Rebalancing Medicines Legislation and Pharmacy Regulation Programme Update

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Programme Board – Terms of Reference

A Programme Board for Rebalancing Medicines Legislation and Pharmacy Regulation has been established to examine the respective scope of legislation and regulation, and the interface between them, with a view to ensuring these are optimally designed to provide safety for users of pharmacy services, while facilitating a systematic approach to quality in pharmacy and responsible development of practice and innovation, whilst reducing the burden of unnecessary and inflexible regulations.

The Board’s role is

1. to advise Ministers and the Devolved Administrations on policy within their Terms of Reference, and

2. to oversee implementation of policy outcomes agreed by Ministers and the Devolved Administrations.

For full terms of reference see:

https://www.gov.uk/government/policy-advisory-groups/pharmacy-regulation-programme-board
Rebalancing Programme Portfolio

- Dispensing error offence
- Pharmacies and pharmacy owners
- Superintendent pharmacists (SPs) and responsible pharmacists (RPs)
- Hospital and other pharmacy services
- Pharmacist supervision
Dispensing errors: Proposals

New defence
- Retain criminal offences in respect to section 63 (adulteration) and section 64 (not of the nature or quality ordered)
- Pharmacists and pharmacy technicians have a defence to those offences for inadvertent dispensing errors, providing certain conditions are met - apply to unregistered pharmacy staff and owners too

Conditions
- Medicine sold or supplied by a registered pharmacist/pharmacy technician from registered pharmacy premises
- Sale or supply in pursuance of a prescription/directions
- Registered pharmacist/technician acting in course of their profession
- Patient promptly notified of the error, unless considered unnecessary

Not acting in course of their profession
- Used professional skills for an improper purpose
- Deliberately failed to have due regard for patient safety
Pharmacy owners, SPs and RPs: Key aims

• **Criminal law and professional regulation** - pharmacy practice matters that should properly be within the ambit of the pharmacy regulators are in fact dealt with by them – and by registration sanctions, rather than by the criminal courts

• **Ministers and pharmacy regulators** - less is set by the Ministers - and in primary legislation - and more is set instead by the pharmacy regulators

• **Legislation and standards** - for pharmacy practice matters, less is set in inflexible legislation and more is set more flexibly in standards, enabling an ‘outcomes’ approach

• **The three key players** - to ensure the safe and effective practice of pharmacy in a retail pharmacy context:
  – the RP, who is in charge of a particular pharmacy on a given day
  – the SP, who is intended to be the professional lead within the company
  – the pharmacy owner
Pharmacy owners, SPs and RPs: Overview of proposals

Overall outcome:

• Coherent regulation framework for the sale and supply of medicines and other pharmacy services set and enforced through the pharmacy regulators – GPhC and PSNI
• Greater clarity of relative roles and responsibilities – pharmacy owners, superintendent pharmacists (SPs) and responsible pharmacists (RPs)

Overall approach:

• Purpose of the SP and RP defined in primary legislation
• How the SP and RP fulfils that purpose to be defined in professional regulation
Registered Pharmacy and Pharmacy Owner: Changes

Registered pharmacy standards
• Remove the requirement for GPhC pharmacy standards to be in rules
• Place duty on PSNI to set and publish pharmacy standards
• List of broad domains to be covered – not specific activities
• Enable standards to be set for associated premises
• Obligation on pharmacy owners to meet standards, not SPs
• Legal status of standards for registered pharmacies aligned with those for individual registrants and subject to registration sanctions

Related matters
• Enable GPhC to publish inspection reports and outcomes
• Changes to GPhC/PSNI enforcement powers for registered pharmacies
• Correct an error in notification of GPhC of the death of a registrant
• Changes to information obligations on pharmacy owners – now permissive; clarify when information can be sought
Superintendent pharmacist (SP): Proposals

- Senior manager with the authority to make decisions that affect the running of the retail pharmacy business
- New general duty to secure the safe and effective running of the whole pharmacy business – SP always responsible
- Ensure the pharmacy business “is carried on in ways” that secure that duty – not specify the means, for example procedures
- In general, SP responsible for procedures – RP contribute to their development and operation, acting in the best interests of patients
- Remove restriction of SP for one pharmacy retail business
- Pharmacy regulators to set professional standards for SPs, which extend beyond the sale and supply of medicines (POMs, Ps and GSLs) to other pharmacy services
Responsible pharmacist (RP): Proposals

