The Contribution of Pharmacy to making Britain a Safer Place to Take Medicines
## CONTENTS:

<table>
<thead>
<tr>
<th>1.</th>
<th>Introduction</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Scope</td>
<td>3</td>
</tr>
<tr>
<td>3.</td>
<td>The team</td>
<td>3</td>
</tr>
<tr>
<td>4.</td>
<td>The context in Europe and across the UK</td>
<td>3</td>
</tr>
<tr>
<td>5.</td>
<td>Conceptualisation and extent of the problem</td>
<td>6</td>
</tr>
<tr>
<td>6.</td>
<td>Improving medication safety</td>
<td>9</td>
</tr>
<tr>
<td>7.</td>
<td>Discussion and recommendations</td>
<td>15</td>
</tr>
<tr>
<td>8.</td>
<td>Conclusions</td>
<td>21</td>
</tr>
<tr>
<td>9.</td>
<td>List of recommendations</td>
<td>21</td>
</tr>
<tr>
<td>10.</td>
<td>References</td>
<td>23</td>
</tr>
</tbody>
</table>
1. Introduction

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. Hemant Patel, a former President of the RPSGB, set out an ambition to establish Britain as the safest place in the world to receive medicines (Royal Pharmaceutical Society 2007). This report, commissioned by the RPSGB, is intended to be a step towards fulfilling this vision. It examines the current state of knowledge about medication safety in the UK and considers the role of the RPSGB, the future professional body for pharmacy (following the RPSGB’s demerger into separate regulatory and professional bodies in 2010) and of pharmacists working across Great Britain in improving medicines safety. The new professional body will play a key role in strengthening the voice of pharmacy on all issues affecting the safe and effective use of medicines (Transitional Committee 2008).

There is now a considerable opportunity for pharmacy to make a difference to medicines safety, as highlighted in the recent pharmacy White Paper Pharmacy in England (Department of Health 2008).

2. Scope

Whilst safety and quality in healthcare are clearly related, the focus of this paper is on the medication safety agenda. We have not attempted to cover the whole field of the impact of medicines on health. For example drug discovery, development and safety testing by the pharmaceutical industry are encapsulated in the drug licensing process, and so this area is not covered in the paper. Similarly drug marketing and promotion is not covered since little work has been done on this area related to patient safety. Furthermore, the systems for the prescribing, supply and administration of medicines differ worldwide and results from one country cannot necessarily be extrapolated to others. We therefore focus only on patients receiving medicines in Great Britain.

3. The team

The research team was directed by Charles Vincent, Professor of Clinical Safety Research at Imperial College London (www.csru.org.uk) and Director of the NHS National Institute for Health Research Centre for Patient Safety and Service Quality (www.cpssq.org). Professor Nick Barber of The School of Pharmacy, University of London, led the project supported by Professor Bryony Dean Franklin (who works in both institutions) and Susan Burnett (who also works in the Imperial CPSSQ).

In preparing the report we have drawn information from our knowledge and experience and those of our colleagues, from expert opinion and from the literature. Our recommendations are related to this evidence base.

4. The Context in Europe and across the UK

4.1 Medicines safety in Europe

With the global nature of the pharmaceutical industry and with the free movement of goods, services and people in the EU, Brussels and the organisations surrounding the EU have tremendous influence on medicines safety in the UK. It is therefore essential that the RPSGB has influence in Europe. The European Commissions Pharmaceutical Forum has set out the importance of medicines safety as part of the public health agenda (http://ec.europa.eu/health/ph_overview/other_policies/pharma_forum_en.htm):

“The European Union is strongly committed to ensuring a high level of public health and innovation in the field of pharmaceuticals. In the context of medicines and treatments the key objectives are to guarantee access to medicines at an affordable cost, ensure that medicines are safe and effective, and improve the quality and dissemination of information to citizens to enable them to make informed choices about their own treatment. This needs to be balanced by supporting the competitiveness of the pharmaceutical industry to ensure that Europe continues to benefit from new medicines”

1. Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety — The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.
The RPSGB is well placed to advise and influence this agenda through formal links with European bodies such as the European Medicines Agency and also through bodies such as the European Association of Hospital Pharmacists (www.eahp.eu), the Pharmaceutical Group of the European Union (PGEU) representing community pharmacists (www.pgeu.eu) and others.

