



New Zealand Hospital Pharmacists' Association (Inc)

Te Kāhui Whakarite Rongoā Hōhipera o Aotearoa

Position Statement on the Reconstitution and Administration of High Dose Bacillus Calmette-Guérin (BCG) Bladder Instillation in the Ward or Clinic Setting

Introduction

BCG (Bacillus Calmette-Guérin) is a live vaccine used for prevention of tuberculosis and treatment of some forms of bladder cancer.

Background

Whilst there are no published studies showing adverse effects, there is theoretical evidence that prolonged exposure to live vaccines can be harmful. This is due to the mode of action of the product. It is international best practice to reconstitute high dose BCG in safety cabinets or provide staff involved in reconstituting and preparing this medication with safety systems to minimise the risk of exposure and therefore harm.

The Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme (PIC/S),¹ which provides international good manufacturing practice (GMP) guidelines recommends that BCG for bladder instillation is reconstituted in a separate area to any other medicine.

Upon investigation, there appears to be a variance in where and how these vaccines are being reconstituted in New Zealand hospital. These include being reconstituted and prepared unprotected in the ward or clinic by the administering nurse, in a pharmacy aseptic unit where other medicines are prepared and/or in separate safety cabinets.

NZHPA Position

The New Zealand Hospital Pharmacists' Association (NZHPA) acknowledges the risk posed to staff reconstituting and preparing BCG for bladder instillation in the ward or clinic setting without sufficient safety measures in place.

The NZHPA believes in terms of safety that it is essential that BCG bladder instillation is prepared in an aseptic environment or designated safety cabinet and separated from any other compounding or that the healthcare personnel reconstituting and preparing BCG for bladder instillation use a closed system transfer device to do so.

The use of a closed system transfer device also provides staff protection during the administration and withdrawal processes. A closed system transfer device is a needle free (meaning that needles are enclosed) system whereby the equipment ensures the operator cannot come into contact with

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the medication they are preparing. The NZHPA strongly recommends these devices are employed.

This position statement is a strong recommendation that hospitals investigate their protocols for the reconstitution and administering of BCG for bladder instillation and purchase closed system transfer devices to protect their healthcare staff and patients.

References

1. Health and Disability Services. Pharmacy Services Standard. Standard 5.22.
2. PIC/S (Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme)). Guide to Good Manufacturing Practise for Medicinal Products. PE 009-9 Annexes, <http://www.picscheme.org/publication.php?id=4>.
3. [No author listed]. Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice. [FDA website]. September, 2004. Available at <http://www.fda.gov/cder/guidance/5882fnl.htm>. Accessed: March 2006.
4. NHS National Patient Safety Agency. Promoting safer use of injectable medicines. <http://www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/injectable-medicines/>.

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