Positional Statement by the NHSPQA Committee

PIC/S Guide to Good Practices for the Preparation of Medicinal Products In Healthcare Establishments (PE 010)

1st Edition

September 2009

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PIC/S 'Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments' (PE 010-03)

The PIC/S 'Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments' (PE 010-03) could be used to support the important role NHS hospital pharmacists have in preparing unlicensed aseptically compounded products under Section 10 exemption to the Medicines Act 1968. Within the United Kingdom this activity is subject to external audit under the direction of EL97(52) to standards contained within the publication Quality Assurance of Aseptic Preparation Services, 4th Edition[(1)], that are equivalent to those for licensable activity and which more than covers the PIC/S requirements.

The NHS Pharmaceutical QA Committee (NHSPQA Committee) is currently updating the standards in its 'Guide to the Preparation of Non-Sterile Extemporaneous Products in NHS Hospitals[(2)] and a new version will be published in 2009. The PIC/S Guidance document has been reviewed during this process and all sections of the NHSPQA Committee's Guide have been updated accordingly to ensure compliance where relevant. The new version of the NHSPQA Committee's 'Guide to the Preparation of Non-Sterile Extemporaneous Products in NHS Hospitals' will form the standard for extemporaneous dispensing in the NHS.

The MHRA 'acknowledge that the United Kingdom has a system of Licensing the Manufacture of Unlicensed Products' and 'this is not necessarily so in other Member States'[(4)]. The NHS holds a considerable number of these Manufacturer's 'specials' Licences. The MHRA is preparing questions and answers on Good Manufacturing Practice (GMP) issues has further stated that 'future guidance will be published in 2009 and will take into account the PIC/S document and be expanded, as issues are raised'[(3)].

Martin Knowles
(on behalf of the NHSPQA Committee)

References:

1. Quality Assurance of Aseptic Preparation Services, Alison M. Beaney (Editor), 4th Edition, London: Pharmaceutical Press, 2006
2. Guide to the Preparation of Non-Sterile Extemporaneous Products in NHS hospitals, V'Iain Fenton-May (Editor), NHSPQA Committee, 2003
3. Minutes of the Liaison meeting between MHRA and the NHS Pharmaceutical QA Services Committee, 3 March 2009 (Confidential to NHS/MHRA)

Supporting Notes

Background to PIC/S

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme are jointly known as PIC/S. To quote from the PIC/S homepage (http://www.picscheme.org/) 'PIC/S are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.'

> 'PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."
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> 'This is to be achieved by developing and promoting harmonised GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international organisations.

Country membership or 'participating authorities' who meet at least twice a year is not restricted to the European Union (EU) but is world wide with currently 34 countries involved. The Medicine and Healthcare products Regulatory Agency (MHRA) represent the United Kingdom. There are also four partners / observers : European Directorate for the Quality of Medicines and Healthcare (EDQM), European Medicines Agency (EMEA), Unicef and the World Health Organisation (WHO).

PE 010

Within the United Kingdom there is no accepted definition of a 'healthcare establishment' and the definition in the PIC/S Guide is not helpful:

> 'the basic requirements presented in this Guide apply to the preparation of medicinal products normally performed by healthcare establishments for direct supply to patients.'

The original PE 010 draft was directed at preparation in hospital pharmacies but later versions used the phrase 'healthcare establishments' in order that the Guide may be used in 'public pharmacies'.