Of particular interest to the RPSGB is the European Network for Patient Safety: EUNetPas (www.eunetpas.eu) where medicines safety is being led by HOPE, the European Hospital and Healthcare Federation (http://pr.euractiv.com/?q=node/1849.)

4.2  The UK context

Adverse events have been shown to cause harm in 10% of hospital inpatients in the UK; with over half of these events deemed as preventable (Vincent et al, 2001). It is not surprising therefore that reducing rates of adverse events or patient safety incidents is a national priority for the governments in England, Scotland, Northern Ireland and Wales; this is evident by the number of policy documents and reports that centre on this issue and the recent start of national campaigns.

In the Parliamentary Under Secretary of State’s own words, in his report ‘High Quality Care for All’, Lord Darzi (2008) declared that:

‘Continually improving patient safety should be at the top of the agenda for the 21st century’.

The injunction ‘to do no harm’ is one of the defining principles of the clinical profession and as my interim report made clear safety must be paramount to the NHS’ (p44).

The House of Commons Health Select Committee has recently begun an inquiry into patient safety, again highlighting the importance of the issue nationally.

National reports and policy documents have helped pharmacists improve patient safety in recent years. For example pharmacists in hospital have significantly changed practice following the publication of the Audit Commission’s report in 2001 a Spoonful of Sugar (Audit Commission, 2001). Examples here include the widespread adoption of admissions policies (reconciling medicines on admission to hospital), ‘one stop dispensing’ and adoption of automation. Further examples of national patient safety initiatives follow.

4.3  National and International Patient Safety Campaigns

In 2004 the Health Foundation set up the Safer Patients Initiative, working with the US Institute for Health Improvement (IHI) together with four UK healthcare organisations, to implement reliable care based on the interventions and methods used in the IHI campaign in the USA. A further 20 organisations joined the initiative in 2006 and this has now been taken up in the national campaigns. The Health Foundation is now starting a new programme, Safer Clinical Systems, working with four UK healthcare organisations to develop methods to reduce variation and increase reliability in clinical systems. This work will undoubtedly influence future programmes to improve patient safety.

National campaigns to improve patient safety are now being run in England, Wales, Scotland and Northern Ireland as well as in many other countries worldwide. The emphasis of these initiatives is to implement evidence based clinical interventions that are known to reduce harm on a reliable basis, i.e. every day to every patient. These campaigns have been influenced by IHI’s ‘100,000 Lives Campaign’ (www.ihi.org). This was aimed at avoiding 100,000 unnecessary deaths in US hospitals over the 18 months from January 2005 to June 2006, largely through encouraging and helping hospitals to adopt six evidence based interventions that are known to significantly reduce harm and death when implemented reliably. The campaign has now developed into the ‘5 Million Lives Campaign’: (http://www.ihi.org/IHI/Programs/Campaign/). Given the influence of the first IHI campaign, it is likely that their current campaign will also influence the next stage in the UK. In summary, the campaign challenges American hospitals to adopt twelve changes in care that save lives and reduce patient injuries.
Of interest here is the methodology being used. The ‘model for improvement’ asks clinical teams to collect baseline data about clinical processes and outcomes and to record them on run charts using statistical process control techniques. They are then encouraged to make changes to their processes, using PDSA methodology – plan, do, study, act – with interventions based on clinical evidence in the form of ‘care bundles’. For example, to reduce ventilator associated pneumonia, intensive care units are asked to make changes in practice to ensure that every patient on a ventilator has the following reliably every day:

- Elevation of the head of the bed to 30°
- Daily “sedation vacations” and assessment of readiness to extubate
- Peptic ulcer disease prophylaxis
- Deep venous thrombosis prophylaxis

With the data collection charting progress, the teams can see the effect of their intervention, answering the question: has the change been an improvement?

The medicines reconciliation intervention requires that each time a patient moves from one setting to another there are reliable processes in place to ensure that clinicians review previous prescriptions alongside new ones and plans for care, and reconcile any differences. National Institute for Health and Clinical Excellence (NICE) have recently issued national UK guidance on this (NICE, 2007). In Pharmacy in England, the recent white paper, transfer of care and discharge were highlighted as key areas for research, improvement and pharmacist intervention.

