA

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- From 1<sup>st</sup> September 2010 all SUSARs that occur in clinical trials in the UK will have to be reported electronically to the MHRA.
- The eSUSAR website collects all 'UK-relevant' SUSARs – those that originate in the UK or originate outside the UK but where the sponsor has an ongoing trial in the UK involving the same IMP.

# MHRA Enforcement Strategy

- A new enforcement strategy has been published on 20<sup>th</sup> June 2010 by the Inspection, Enforcement and Standards Division of the MHRA.
- The document sets out the MHRA strategy for the enforcement of medicines and medical devices legislation. It reflects Government Better Regulation initiatives, as well as the recommendations contained in the Hampton Review, and the Regulators' Compliance Code, which set out the principles and characteristics to be applied in the enforcement of regulations.
- As part of the strategy, the MHRA is also actively considering extending its existing toolkit of sanctions, based on the recommendations of the **Macrory Review**, which found that the range of sanctions available to regulators was too limited and predicated on criminal prosecution.
- Published on MHRA web site by Inspections, Enforcement and Standards Division:  
<http://www.mhra.gov.uk/NewsCentre/CON084793>

# MHRA GCP Inspection Dossier Update

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- This has been updated in August , version 3

## Annex VI - Guidance for the Conduct of Good Clinical Practice Inspections

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- **Record keeping and archiving of documents (Updated March 2010)**
- The retention period of the inspection files is determined by national requirements. The inspection files should be preferably maintained for a period at least of 30 years, or for 10 years after the product has been withdrawn from the market, whichever is the longer.

### 4 New Questions & Answers:

- ⑩ 1.3. Question: Is the definition of 'medicinal product' relevant for the scope of the Directive 2001/20/EC?
- ⑩ 1.4. A study might involve the administration of a medicinal product, while the object of the investigation is not the administered medicinal product, but exclusively the physiology of the body. Are these studies 'clinical trials' as defined in Directive 2001/20/EC?
- ⑩ 1.5. Question: How does the issue set out in Question 1.4. apply to PET studies?
- ⑩ 3.1. Question: The detailed guidance CT-1 refers, in its section 2.9., subsection 4, to the content of the labelling of the IMP. Does this mean a mock-up?

## Good Practice in Research & Consent to Research – new GMC Guidance

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Research is vital but it can be a difficult area to navigate. The guidance provides a framework to guide doctors' decisions throughout all stages of a research project. They include specific advice on:

- The law and governance arrangements that apply to research in the UK
- Good research design and practice, including the importance of promoting equality and preventing discrimination at all stages of research
- Avoiding conflicts of interest and protecting participants from harm
- The process of seeking participant consent
- Involving adults who lack capacity in research
- The considerations about involving children or young people in research

[www.gmc-uk.org/guidance/research\\_guidance](http://www.gmc-uk.org/guidance/research_guidance)

# New FDA Guidance on 1572 Form

- Issued May 2010. FAQs: 15 page clarification on use of the form
- Key aspects relevant to Europe:**
- Foreign studies do not have to be conducted under an IND
- If foreign studies are conducted under an IND:
  - 1572 Form is required
  - IRB Waiver is required
- If US Sites under an IND and foreign sites NOT under an IND:
  - Use the same protocol or use a similar protocol
  - 1572 form not required
  - Provisions to be made for safety reporting (to sites and to FDA)
  - Data submitted must conform with FDA regulations on foreign data - discussions with FDA are recommended re. pooling of data from non-IND studies
- **Guidance on completion of the 1572 form:**

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

## European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) extended confidentiality

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- The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have extended their confidentiality arrangements related to medicinal products for human and veterinary use, following the positive experience gained since the initial arrangements were signed in September 2003. This cooperation will now continue indefinitely without the need for further renewal.
- The confidentiality arrangements allow both Agencies to exchange confidential information as part of their regulatory and scientific processes. Their aim is to promote public and animal health and to protect European and U.S. patients. The types of information covered by the arrangements relate to scientific advice, orphan drug designation, paediatric development, good manufacturing practice (GMP) and good clinical practice (GCP) inspection planning and reports, marketing authorization procedures and subsequent changes to the marketing authorizations together with post-marketing surveillance.
- The confidentiality arrangements cover medicines that are subject to evaluation or authorized under the centralized procedure as well as medicines that are authorized at national level by the EU Member States and that are subject to official European Community arbitrations and referrals.

# EMA Reflection Paper on Trials in 3<sup>rd</sup> Countries

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- End of consultation 30<sup>th</sup> September.
- A very good and important document with emphasis upon the vulnerability of the studied populations.
- Concern that EU follows, even if in a less radical way, the FDA position to depart from the Declaration of Helsinki.
- The document covers research in countries outside the EEA. However, it appears to be more focussed on countries where the ethics and regulatory systems are not fully developed. For example, it does not appear to relate to the United States.
- Conversely, when considering specific countries, third world countries are not included. They have smaller numbers of subjects in clinical trials, but studies in these countries are almost certainly at a higher risk because of infrastructure and education issues. It would be good to see consideration of research in these areas.

# New ICH Guidelines

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## **Newly Released Guidelines Step 4 September 2010 :**

Recommended for implementation:

- ICH E16: Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure and Format of Qualification Submissions
- ICH E2F: Development Safety Update Report

## **Newly Released Q&As Step 4 July 2010 :**

- ICH E7 Q & As Guideline: Studies in Support of Special Populations : Geriatrics.

## **Coming soon.....**

- ICH E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
  - Additional Q & As: finalise Phase I Nov 2010



## Q & A