- Retain requirement for a RP in charge of each pharmacy, with current statutory duty to ensure the safe and effective running of the particular pharmacy, when they are in charge
- In general, a pharmacist can only be the RP for one pharmacy at the same time, unless an exception is specified
- RP may be absent from the pharmacy when GSL medicines are sold and as specified
- Pharmacy regulators to be given general powers to set out the detailed requirements of the RP in rules/regulations
- Pharmacy regulators to set professional standards for RPs, which extend beyond the sale and supply of medicines (POMs, Ps and GSLs) to other pharmacy services
Hospital & other pharmacy services: Proposals

• Based on recommendations of Expert Advisory Group
• Community pharmacies must be registered – hospital pharmacies do not
• Variation in governance arrangements across the four home countries
• Dispensing error offence – Put on even footing to community pharmacy
• All registered pharmacy professionals working in hospitals or other specified pharmacy services have the defence for inadvertent dispensing errors
• Different, proportionate, approach to system governance
Dispensing error defence: Common features

- Medicine sold of supplied by a registered pharmacist or registered pharmacy technician (pharmacy professional)
- Sale or supply in pursuance of a prescription or directions
- Pharmacy professional was acting in the course of their profession
- Patient promptly notified of the error, unless considered unnecessary

Replace – “at or from registered pharmacy premises” with a reference to various types of pharmacy service, overseen by a chief pharmacist
Hospital & other specified pharmacy services

Programme Board general view – the principles:

• Registered pharmacies – covered by defence already consulted on

• Regulated and NHS governed healthcare activity – should be covered

• Unregulated healthcare activity – fall outside current proposals
Hospital & other specified pharmacy services

- Refer to pharmacy services rather than premises
- Use definition of “hospital” from Human Medicines Regulations 2012: “Hospital” includes a clinic, nursing home, or similar institution

Cover pharmacy services:
- Hospital, including clinic, nursing home or similar institution
- Institutions where people are lawfully detained – prison, mental health and immigration/asylum
- Subject to registration - activity, service, person - ie by CQC, HIS and HIW.
- Further consideration of NI
Hospital & other specified pharmacy services

Governance (1)

• Concerns criminal law, with a defence to a criminal offence
• Essential system governance element of the defence is clearly understood – by:
  – Pharmacy professionals making out the defence
  – Senior pharmacists accountable for hospital and other specified pharmacy services
  – Judicial system
• Statutory term like “chief pharmacist” with a statutory duty in respect to the safe and effective running of the pharmacy service provides the necessary certainty
• “Chief pharmacist” need not be adopted as a job title as long as statutory function included in job responsibilities
Hospital & other specified pharmacy services
Governance (2)

To benefit from the defence:

• Must be a chief pharmacist for the pharmacy service

• Chief pharmacist:
  – Is a registered pharmacist
  – Has significant role, in respect to the undertaking in which the pharmacy service is located, akin to superintendent pharmacist in community pharmacy
  – Has authority to make decisions that affect the running of the pharmacy service in relation to medicine sale/supply
  – Responsible for securing safe and effective running of pharmacy service in relation to medicine sale/supply

• Enable the pharmacy regulators to set standards in respect of chief pharmacist, including a description of their professional responsibilities.
Review of pharmacist supervision

Short Life Working Group
• To support the four CPhOs in providing advice to the Board
• Jointly chaired by the CPhOs for England and Scotland
• Membership from the Rebalancing Programme Board

Terms of reference
Inform proposals, which ensure patients, the public and healthcare professionals have safe, efficient effective and convenient access to suitably trained, competent, clinical pharmacists, whilst ensuring that the sale and supply of medicines, including preparation and assembly, from registered pharmacies remains safe and becomes more efficient. This includes the deployment of modern technologies and more effective use of the whole pharmacy team including registered pharmacy technicians.
Rebalancing Programme: s60 Order Process

- Proposals developed and agreed by Programme Board
- Sense checked with Partners Forum
- Cross government approval to consult
- Formal public consultation (12 weeks), including draft legislation and impact assessment
- Analyse consultation responses
- Refine legislation and impact assessment
- Cross government clearance
- Publish consultation report
- Lay section 60 Order
- Parliamentary debates to secure enabling legislation
- Secondary legislation, e.g. for pharmacy regulators
- Implementation: Planning throughout process
“Rebalancing” Programme – Current position

Dispensing error defence (community pharmacy)
- Consultation held on proposals – broad support
- Following government clearances, next step lay Order for debate

Registered pharmacy/pharmacy owner changes
- The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 approved by Parliaments and Privy Council
- Next step – commencement orders

Superintendent and responsible pharmacists
- Programme Board agreed proposals, informed by Partners Forum
- Following government clearances, next step consultation

Hospital and other specified pharmacy services
- Programme Board agreed proposals, informed by Partners Forum
- Following government clearances, next step consultation

Pharmacist supervision
- Short Life Working Group informing development of proposals
Thank you

Any questions or comments?