



Responsible Pharmacist: The latest news

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Scope of presentation

- Why the changes?
- Personal control & supervision
- Phased approach
- Responsible pharmacist changes
- Timetable
- Next steps



Health Act 2006 changes: Why?

- To address issues raised by the pharmacy profession



Health Act 2006 changes: Why?

- Originally to enable pharmacists to pursue a greater clinical role
 - within the pharmacy
 - in the same location adjacent to the pharmacy
 - elsewhere
- Focus was on reviewing supervision



Health Act 2006 changes: Why?

- But personal control also interpreted as requiring physical presence
- So GSL medicines can only be sold in a pharmacy when the pharmacist is present
- Even though pharmacist presence not necessary for other retail outlets
- Focus shifted to include personal control



Personal control & supervision

- Separate concepts in separate parts of the Medicines Act
- Personal control is about the running of the pharmacy
- Supervision concerns individual transactions
- Interpretation merged so that both require the pharmacist's physical presence



Health Act 2006 changes: Concern about absence

- Some fear changes will result in pharmacies without pharmacists



Health Act 2006 changes: Concern about absence

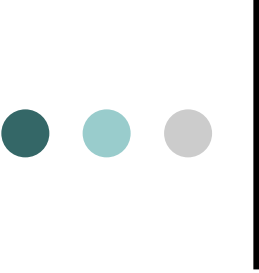
Not so:

- Responsible pharmacist for all pharmacies
- Can restrict absence of the responsible pharmacist (MA regs)
- Can require pharmacist presence to provide NHS services (NHS regs)
- Not make good business sense



Health Act 2006 changes - Phased approach

- Complex changes – significant impact on pharmacy practice
- Ensure maintain patient safety
- Responsible pharmacist changes are largely mandatory and will set the quality framework
- Supervision changes are enabling
- Therefore start with responsible pharmacist first



How will the responsible pharmacist changes be achieved?

- Through combination of :
 - 1^o legislation
 - Health Act 2006 amends Medicine Act (MA) 1968
 - UK wide
 - Regulations under the MA 1968
 - UK wide

Responsible pharmacist changes: Timescale

- 1^o legislation in place
- Consulted widely on content of responsible pharmacist regulations
- Discussed draft regulations
- Expect regulations to
 - be laid by end September 2008
 - come into force 1 October 2009
- Supported by guidance



Responsible pharmacist changes: Scope

- Affects all registered pharmacies
 - Community pharmacies
 - Registered hospital pharmacies

- ● ● | Responsible pharmacist:
Statutory duty

- “Personal control” replaced with “responsible pharmacist”
 - each premises where retail pharmacy business carried out - individual, partners, bodies corporate etc (s.70-72)
- Responsible pharmacist has statutory duty
 - to secure the safe and effective running of the pharmacy



Responsible pharmacist: Superintendent role

- Superintendent pharmacist role continues
- Pharmacies carried on by bodies corporate required to be under the management of a superintendent pharmacist
- Responsible pharmacist, where he is not the superintendent pharmacist, remains subject to the directions of the superintendent pharmacist



Responsible pharmacist: Procedures

- Establish (if they are not already established), maintain and keep under review procedures
- Cover arrangements to secure that medicines are ordered, stored, prepared, sold, supplied, delivered & disposed of in safe & effective manner
- The giving of advice on medicines



Responsible pharmacist (RP): Procedures

- Identify pharmacy staff competent to undertake specific activities
- Record keeping
- Arrangements when RP absent
- Steps to be taken when RP changes
- Procedure when there is a complaint
- Procedure when there is an adverse incident



Responsible pharmacist (RP): Procedures

- Notification of changes to procedures to pharmacy staff
- Kept in writing or electronically
- Accessible to owner, superintendent, RP, and pharmacy staff
- Reviewed regularly



Responsible pharmacist (RP): Record

- Responsible pharmacist to make a record of who the responsible pharmacist is at any time, including when absent
- Record kept in writing or electronically
- Accessible to owner, superintendent, RP, and pharmacy staff



Responsible pharmacist (RP): Record

- Record to include:
 - Responsible pharmacist's name and registration number
 - Date and time became RP
 - Date and time ceased to be RP
 - Date and time any absence began and ceased



Responsible pharmacist: Record

- The pharmacy owner must ensure the record of the responsible pharmacist is properly maintained
- And preserved for not less than five years



Responsible pharmacist: Public notice

- A notice with name of responsible pharmacist, their registration number and the fact that they are in charge of the pharmacy is to be displayed conspicuously
- The record and notice replaces the need to display registration certificate & make annual return to RPSGB/PSNI



Responsible pharmacist: Number of pharmacies

- In general the responsible pharmacist may not be responsible for more than one pharmacy at the same time
- Regulations can specify the circumstances where an exception can be made from this general rule and the conditions to be met



Responsible pharmacist: Number of pharmacies

- Regulations will enable Ministers to authorise an exception in the case of severe emergencies, nationally – eg pandemic flu - or affecting part of UK
- Only for period authorised
- Responsible pharmacist in charge of no more than two pharmacies



Responsible pharmacist (RP): Absence

- The responsible pharmacist is able to be absent from the pharmacy
- Absence limited to a maximum of two hours per day, whether one or more responsible pharmacists
- Absence limit does not apply in the exceptional circumstance when RP is in charge of two pharmacies

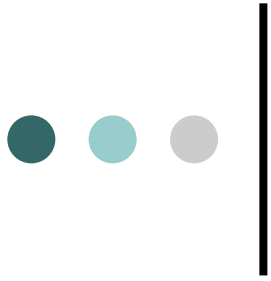
Responsible pharmacist (RP): Absence

- RP must make arrangements to be
 - contactable by pharmacy staff
 - able to return to the pharmacy with reasonable promptness
- Where not reasonably practical, RP must arrange for another pharmacist to be available and contactable
- GSL medicines can be sold when the RP is absent



Next steps

- Responsible pharmacist:
 - Lay regulations – expected to commence 1 October 2009
 - Health Departments collectively issue factual guidance
 - RPSGB/PSNI issue professional regulatory guidance
- Supervision changes follow
 - Initially informal discussions



Thank you