

# HEALTH ACT 2006: SKILL MIX The Responsible Pharmacist

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## Scope of presentation

- Why the changes?
- Personal control & supervision
- Legal framework
- Phased approach
- Responsible pharmacist proposals
- Proposed timetable
- What can you do?



# 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



## Health Act 2006 changes – Other inconsistencies

- A van driver can deliver medicines to a patient's home
- But if a patient goes into a pharmacy when the pharmacist is absent, they cannot collect their medicines, even though they are already dispensed



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



# How are the changes to be achieved?

- Combination of :

- 1<sup>o</sup> legislation: Health Act 2006 amends:
  - Medicine Act 1968 – UK wide
  - NHS Act 1977 – England & Wales
  - NHS (Scotland) Act 1978 – Scotland
- Order making powers
  - s.15 & s.55 Medicines Act 1968
- Regulations



## 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



# Health Act 2006 - Responsible pharmacist

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

# Health Act 2006 - Responsible pharmacist – statutory duty

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



## Health Act 2006 - 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



## Health Act 2006 - Responsible pharmacist – procedures

- Establish (if they are not already established), maintain and keep under review procedures
- Regulations can set out:
  - the matters to be covered in procedures
  - the form in which procedures are to be recorded



# Health Act 2006 - Responsible pharmacist – records

- Responsible pharmacist to make a record of who the responsible pharmacist is at any time, including when absent
- Regulations can set out
  - other matters to be covered in the record
  - the form in which record is to be kept



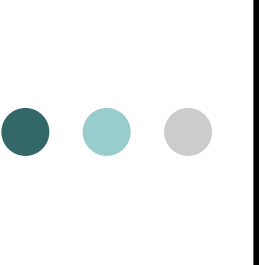
## Health Act 2006 - Responsible pharmacist – records

- The pharmacy owner must ensure the record of the responsible pharmacist is properly maintained
- And preserved for at least as long as specified
- Regulations can
  - specify the length of time the record must be maintained



## Health Act 2006 - Responsible pharmacist – records

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




## Health Act 2006 - Responsible pharmacist – absence

- The responsible pharmacist is able to be absent
- Regulations can
  - set parameters for absence

# Health Act 2006 - 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 & the conditions to be met



# Health Act 2006 - Responsible pharmacist – supervision

- Regulations can make provisions about:
  - supervision by the responsible pharmacist when they are not on the premises
  - circumstances in which the responsible pharmacist may supervise activities in another pharmacy where they are not the responsible pharmacist

- ● ● | Health Act 2006 - Responsible pharmacist – qualifications & experience

- Regulations can specify the qualifications and experience a person must have to be a responsible pharmacist



## Health Act 2006 - Responsible pharmacist - GSL medicines

- No need for responsible pharmacist to be present, as for other retail outlets
- Public view pharmacies differently
- Statutory duty of responsible pharmacist includes sale of GSL medicines
- Covered in procedures
- Differences for NHS services



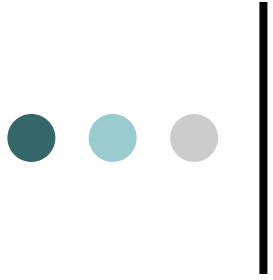
## Proposed timetable

- Responsible pharmacist:
  - Informal consultation: Feb/Mar 2007
  - Formal consultation (12 weeks): from Autumn 2007
  - Regulations laid: ?? Spring 2008
  - Commencement: subject to consultation
- Supervision changes – follow similar process



## What can you do?

- Understand the proposed changes
- Discuss the proposals
- Inform the debate
- Help shape the regulations – respond to the consultation
- Inform implementation



Thank you