The medication reconciliation process involves three steps:

- Verification (collection of the medication history);
- Clarification (ensuring that the medications and doses are appropriate); and
- Reconciliation (documentation of changes in the prescription)

Other bundles are designed to reduce the risks associated with high risk medicines (heparin, warfarin, insulin, narcotics etc) and to conduct failure modes and effects analysis (FMEA) on key medication processes to assess risks in the process and take steps to improve these.

4.3.1 England: Patient Safety First Campaign
The NHS Institute and the National Patient Safety Agency (NPSA), together with the Health Foundation, recently launched the English Patient Safety First Campaign: (http://www.npsa.nhs.uk/nrls/improvingpatientsafety/nhs-patient-safety-campaign/)

One of the campaign’s five key interventions aims to prevent harm from high-risk medicines.

4.3.2 Wales – 1000 Lives Campaign
The aim of the Welsh campaign (www.wales.nhs.uk/sites3/home.cfm?orgid=781) is to save 1000 lives and to avoid up to 50,000 episodes of harm in Welsh healthcare in two years from the launch date. The evidence-based content areas, which have been developed by clinicians working together in Wales, involve work in the following areas:

- Improving Leadership for Quality
- Reducing Healthcare Associated Infections
- Improving Critical Care
- Improving Medicines Management
- Reducing Surgical Complications
- Improving General Medical and Surgical Care

Two development areas will also be tested during the Campaign: Transforming Care at the Bedside and Pressure Ulcers.
4.3.3 Scotland – Scottish Patient Safety Programme

The Scottish Patient Safety Programme (www.patientsafetyalliance.scot.nhs.uk) builds on work that is already taking place through the UK Safer Patients Initiative. Over the next five years, steps will be taken to:

- Ensure early interventions for deteriorating patients
- Deliver evidence-based care to prevent deaths from heart attack
- Prevent adverse drug events
- Prevent central line infections
- Prevent surgical site infections
- Prevent ventilator associated pneumonia
- Prevent pressure ulcers
- Reduce staphylococcus aureus (MRSA and MSSA) infection
- Prevent harm from high alert medications
- Reduce surgical complications
- Deliver evidence-based care for congestive heart failure

4.4 Summary

It is clear from the considerable work underway in the EU and across the UK that patient safety is a high priority and within this, tackling medication safety is firmly on the agenda and pharmacists are actively involved in this. The new professional body will be well placed to influence at the EU level and the national agenda across the UK and in the recommendations section we discuss how this might be developed. First, however, we consider what is known about medication safety in the UK.

5. Conceptualisation and extent of the problem

The safety of medicines has traditionally fallen into three distinct areas which have had little interaction with each other:

1. The safety of the medicine itself. This includes manufacturing a product of suitable quality, and assessing the side-effects and adverse drug reactions that the medicine produces. The process by which medicines are licensed provides some assurance of safety in these areas, and the processes leading up to the licensing are outside the scope of this paper. However, safety may become an issue after licensing, or if the drug is used outside its licence.

2. Safe and appropriate use of the medicine by healthcare professionals and carers. Failures in these processes have traditionally been considered as medication errors, which include errors in prescribing, dispensing, preparing, administering and monitoring medicines.

3. Non-adherence to medicines by patients. This area is complex, as it involves autonomy and free will; hence the concept of error is much more contestable. In addition, non-adherence may be the correct action by a patient. So, we will not take non-adherence as necessarily a bad thing; however we will focus on the many cases where it reduces the safety and effectiveness of medicines.
In reality these three areas are related – adverse drug reactions can cause non-adherence, as can errors; errors can cause avoidable adverse drug reactions, and so on. Pharmacy has a contribution to make in all three of these areas and is ideally placed as a profession to bring them all together in an integrated approach to making medicines safer. The history of pharmacy shows that pharmacists have had a consistent role in reducing the risks around medicines; first by ensuring correct ingredients were used in the right way, and more recently by identifying and correcting errors in prescribing, and helping patients improve their adherence. The safety of the product is carefully controlled in legislation and in some ways there is less freedom to act in this area, although we make some suggestions in the next section. The reduction of medication errors is an agenda that pharmacists are already engaged in, and we feel there are significant ways in which this could be developed. Finally, non-adherence has been an intractable challenge for many years, but recent advances in research suggest ways in which it can be reduced.

