

# Summary of findings in Northern Ireland

## *Impact evaluation of the Responsible Pharmacist Regulations, with a specific focus on Northern Ireland*

### Background

The Responsible Pharmacist Regulations<sup>1</sup> came into force in October 2009, creating a legal duty for the pharmacist to ensure the safe and effective running of the pharmacy at all times. The Regulations built on the 1968 Medicines Act, which governs the sale and supply of medicine, and sought to bring clarity to the role and responsibilities of the pharmacist as well as 'to support pharmacists in developing their clinical role'<sup>2</sup>. A second phase of amendments to the Act, involving changes to the supervision requirements, will follow a public consultation this autumn.

In this context, the Royal Pharmaceutical Society and the Professional Forum of the Pharmaceutical Society of Northern Ireland commissioned TNS-BMRB to carry out an independent evaluation of the impact of the Responsible Pharmacist Regulations, headlines of which, as they relate to Northern Ireland specifically, are provided below.

### Research objectives

The overarching aim of the research was to understand from practitioners whether the Responsible Pharmacist Regulations have delivered on their policy intent of supporting an increased clinical role alongside safe and effective running of the pharmacy.

Specific research objectives were as follows:

- To **assess comprehension** amongst pharmacy staff of the Responsible Pharmacist Regulations and the extent of compliance
- To **understand** how the Regulations are being enacted in practice
- To **capture views** to determine the perceived advantages and disadvantages of the Regulations (operational and strategic)
- To **measure impact** on patient safety and on clinical leadership, extension of services and personalised care

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<sup>1</sup> The Medicines (Pharmacies) (Responsible Pharmacist) Regulations (2008). Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_095570](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_095570)

<sup>2</sup> The Responsible Pharmacist: Consultation on the Content of the Responsible Pharmacist Regulation. Department of Health (2007:16), Sections 1.4, p.13. Also covered in Section 5.6, p 45.

- To **highlight solutions** to any issues arising in terms of barriers to implementation or impact and build ownership of them in the process.

## Research method

The study used a mixed-method quantitative and qualitative methodology, engaging 2,028 pharmacists and 509 support staff across Great Britain and Northern Ireland via online and paper-based surveys, with an additional 45 in-depth telephone interviews and five in-situ case studies. The sample included all pharmacy settings affected by the Regulations. In Northern Ireland, 230 pharmacists and 39 support staff responded to the quantitative survey, and 10 in-depth interviews and one case study were carried out.

The main data capture was informed by a development phase involving a review of grey literature, interviews with stakeholders and pilot and scoping interviews with pharmacists and support staff. It was followed by a stakeholder event designed to take findings forward and agree on any areas for change.

## Summary of findings

Key findings from the study as a whole are outlined below, with results for Northern Ireland shown against those for the United Kingdom (UK) as a whole. Where results differ significantly this is noted as a difference and highlighted in the summary box below. Due to the small number of support staff responding to the survey in Northern Ireland, it is not possible to provide quantitative analysis based on support staff in Northern Ireland.

To put some of the differences in Northern Ireland into context, it should be noted that respondents in Northern Ireland, compared with those in the UK as a whole were:

- Less likely to work in primary care (2% compared with 7%)
- More likely to work in independent pharmacies (29% of community pharmacists in Northern Ireland compared with 21% of community pharmacists in the UK as a whole)
- Less likely to work in supermarkets chains (1% of community pharmacists in Northern Ireland compared with 9% of community pharmacists in the UK as a whole)
- Less likely to hold the role of RP all the time (52% compared with 63%) and more likely to hold this role less than three quarters of the time (26% compared with 18%)
- Less likely to be currently employed as a locum (21% compared with 31%), but more likely to have previously held this role (40% compared with 30%)

### Key differences in Northern Ireland

- Pharmacists in Northern Ireland were more likely to feel they had a thorough or good awareness of the Regulations.
  - There was also higher satisfaction with training in Northern Ireland. Qualitatively, pharmacists referenced the value of online workshops and training sessions, presentations and Continuing Professional Development (CPD) courses instituted by the PSNI and NICPLD (Northern Ireland Centre for Pharmacy Learning and Development).
  - The RP's role in establishing roles and responsibilities of other members of staff and in establishing, maintaining and reviewing pharmacy procedures was better understood in Northern Ireland than in the rest of the UK.
  - RPs in Northern Ireland were more likely to believe they had the authority to change an SOP or to change staff roles and responsibilities.
  - Locums in Northern Ireland were more likely to read SOPs before commencing work as an RP.
  - In terms of the impact of the Regulations, pharmacists in Northern Ireland were less likely to perceive negative impacts on breaks and more positive about the impact on patient safety.
  - Pharmacists in Northern Ireland were more likely to believe the Regulations made the use of SOPs more important to protect them from accusations of unprofessional behaviour.
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- The Regulations were being introduced into a context of **overall job satisfaction**, but with distinct frustrations around **breaks, training** and, in the community sector in particular, a degree of stress relating to taking on **more roles and services** with the **same or less staff**. Training was less of a concern in Northern Ireland, where 55% of pharmacists were very or fairly satisfied (compared with 45% in the UK as a whole), although this area was still rated lower than other elements of the job such as the number of hours worked and the level of responsibility. Qualitatively, aspects impacting on the role currently included changes to remuneration for dispensing (of particular concern for independents), increased use of mediboxes and more generics prescribing by doctors.
  - The research found high awareness of the Regulations and **around nine in ten of both pharmacists and support staff understood the basic requirements** for record keeping, overall legal accountability for the safe and effective running of the pharmacy and having a single responsible pharmacist (RP) in charge at all times. Pharmacists in Northern Ireland were more likely than those in the UK as a whole to feel they had a

thorough or good awareness of the Regulations (74% compared with 66%) and were also more likely to correctly answer all nine questions about items covered by the Regulations (30% compared with 21%). Qualitatively, pharmacists in Northern Ireland mentioned the value of online workshops or training sessions, presentations and CPD courses instituted by the PSNI.

