# REFERENCES

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| **Enclosure No:** | 4/AWMSG/1205 |
| **Agenda Item No:** | 4 – Patient safety issues involving generic prescribing |
| **Author:** | Inappropriate Generics Working Group |
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## Action for AWMSG

1. Do members agree with the patient safety issues identified?
2. Are members aware of other patient safety issues?
3. Is there a need to consult with other organisations?
4. Do members agree with the means of disseminating the advice?
5. Can members suggest other means of disseminating the advice?
6. How should the dissemination of the advice be taken forward?

## Purpose

AWMSG is asked to consider-

- The list of patient safety issues raised
- Further issues for inclusion on the list
- Means of disseminating the issues highlighted
- The need for the existing or a revised working group to progress this work.

## Summary

This paper highlights a number of patient safety issues related to the prescribing of a preparation by generic name. It also considers how awareness of these issues can be raised with health care professionals.

## Background

A paper entitled 'National Prescribing Indicators 2005/2006' was presented at the AWMSG meeting held in June 2004. One of the indicators related to inappropriate generic prescribing. A small working group was established to produce a list of drugs for which generic prescribing was not appropriate. This list was included in a subsequent paper which was approved at the AWMSG meeting in March 2005.

The consultation process used in the development of this list highlighted a number of issues which could not be addressed by the prescribing indicator. These were situation in which it may be necessary to prescribe by brand name for reasons of patient safety or practicality. AWMSG requested an enlarged working group to address these issues and to consider how to make prescribers aware of them.

## Consideration

The issues which the group thought needed to be raised are included in Table 1.

A number of possible means of disseminating this advice were considered, namely

- Postgraduate education organisations e.g. WCPPE
- LHB newsletters to GPs and pharmacists
- Correspondence or an article in the Pharmaceutical Journal or BMJ
- GP vocational schemes
- AWMSG/WMP website
- CSM Newsletter

**TABLE 1**

| DRUG | PATIENT SAFETY ISSUE | RECOMMENDATIONS |
|---|---|---|
| a) Hyoscine | Available as 2 salts which have different indications and doses- Hydrobromide & Butylbromide | Hyoscine butylbromide should be prescribed as Buscopan<br><br>GP & hospital pharmacy computer systems should be set to default to Buscopan<br><br>Clinical pharmacists should endorse prescriptions for hyoscine butylbromide as Buscopan |
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| b) Oxycodone | Potential for confusion between normal release (Oxynorm) and modified release (Oxycontin) preparations. Patient could experience respiratory depression or breakthrough pain if unintended preparation given. | Need for education for health care professionals about the implications of different strengths, forms, release and drug delivery mechanisms. Dual prescription and labelling (i.e. using generic and brand names) would aid education of all professionals. |
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| c) MR morphine preparations | Release mechanisms of different preparations vary. Patient could experience poor pain control if unintended preparation given. | Need for education for health care professionals about the implications of different strengths, forms, release and drug delivery mechanisms. Dual prescription and labelling of MXL (24 hour release morphine sulphate) would distinguish between the 12 hour and 24 hours preparations. |
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| d) Fentanyl patch | Originator patch, previously of a reservoir design has been reformulated as a matrix patch, subsequent generic products were of a reservoir formulation. Matrix patches can be cut in half without altering drug delivery mechanism, reservoir patches cannot. Originator patch manufacturer states its patch should not be cut | Prescriber to inform patient of off-licence prescription if need to cut matrix patch. Clinical and dispensing pharmacists to be alert for interventions in this situation. Clinical pharmacists should confirm the clinical need for cutting the patch. |
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| e) Insulins | Many products.<br><br>Need for patients to maintain appropriate supply. | Insulins should be prescribed by brand name |

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| f) Growth hormone | Different products have different administration mechanisms and techniques. As preparations are self-administered by the patient there is potential for confusion. | Growth hormone should be prescribed by brand name |
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| g) Alprostadil | Different products have different administration mechanisms and techniques. As preparations are self-administered by the patient there is potential for confusion | Alprostadil should be prescribed by brand name |
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| h) Cyproterone | There are 2 preparations of cyproterone available:<br><br>Androcur which is licensed for control of libido and/or sexual deviation, and Cyprostat which is licensed for management of patients with prostatic cancer. The PILS will reflect these indications and it would be extremely distressing for the patient to receive the unintended leaflet. | Cyproterone should be prescribed by brand name according to the indication |
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| i) Anticonvulsants | The bioequivalence standards required by the MHRA ensure brand and generic products demonstrate essential similarity. Patient confidence is however of paramount importance and given the medical and social implications of a seizure, some patients may wish to receive the same anticonvulsant preparation whether a brand or generic product. | Switching between brand and generic preparations or between different generic preparations for patients with a history of seizures may not retain patient confidence. In this situation it would be good practice to maintain a consistent supply of a particular preparation (brand or generic) for an individual epileptic patient. |
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| j) Anadin and Canesten | The same brand name (with different suffixes) may contain different ingredients. | There is a need for education for health care professionals and patients about this issue. |