Medication safety research often identifies the harmful effects of medicines. The avoidable harm caused by medicines use is a function of the effects of the medicines themselves, the way they are used, and the way they are monitored.

It has been estimated that preventable harm from medicines could cost the NHS more than £750m each year in England alone (NPSA 2007). Box 1 summarises some studies of harm, both avoidable and unavoidable, from medicines use in the UK.

- 9 (1%) of 840 inpatients suffered preventable harm due to medication in two UK hospitals (Neale et al, 2001).
- 265 (6.5%) of 4093 patient admissions were judged to be drug related and 178 (67%) of these were judged to be preventable in a UK hospital. The drugs most commonly implicated were NSAIDs, antiplatelets, antiepileptics, hypoglycaemics, diuretics, inhaled corticosteroids, cardiac glycosides, and beta-blockers (Howard et al, 2003).
- 6.5% of 18,820 admissions were due to an adverse drug reaction in two large hospitals, with the reaction directly leading to the admission in 80% of these cases. Most reactions were either definitely or possibly avoidable. Drugs most commonly implicated in causing these admissions were low dose aspirin, diuretics, warfarin, and non-steroidal anti-inflammatory drugs, the most common reaction being gastrointestinal bleeding (Pirmohamed et al, 2004).
- 30 (2.7%) of 1,101 emergency admissions to a Scottish hospital were related to an adverse drug reaction. Three (9.7%) of the 30 were associated with non-prescription medicines. The adverse drug reaction was the dominant reason for admission in 17 cases (56.7%) and only 4 (13.3%) were considered to be unavoidable (Hopf et al, 2008).

Box 1: Key studies of the incidence of medication-related harm in the UK

The process of medicines use generally comprises the events of prescribing, dispensing/supplying, sometimes preparing the medicine, then administration (whether self administration or by others); there should then be monitoring and review to ensure the medicine is still required and if so, it remains effective and acceptable. These events differ partly according to the drug and the setting; however all need to be communicated clearly and recorded accurately.

To give an appreciation of the extent of the problems and their inter-connectedness, Box 2 presents the error rates at each stage of the process, using primary care data (where around 80% of medicines use occurs).
1. Patient sees GP.

2. Patient is prescribed medication:
   - Prescribing error rate: 7.5% of prescription items written (Shah et al, 2001)

3. Prescription taken to community pharmacy:
   - 2.6% prescriptions or 5.2% of prescribed items are not “cashed” by patient (Jones and Britten, 1998; Bearden et al, 1993)

4. Medication dispensed:
   - Dispensing error rate: 3.3% of all items dispensed (Franklin and O’Grady, 2005)

5. Patient takes medication:
   - Patient non-adherence: 30-50% (Horne et al, 2005)
   - Drug related admissions to hospital: 2.7 - 6.5% of all admissions, 67% of which are preventable (Pirmohamed et al, 2004; Howard et al, 2003; Hopf et al, 2008)

6. Prescribing reviewed at least every 6th request:
   - Medication not reviewed in 15 months: 72% of medications (Zermansky, 1996)

7. For patients seen in hospital outpatients:
   - Medication details not added to GP records: 5% of prescribed items (Collins et al, 2004)
   - Dose taken not added to GP records: 13% of consultations (Cox et al, 2003)

8. For patients admitted to hospital:
   - Unintentional discrepancies in medication prescribed on admission: 58% of patients / 18-60% of prescribed medicines (Ahmed et al, 2005; Pickrell et al; 2001; Brady and Franklin, 2004)
   - Inpatient prescribing error rate: 1.5-9.2%. (Dean et al, 2002; Haw et al, 2003; Tesh et al, 1975; Franklin et al, 2007a; Franklin et al, 2007b)
   - Unintentional discrepancies in discharge medication: 11% items (Duggan et al, 1996)
   - Unintentional discrepancies in discharge medication subsequently received from GP: 46-60% items; 57% patients (Pickrell et al, 2001; Duggan et al, 1996; Duggan et al, 1998; Smith et al, 1997)

Box 2: Error rates at each stage of the medicines use process, based on published UK studies. This summary is adapted from an unpublished report by Garfield, Barber, Walley and Wilson (2008), commissioned by the National Leadership and Innovation Agency, NHS Wales. Studies based on self-reporting were excluded.