- There was **less clarity around how the Regulations work in practice**, in relation to:
  - Absence, with one in four (26%) pharmacists and four in ten (39%) members of support staff across the UK incorrectly believing that the RP could be absent for more than two hours if another pharmacist was present;
  - The RP’s role in establishing roles and responsibilities of other members of staff and in establishing, maintaining and reviewing pharmacy procedures although this was better in Northern Ireland than the other nations (80% were clear on their roles, compared with 72% and 75% compared with 62% respectively – a low figure given the importance of these duties).
  - Lines of responsibility between the RP and the superintendent, with only half of pharmacists (53%) and support staff (46%) being clear on this;
  - The legal requirement to keep the record: almost a third across the UK did not know it was a criminal offence not to do this.
- Qualitatively, there was found to be **much lower awareness of the policy intent of the Regulations**; with some interpretation of a link to patient safety but very little to supporting more personalised care and enhancing the pharmacist’s clinical role<sup>3</sup>.
- **Nine in ten RPs think they have implemented the Regulations well** and, qualitatively, the processes did seem to be in place, particularly with regard to SOPs and the record.
- **Processes were not necessarily translating into practice**, with:
  - Only around one in three RPs believing they have the authority to make changes to SOPs and staff roles and responsibilities and fewer (18% and 25% respectively in the UK as a whole) having done so. This was less of an issue in Northern Ireland, where almost half believed they had the authority to change an SOP (45%) or to change staff roles and responsibilities (49%). Almost three in ten (28%) had actually changed an SOP (which may relate to there being more independents, less supermarkets chains and less locums in Northern Ireland), although RPs in Northern Ireland were no more likely than those in the UK as a whole to have made changes to staff roles and responsibilities (24%).
  - Only four in ten (43%) locums reading the SOPs at all or most of the premises that they work in as an RP, a quarter (24%) never doing this and one in five (20%) doing so at very few premises where they work. Again, in Northern Ireland this was less

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<sup>3</sup> As was the intention of the Regulations as stated in the Responsible Pharmacist: Consultation on the Content of the Responsible Pharmacist Regulation. Department of Health (2007:16), Sections 1.4, p.13. Also covered in Section 5.6, p 45

of an issue with only one in ten (9%) locums saying they never read the SOPs before commencing work as an RP.

- **Distinct barriers to using the absence provision:**
  - Qualitatively, in terms of perceptions of pressure from employers and patients and lack of perceived need; and
  - Both qualitatively and quantitatively, in terms of a strong professional culture of ‘being present’ with 44% strongly disagreeing, irrespective of the Regulations, that a pharmacy should be able to continue to operate while the pharmacist is absent (no statistically significant difference in Northern Ireland – 49%).
- **Seven in ten pharmacists agreed that the Regulations put the RP in a difficult position** by making them legally responsible for people and processes outside their control. This was slightly lower in Northern Ireland (63%). Qualitatively, this was driving behaviours which were felt to undermine patient safety, as well as adding professional stress and workplace tension.
- **Just over half of pharmacists (54% in the UK as a whole, 50% in Northern Ireland) felt that the Regulations had had no impact;** reasons given qualitatively were that SOPs had already been in place, very few pharmacists were making use of absence, and some felt that the level of responsibility and accountability had not changed.
- **Perceived changes were largely operational** with some negatives for pharmacists in the UK as a whole around administrative/paperwork (26%) and breaks (14%) and benefits around patient safety (12%). Pharmacists in Northern Ireland were less negative about breaks (8%) and more positive about the impact on patient safety (20%).
  - Support staff were generally more positive than pharmacists overall, and particularly about patient safety (20% in the UK as a whole) and the quality of patient care (15% in the UK as a whole).
- However, there was also evidence that the Regulations were driving RPs towards **more defensive practice:**
  - Half of pharmacists (46% in the UK, 42% in Northern Ireland) felt they should be more empowered to exercise professional judgement but in reality need to follow SOPs more closely.
  - Similarly, half (45% in the UK, but more in Northern Ireland – 59%) thought the Regulations made the use of SOPs more important to protect them from accusations of unprofessional behaviour.
- **Few changes were perceived in terms of professional empowerment** and little impact on autonomy; less than one in five pharmacists felt the Regulations had empowered them to exercise their personal professional judgement (17% in the UK as a whole, 19% in Northern Ireland) or had allowed them greater personal control (16% in the UK as a whole, 20% in Northern Ireland), with the differences in Northern

Ireland not being significant. However, in a few cases where SOPs were written as a team, positive effects on team work, efficiency and likelihood for the SOPs to be practicable were reported.

- The qualitative research revealed **a fundamental tension within the Regulations** between a perception of a broadened definition of legal accountability on the one hand driving RPs to be more present, and the absence provisions on the other.
- **Contextual factors were compounding the pressure to remain physically present** and preventing a greater clinical leadership role: commercial and customer demands for continual access to medicines; a perceived lack of authority to make changes to the working environment; a lack of clarity about what legal responsibilities meant for practice and the professional identity of the pharmacist (rooted firmly in physical presence in the pharmacy).
- Around half of pharmacists felt having the **right mix of staff** (58% in the UK as a whole, 56% in Northern Ireland) and **better training** (46% in the UK as a whole, 45% in Northern Ireland) would aid the implementation of the Regulations; qualitatively, it was felt that better team working and effective relationships with senior management enabled an increased sense of ownership of the Regulations and authority to make changes.
- In conclusion, if the Regulations are to meet their strategic purpose, more fundamental changes may need to be considered.