

English Pharmacy Board 24 June 2009

**PUBLIC BUSINESS**

## **POM to P Guidance**

### **Purpose**

To inform national board members of the process for the development of practice guidance on newly reclassified medicines (POM to P guidance) with a view to encouraging more members to provide feedback on future draft guidance.

### **Strategic objective domain**

- The public recognise and use pharmacists as the professionals with expertise in medicines

### **Action required**

The national board members are asked to:

- i. note the progress to date
- ii. collaborate more actively with the office in terms of developing future POM to P guidance

### **1. Background**

- i. **Reclassification Strategy**

In 2002, a working group led by the Royal Pharmaceutical Society produced a list of potential candidates for reclassification from POM to P status. The original list and background information concerning the initiative can be accessed via:

<http://www.rpsgb.org/pdfs/pomtopreclasslist.pdf>

<http://www.rpsgb.org/pdfs/pomtopreclassbkgnnd.pdf>

<http://www.rpsgb.org/pdfs/pomtopreclassinfr.pdf>

In 2005, [former] Practice Committee debated the list and agreed that rather than updating it, the approach to reclassification needed to be reviewed to reflect the needs of community pharmacy and practice. It was recommended that any future switches should be considered in the context of a wider pharmacy self-care policy / patient and customer wants and needs. This position was relayed to the MHRA Reclassification Strategy Group who subsequently ran two conferences that focussed on the needs and wants of customers and patients in terms of reclassifications.

(Note: The Society also published a self-care policy document entitled 'The Self Care Challenge: A Strategy for Pharmacists in England' that aimed to create a call of action for pharmacists to engage more closely with the self-care agenda).

- ii. **ARM Consultations**

The MHRA formally consults organisations representing public and professional interests, trade associations and industry on valid applications to change the legal status (prescription only, pharmacy or general sale list) of medicines; these consultations are given the prefix, 'ARM' (applications to reclassify medicines).

The ARM consultations are sent by the office to various stakeholders for comment (national boards, HPG committee, CPG Committee, Legal and Advisory Services, RPSGB Information Pharmacists,

BNF) and the final RPSGB response is available via:  
<http://www.rpsgb.org/informationresources/downloadsocietypublications/consultationresponses.html>

### iii. POM to P Practice Guidance

The Lead Pharmacist for Self-care writes practice guidance for reclassified products that are 'first' to be reclassified in a therapeutic class. The guidance is published as a two-sided A4 card and is based on a variety of information sources (comments from stakeholders, summary of product characteristics, company training material, evidence-based literature sources etc). The guidance is GB-wide and is circulated to all practising pharmacists. Examples include:

Orlistat (April 2009)  
Azithromycin (November 2008)  
Sumatriptan (June 2006)  
Amorolfine nail lacquer (May 2006)  
Chloramphenicol eye drops (June 2005)  
Omeprazole (May 2004)  
Simvastatin (July 2004)  
Emergency Hormonal Contraception (updates September 2004)

Note: The more recent reclassifications have involved more complex models for supply and include information relating to the Code of Ethics etc.

### iv. Role of [former] Practice Committee / national boards

The [former] Practice Committee discussed draft POM to P guidance at Committee meetings and provided detailed feedback on content.

The national boards all receive electronic copies of draft guidance for comment however no single board currently takes an active lead in developing content. Responsibility for determining content rests primarily with the Lead Pharmacist for Self-care. Any feedback from the national board members is welcome and taken into account when the guidance is being developed, however the level of feedback received varies and can sometimes be relatively low. The office would like to raise awareness amongst national board members of the processes for developing POM to P guidance with a view to encouraging more active collaboration / possibly more detailed feedback from board members on future drafts.

## 4. Risk Implications

Failure to ensure active collaboration from national board members into the development of POM to P guidance may create a risk to the organisation if content of guidance is queried by stakeholders.

## 5. Resource Implications

None

## Recommendations

The national board members are asked to:

- i. note the progress to date
- ii. collaborate more actively with the office in terms of developing future POM to P guidance

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