It can be seen that in primary care the highest incidence of errors arise through non-adherence, and inadequate monitoring and review of therapy – these must become prime targets for change. In addition there are risks of harm from over the counter (OTC) medicines, herbal remedies (of varying quality) and nutrition supplements. All of these may be a risk if used alone, or may increase the risk of harm from prescribed drugs because of drug interactions. For example OTC consumption of nonsteroidal anti-inflammatory drugs has been shown to increase the risk of gastrointestinal complications (Biskupiak et al 2006). Hopf et al (2008) found that one in ten drug-related admissions to hospital were associated with OTC medication.

In secondary care, errors in prescribing and administration (particularly intravenously) of medicines probably have a similar frequency (see Box 3). Medication errors are also frequent on admission to, and discharge from, hospital.
6. Improving Medicines Safety

In the previous section we have shown the extent of harm from medicines in the UK. This is a significant problem which despite much work by pharmacists and others has, to date, appeared to be a fairly intractable problem. However, it may now be amenable to intervention. There are several reasons why this is the case. First, our understanding of the causes of medication error, of adverse drug reactions and of non-adherence has taken substantial steps forward in recent years. This can also be said of the development of change tools and strategies which can be brought to bear to improve the situation. What is more, structural changes to the NHS and the rapid development of information technology are enabling new ways of working that begin to look at the whole system rather than the individual practitioner or act.

6.1 Overview of safety and reliability

It is now widely recognised that errors and human behaviour cannot be understood in isolation, but must be considered in the context or system in which people are working. Clinical staff prescribing, dispensing or administering medicines are influenced by a wide range of systems factors such as the technology available (which includes the medicines and any technology used in their administration); the team and staffing levels; their hours of work; the design of their work areas (lighting, cramped space etc); distractions...
in the workplace (interruptions during a drug round); and of course patient factors. This is illustrated by Reason’s Accident Causation Model (figure 1) (Reason, 1990) which has more recently been adapted for use in healthcare (Vincent et al., 1998). An understanding of this model helps guide us to ways in which safer medication systems can be established and maintained. Box 5 below describes the known factors that affect safety in clinical practice.

## Accident causation model

**Reason/Rasmussen**

![Figure 1: The Accident Causation Model](www.pharmacy.ac.uk)

**Box 5: Factors influencing safety in clinical practice (from Vincent et al., 1998)**

1. Institutional context
   - Economic and regulatory context
   - National Health Service Executive
   - Clinical negligence scheme for trusts

2. Organisational and management factors
   - Financial resources and constraints
   - Organisational structure
   - Policy standards and goals
   - Safety culture and priorities

3. Work environment
   - Staffing levels and skills mix
   - Workload and shift patterns
   - Design, availability, and maintenance of equipment
   - Administrative and managerial support

4. Team factors
   - Verbal communication
   - Written communication
   - Supervision and seeking help
   - Team structure

5. Individual (staff) factors
   - Knowledge and skills
   - Motivation
   - Physical and mental health

6. Task factors
   - Task design and clarity of structure
   - Availability and use of protocols
   - Availability and accuracy of test results

7. Patient characteristics
   - Condition (complexity and seriousness)
   - Language and communication
   - Personality and social factors
In the past, the approach to improving medicines safety has been to take one type of error and try to reduce its frequency. However, as patient safety research has shown, it is important that we look at the whole system. To focus on improving one error type is analogous to polishing one cog in a rusty clock. Most of the hard work can be undone by errors elsewhere in the system. Eventually, ‘polishing the cog’ will deliver improved safety as more and more cogs are polished, however an increasingly realistic alternative is to redesign the whole system, recognising and being driven by its interconnectedness. However before we can begin to consider redesigning the system we need to identify the component parts. In this section we identify the main elements in the medication system and what we know from experience are their potential for improvement. In preparing this report we have become increasingly aware of the dearth of robust evidence about the potential for systems improvements to improve medicines safety and this is clearly an area calling for more research.

