

Impact of the clinical trials directive on NHS practice “one year on”

How the EU clinical trials directive impacts on NHS practice, a year after its implementation, was among the subjects discussed at a meeting in London organised by the Royal Pharmaceutical Society’s Hospital Pharmacists Group and others. Rachel Graham reports

Over 95 per cent of UK hospitals are involved in some way with clinical trials, and so assessing the impact of the clinical trials directive “one year on” on NHS practice is important. This is according to Paul Forsey, production manager at Guy’s and St Thomas’ NHS Foundation Trust, London. Mr Forsey pointed out that, for many hospitals, involvement in clinical trials is limited mainly to dispensing. But, from figures published earlier this year, 22 NHS sites are now licensed to manufacture investigational medicinal products (IMPs), with only two of these sites not being pharmacy-managed units.

At Guy’s and St Thomas’ itself, about 60 trials are in progress at any one time, with around 25 per cent of these involving products that require aseptic manipulation before administration and 5 to 10 per cent involving products that need to be manufactured at the trust. Getting a licence to manufacture IMPs was therefore a strategic need for the trust, Mr Forsey said. This required managers to identify and address several issues, including:

- Introducing an overarching framework for managing and handling new clinical trials
- Ensuring that product specification files match the requirements set out in Annex 13 of the directive
- Training staff to understand what constitutes a clinical trial (so they know when they are manufacturing under an IMP rather than a “specials” licence)
- Defining the qualified person (QP) role in relation to clinical trials
- Reviewing technical agreements and labelling procedures

The meeting of the Royal Pharmaceutical Society’s Hospital Pharmacists Group, Industrial Pharmacists Group and Academy of Pharmaceutical Sciences of Great Britain, and of the Joint Pharmaceutical Analysis Group of the Society and Royal Society of Chemistry, was held on 19 May in London. **Rachel Graham** is staff editor at *Hospital Pharmacist*.



About 60 clinical trials are underway at any one time at Guy’s and St Thomas’ NHS Foundation Trust

Expanding on some of these issues, Mr Forsey said that the arrangements at Guy’s and St Thomas’ now require a QP to be nominated for each particular trial. He or she is involved right from the start in, for example, approving the design of the trial and the labels and worksheets used, and not just in sanctioning product release. Mr Forsey also explained that technical agreements were being reviewed, both in relation to the changes in clinical trial regulations and as a consequence of the trusts’ foundation status. Indemnity and insurance provisions can be issues. These “need not be a barrier”, but “do mean that more preparatory work is needed”, he added. Regarding labelling, Mr Forsey stressed that it is important to take a view of what will happen to the IMP when it leaves the manufacturing unit for the dispensary. This can help decide, for example, whether to provide bulk supplies or randomised patient packs.

Outstanding issues include problems in manufacturing placebos that look identical to tablets with active ingredients, because of intellectual property law constraints. Ensuring that there are enough QPs in the NHS is also an issue, especially with the “grandparenting” provisions set to finish next year.

Finally, Mr Forsey said that there is a real need for manufacturing units to work together to set up a support network to

ensure that the NHS gets the most from its resources. There are needs, for example, to develop a consensus about the terms to be included in technical agreements and to ensure that local interpretations of regulations are shared to spread best practice.

Non-commercial trials

The health of the nation depends on non-commercial clinical trials being run, according to V’Iain Fenton-May, scientific editor of the *European Journal of Hospital Pharmacy*. However, there was a perception that carrying out non-commercial trials would be made more difficult by the introduction of the clinical trials directive, because of added costs (eg, registration fees), more obligations on sponsors and a perceived increase in bureaucracy.

Regarding the issue of sponsors, Mr Fenton-May said that this had largely been overcome for multicentre trials in the UK by having “joint responsibility” — ie, each hospital chief executive is responsible for clinical trial activities carried out at his or her hospital, but not at the other sites in the trial. Challenges still remain regarding international multicentre non-commercial trials. Other issues include the emergence of research and development offices in trusts and ensuring that QPs “know their rights” when dealing with research and development staff. Labelling of trial products can be a problem, he said, particularly if a trial started before the directive was introduced and the labels used then did not comply with the provisions of the directive.

New practice guidelines launched

Guidance on the provision of pharmacy services for clinical trials, produced jointly by the Royal Pharmaceutical Society and the Institute of Clinical Research, was launched by John Gilroy, chair of the Institute’s pharmacy subcommittee, at the joint meeting. See the news story on p197 for further details