Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

Ms Veronica Popo
Department of Health
Medicines and Healthcare products Regulatory Agency
Room 14-138 Market Towers
1 Nine Elms Lane
London
SW8 5NQ

PRACTICE AND QUALITY
IMPROVEMENT DIRECTORATE
Practice Division
Telephone: 020 77572 2537
Facsimile: 020 7572 2501
e-mail: sadia.khan@rpsgb.org

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Dear Ms Popo,

Re: ARM 51 - Request to reclassify Cystobid (nitrofurantoin) 100mg Capsules from POM to P

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation document.

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society supports this reclassification and requests that the following points be taken into consideration:

Reclassification Summary

Section 2. Product Details. Dosage states: 100mg twice daily for three days. This dosage does not tie in with that published in the British National Formulary 55 (page 320) for acute uncomplicated infection.

Section 4.1.2 Resistance to Nitrofurantoin. States 'Currently, nitrofurantoin accounts for less than 10% of prescriptions for uncomplicated cystitis in women in the UK'. The Society suggests that consideration should also be given to switching products that may be more effective / used more frequently than nitrofurantoin for the same indication.

Section 4.1.4 Risk of Misuse. States that the supply of this medicine will be under a pharmacist's supervision. The Society wishes to highlight that in time pharmacy technicians will be able to supervise supply.

Section 8. Safety profile. Consideration should be given to including 'This medicine may colour the urine' as a counselling point.

Patient Information Leaflet

Section 2:

Before you take Cystobid – Point 4. In order to ensure that supply is not made under these circumstances this advice should be included in the questionnaire.

Do not take Cystobid if – Point 2. The patient may not know whether they lack an enzyme called 'glucose-6-phosphate dehydrogenase'.

Do not take Cystobid if – Point 3. Patients with diabetes may not necessarily be aware that they have neuropathy.

End of page 2 refers to Cysticlear not Cystobid.

Taking Cystobid with food and drink states: 'Cystobid capsules can be taken at meal times with food or milk'. Wording needs to be more explicit and state it should be taken with or after food (see BNF).

Pregnancy and breast-feeding. The Reclassification Summary states the products is contra-indicated for use in pregnancy / breast-feeding. The Patient Information Leaflet does not give the same message.

Section 3. How to take Cystobid. Highlights that the product is 'for treatment of bladder infections'. In other parts of the Patient Information Leaflet reference is made to treatment of both cystitis and bladder infections. In order to avoid confusion the Society suggests consistency in terminology.

Section 4. Possible Side Effects. Martindale The Complete Drug Reference (35) On-line (accessed April 2008) states:

'The estimated incidence of adverse effects with nitrofurantoin has varied enormously, but may be around 10% overall; an incidence of serious reactions of about 0.001% for pulmonary, and 0.0007% for neurological reactions has been suggested. The most common adverse effects of nitrofurantoin involve the gastrointestinal tract. They are dose-related and generally include

nausea, vomiting, and anorexia; abdominal pain and diarrhoea occur less frequently. It has been reported that adverse effects on the gastrointestinal tract are less common when nitrofurantoin is given in a macrocrystalline form or with food'. In terms of the most common side effects, the information in the Patient Information Leaflet does not tie-in with the statement from Martindale.

Discoloration of urine (page 5). The statement on urine discoloration should be given a higher priority and included near the beginning of the section.

'Remember'. This medicine has been recommended **by for** your pharmacist – delete extra word.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Practice Pharmacist - Lead for Self-care