6.2 Pharmacovigilance
Pharmacovigilance is an enormous field in its own right so for the purposes of this paper we have limited this section to noting the major issues in the contribution of pharmacovigilance to improving medicines safety. Adverse drug reactions (ADRs) are usually identified by clinical trials (which are normally designed to identify the positive effects of the medicine, not its adverse effects), spontaneous reporting (the yellow card scheme), and pharmacovigilance studies (often conducted by studying large databases). None of these methods are infallible. Clinical trials exclude many groups, including children, the elderly and pregnant women. Spontaneous reporting, while valuable, only identifies a tiny proportion of adverse drug reactions. Pharmacovigilance studies are usually retrospective and require large databases which are currently not available for secondary care in the UK.

There is a clear need to improve the identification of previously unreported adverse drug reactions, and to quantify the frequency with which ADRs occur; the recent White Paper in pharmacy (Department of Health, 2008) identifies this as an area in which pharmacists should be making further contributions, beyond their current involvement with the yellow card scheme. In the final section of the report we make recommendations concerning the establishment of pharmacovigilance networks particularly for those patient groups not currently covered: pregnant women and children.

6.3 Prescribing
Prescribing errors (Dean et al, 2000) fall into four main categories:

- **Prescriptions inappropriate for the patient**, for example a drug that is contraindicated or to which the patient has an allergy
- **Pharmaceutical issues** such as prescribing an intravenous infusion with the wrong diluent or concentration
- **Failure to communicate essential information** for example not specifying the formulation, dose or route, or writing illegibly
- **Transcription errors**, such as not prescribing a drug in hospital that the patient was taking prior to admission, or prescribing the drug incorrectly, or prescribing a drug which is no longer needed

The role of hospital pharmacists in identifying and rectifying prescribing errors is well documented (Batty and Barber, 1992; Dale et al, 2003); they can be seen as one of the defence mechanisms in Reason's model. There are few studies of interventions to reduce errors at source. Electronic prescribing has been shown to reduce the incidence of prescribing errors in UK hospitals, but only by an absolute reduction of about 1-2% (Franklin et al, 2007a; Shulman et al, 2005). It has also been shown that giving patients a copy of their discharge prescription to take to their community pharmacist reduces prescribing errors in the community following discharge (Duggan et al, 1998). There is a dearth of studies of interventions to reduce prescribing errors in primary care and again this is an area calling for more research.
6.4 Dispensing
Dispensing errors comprise labelling errors, content errors, clinical errors (such as dispensing a drug to which the patient has a documented allergy or contraindication) and documentation errors (such as for controlled drugs) (Franklin and O’Grady, 2007).

As is the case of prescribing error, there is little evidence base in the UK to support interventions to reduce dispensing errors. In the hospital setting, dispensing robots have been shown to reduce errors involving wrong content (Franklin et al, 2008), but have no significant effect on the labelling error rate. There are numerous other studies of various initiatives that have been conducted in hospital pharmacy departments, but these are either unpublished or published only in abstract form. In community pharmacy, it has been suggested that authentication at the point of dispensing (using barcodes or radiofrequency identification (RFID) tags) could reduce dispensing errors to nearly a half (Franklin and O’Grady, 2007), but this has not been tested in a controlled trial. There is also an absence of economic evaluation – technological interventions can require large capital investment and the financial case for them is not yet established.

6.5 Administration of medicines
Administration errors are unintentional deviations between the medication prescribed and that administered to a hospital inpatient or care home resident. These include the unintended omission of prescribed medication. There are few studies of initiatives to reduce these errors, and those that exist are relatively small scale studies from which it is hard to draw generalised results.

Introduction of individual patient lockers and patients’ own drugs was shown to have no effect (Dean and Barber, 2000) although the practice is widespread. Technology has sometimes reduced errors. An internet-based education package reduced the incidence of non-intravenous medication administration errors on one hospital ward from 6.1 to 4.1% (Franklin et al, 2006). An automated ward-based dispensing system reduced non-intravenous medication administration errors from 7.0% to 4.3% (Franklin et al, 2007a). Approaches such as smart pumps (intravenous pumps which can recognise the drug and ensure dosing is within approved limits) have not yet been formally evaluated in the UK.

6.6 Storage and disposal of medicines
There are a plethora of standards that deal with medicines, their storage and disposal, and this is a significant and enduring feature of the practice of pharmacy.

