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The (supervision) elephant is still in the room

The General Pharmaceutical Council (GPhC) announced late last month that the government was going to introduce legislative changes to let it decide what specific pharmacist roles will look like in the future. While this is welcome, what about supervision, ask David Reissner and Susan Hunneyball.

The Medicines Rebalancing Board was appointed by the Department of Health in the wake of the Elizabeth Lee case – a pharmacist who was given a suspended prison sentence for making a dispensing error.

The Rebalancing Board's deliberations led to the introduction of a due diligence defence for dispensing errors made in community pharmacies.

However, its remit was much wider and included three other objectives.

The first was proposals to modernise legislation in a way that maintained patient and public safety, while supporting professional and quality systems development, including learning from dispensing errors made in registered pharmacies.

The second was ensuring the effectiveness of the system that supports patient safety, such as the role of superintendent pharmacist (SP) and responsible pharmacist (RP).

The third addressed regulatory matters like supervision, which are considered to restrict full use of the skills of registered pharmacists and registered pharmacy technicians.

The first of these objectives was partly addressed in 2018 by amendments to the Medicines Act 1968.

The amendments meant that if a dispensing error was made in a community pharmacy, a pharmacy employee who was prosecuted, like Mrs Lee was, would have a defence if certain conditions were met, including complying with a duty of candour.

The second objective was addressed by amendments to the Medicines Act that are due to take effect on 1 December 2022.

What's the current state of play?

Currently, every company running a pharmacy business must have a SP, who is in charge of the business so far as retail sales and supplies of pharmacy medicines and prescription-only medicines are concerned.

Currently, the Medicines Act does not impose any legal duties on SPs. However, until the GPhC became the pharmacy regulator, SPs were treated as professionally responsible for anything that went wrong at a pharmacy owned by a company and were frequently brought before a disciplinary committee by the then-regulator, the Royal Pharmaceutical Society of Great Britain.

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In 2008, the Medicines Act was amended to require every pharmacy to have a RP who had a legal duty to ensure the safe and effective running of the pharmacy at the premises where they were on duty.

RPs also have some other legal duties, such as keeping a log to show who the RP would be.

The RP had to be present at every pharmacy except for a permitted absence of up to two hours a day.

Since the GPhC took over as regulator of the pharmacy profession in 2010, if something went wrong at a pharmacy, the finger has tended to be pointed at the RP instead of, or as well as, the SP.

What's changing?

Following the recommendations of the Medicines Rebalancing Board, the Medicines Act 1968 will be amended from 1 December 2022.

In relation to dispensing errors, the defence that community pharmacists have will be extended to hospital pharmacists and pharmacists in similar settings such as prison pharmacies.

There will, however, be an important additional condition; the pharmacy service must have a chief pharmacist.

The chief pharmacist will be a pharmacist who manages or organises the whole or a substantial part of the activities of the pharmacy service or plays a significant role in the decision making in relation to those activities.

They will also have the authority to make decisions that affect the running of the pharmacy service in relation to the sale or supply of medicinal products.

They will be responsible for ensuring that the pharmacy service is carried on safely and effectively as well.

Organisations will not need a specific chief pharmacist role to benefit from the defences, so it will not be necessary to give someone this specific title.

However, they should ensure statutory functions of a chief pharmacist are included in a relevant individual's job responsibilities.

It has been suggested that this change is not consistent with the government's aim of making the best use of the skills of pharmacists and pharmacy technicians, because managerial and organisational activities could be carried out by suitably experienced pharmacy technicians, not only by pharmacists.

Superintendent pharmacists

The Medicines Act will also be amended to adjust the balance of duties between SPs and RPs.

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In particular, SPs must be a senior manager who has authority to make decisions that affect the running of the retail pharmacy business so far as concerns the sale or supply of all medicinal products including those on a general sale list.

They will also, for the first time, have a legal duty to ensure the safe and effective running of the pharmacy business in relation to the supply and retail sale of those medicines.

The restriction preventing SPs from being the SP of more than one pharmacy business will be removed.

However, given the level of involvement in the business that will be required from the SP, it is possible this will be principally relevant for businesses who operate through groups of companies.

Companies and SPs will need to review the SP's contract and ensure that the SP has the appropriate seniority in the business and the appropriate level of decision-making authority.

They will also have to ensure the SP can fulfil their new statutory duty. This will particularly be the case where the SP is not a director of the company that owns the pharmacy and/or is engaged on a locum basis.

Responsible pharmacists

As part of a general trend to move away from legal obligations and replace them with professional obligations, RPs will no longer have a legal duty to keep the RP log and the GPhC will have the power to make rules governing how SPs and pharmacists carry out their roles.

The GPhC has said that it will engage extensively to discuss the requirements and expectations of roles of RPs, SPs and chief pharmacists.

In addition to rules, the GPhC will publish new standards for SPs and RPs. In what may turn out to be a key change, when rules are made, the law that enables RPs to be absent from pharmacy for up to two hours in a day will be abolished.

Instead, the rules made by the GPhC will dictate whether a RP can be absent from a pharmacy, how long for if they can and in what circumstances.

It will then publish standards. It seems likely that new rules or standards will not be in place until some time after the law has been changed. The amendments to the law cover England, Wales, Scotland and Northern Ireland. The rules put in place by the General Pharmaceutical Council (GPhC) will cover Great Britain and the Pharmaceutical Society of Northern Ireland (PSNI) will make its own rules as regards Northern Ireland.

There is, of course, scope for the regulators to diverge in their implementation of the changes.

With the changes to the law that will come into force on 1 December 2022, the Rebalancing Board's life seems to have come to an end.

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There is, however, one elephant in the room in Whitehall. The Rebalancing Board did not manage to tackle supervision.

The government had repeatedly made it clear that it intends to change the law on supervision.

News of a consultation is awaited, but the timescale for further change in the law is not known.

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