There are certainly issues of public health, such as the safe storage and disposal of methadone or cytotoxic medicines and also issues of the disposal of medicines (and their metabolites) and their potential effect on the purity of water.

6.7 Taking medicines at home
In this section we deal with the question of whether patients take their medicines or not (adherence or non-adherence), and medicine taking behaviour outside the health service.

Non-adherence is a common and intractable problem, affecting up to half of patients on chronic medication; this includes patients whose lives depend on the drugs, such as transplant patients, cancer patients and those who have had heart attacks. Systematic reviews have found very few interventions that can be shown to improve adherence. Those that have worked have been extremely expensive, complex, and labour intensive.

Theory has moved on recently and we think we understand the causes of non-adherence better (Horne et al, 2005). Non-adherence is like a symptom rather than a disease, in the past people have treated it by guessing its
cause rather than diagnosing it. For example, assumptions have been made that the problem lies in
Doctor-patient communication, and therefore treated all patients the same, whether this was a problem for
them or not. The result of these simplistic solutions has been failure.

We now know that the causes of non-adherence may be intentional or unintentional, and that these causes
require different approaches. Intentional non-adherence is related to beliefs about medicines; and unintentional
non-adherence results from the many barriers that may stop a patient from taking their medicine properly.
Some recent work suggests that intentional and unintentional non-adherence are both common, and that a
telephone intervention from a pharmacist can alter beliefs, solve some problems that patients experience, and
Helping patients improve their experience with medicines is a significant element in the recent pharmacy White
Paper (Department of Health 2008).

Research into non-adherence has generally focused on the individual, however most patients do not make
health decisions alone, but work with those close to them, such as partners, family, and carers (formal
or informal). There has been little work in this field; however it will become of increasing importance as
government health policy aims to support patients in their own home for as long as possible. Not only are the
beliefs and the barriers of the patient important, but there is also a need to address the beliefs, barriers and,
indeed, competencies of those who are close to the patient.

The role of the pharmacist does not just relate to prescribed medicines. Anthropologists have long recognised
the concept of medical pluralism: that patients will seek advice and treatment from many sources, including
alternative practitioners, relatives etc. This is to be expected. It has many sources, one being that patients
are not always given sufficient information by healthcare professionals, or the information is inadequate and
not fully understood. Furthermore, many patients do not feel confident in speaking up when they notice
unexplained changes in their medication. Another factor is the failure of therapy to provide the desired results.
These factors lead to patients making decisions about their medicines which can affect adherence. This
includes the rejection (or partial acceptance) of prescribed medicines and the parallel consumption of other
products, such as OTC medicines, herbal medicines and nutritional supplements, all of which may interact
with the prescribed medicines or, indeed, each other. The true nature and extent of medicines safety issues in
the home are not well understood or quantified and further research is required in this area.

6.8 The role of technology in improving medicines safety
Technology has great potential to improve medicines safety. Its ability to handle large amounts of information, to
use it to support decisions, and to repeatedly perform the same act, gives the potential to provide many benefits.
For example a cytotoxic reconstitution robot has the potential to reduce operator error, and to reduce repetitive
strain injury in operatives. Decision support can improve treatment (given certain constraints) etc.

Technologies such as those set out in Box 6 below have the potential to prevent medication errors, and
are often widely advocated as such. However technology is not itself good or bad – its effects depend on
many factors, such as how it is used and how human systems work with the technology. For example the
effectiveness of technology depends on context – the problems with different health systems vary, and so a
technology shown to reduce errors in one system may have a very limited effect in another. For example there
has been a tendency to assume technology that is effective in the USA will be similarly effective in the UK;
however the healthcare systems are very different and sometimes the benefits do not transfer. More work is
needed to develop NHS specific technologies, and to characterise the most error prone parts of the current
human systems that technology can improve.
Primary care

• Electronic patient records
• Electronic transmission of prescriptions
• Dispensing robots
• Electronic prescribing

Secondary care

• Dispensary-based dispensing robots
• Electronic prescribing
• Electronic medication administration records
• Barcode verification of medication administration
• Barcode verification of patient identity
• Ward-based automated dispensing systems
• Electronic transmission of discharge prescriptions between secondary and primary care
• Automated compounding machines

Box 6: Examples of technologies used in the medication process

There is now a large body of evidence showing that new types of error can be introduced with new technology, examples of these are set out in Box 7. Introducing new technologies usually requires changes in work processes, which can also introduce risks, particularly if staff develop work-arounds to save time or overcome parts of the technology which they consider slow or they think does not work reliably.

• Over-reliance on the technology to check for errors
• Development of work-arounds
• New types of error introduced, eg errors when selecting from pull-down menus
• Introduction of additional steps into work processes
• System failure
• Deskilling
• Assumption that the technology is more advanced than it is – eg assumption that a computer system includes decision support where none exists

Box 7: Examples of new risks created by technologies

Evaluating technologies to assess their impact on medication safety is essential to create an evidence base for their use, rather than assuming that errors will automatically be prevented. Pharmacy is already involved in several evaluation projects, including the implementation and evaluation of the NHS Connecting for Health Care Records Service and Electronic Prescription Project, the rollout of dispensing robots in Wales, and we note that the RPSGB, Company Chemists Association (CCA), National Pharmacy Association (NPA) and Pharmaceutical Services Negotiating Committee (PSNC) have commissioned an important piece of work on the impact of technology in community pharmacy over the next 5-10 years.
In order to ensure that in implementing new technologies, pharmacists are aware of potential errors and how others have overcome them, we recommend that the RPSGB establishes a knowledge exchange network for its members covering new technology. There is also a need for education in the correct way to achieve safe adoption and implementation of technology.

### 6.9 The role of commissioning

The process of commissioning health services by primary care organisations, and also by local authorities, who commission care-home places and personal care for people living in their own homes, has tremendous potential to be used to drive safety improvements through payment tariffs and contract specifications for example. Patient choice will also influence this agenda as it has in other industries – we now regularly see cars marketed for how safe they are, an agenda driven largely by the consumer. Commissioning for safety improvements is new ground and the RPSGB is well placed to develop the thinking nationally on this, working with its members who are part of the commissioning process.

### 7. Discussion and Recommendations

The RPSGB commissioned this scoping paper as a step towards improving medicines safety in Great Britain. Every day pharmacists make thousands of interventions to improve medicines safety. The new professional body for pharmacy will be in a powerful position to set the agenda and drive change to improve medicines safety. Pharmacists work in all sectors of healthcare and the pharmaceutical industry, covering the entire journey of a medicine from its original conception to finally being taken by a patient: working in the pharmaceutical industry; as purchasers and suppliers of medicines; as formulators and compounders; as dispensers and prescribers; working in multidisciplinary professional teams; as educators and trainers of (i) prescribers and (ii) those administering medicines or assisting people in taking their medicines; and finally giving direct advice to patients.

#### Recommendation 1

*In order to achieve the vision, the new professional body in consultation with other key stakeholders should develop a 5-10 year plan for improving medication safety in GB with key milestones and with firm measures to track progress. The elements of this strategy are described below together with specific recommendations for achieving this.*

#### 7.1 Is Britain becoming a safer place to take medicines? Measuring and monitoring the nature and extent of the problem over time

##### 7.1.1 Monitoring medicines safety improvements

In order to track improvements in medicines safety there is a need for standard definitions and standard methods for measurement. The World Health Organisation is developing a classification system for patient safety incidents and the NPSA has developed a set of codes for analysing incidents reported through local risk management systems. However, specific UK-appropriate definitions are required, specifying what should be included and excluded as errors in quantitative studies. This will allow comparison between studies, benchmarking between sites, and more rigorous evaluation of interventions designed to reduce errors. Other methods are now being recommended through campaigns and initiatives such as the global trigger tool and case note review. A toolkit of standard methods is required. We believe that in working towards making Britain a safer place to take medicines, a goal should be set in the UK for developing a standard set of measures for medicines safety and of commissioning work to establish a baseline from which to monitor improvements. One example here is the NPSA's work on ‘never events’ – adverse events which are known to be avoidable such as wrong route chemotherapy or administering wrong strength potassium chloride.
Recommendation 2
Specific UK-appropriate standard definitions are required to establish a baseline and track improvements in medicines safety.

7.1.2 Patients, families and carers: taking medicine at home
Whilst we can analyse and capture adverse events during the drug journey from development to dispensing, less is known about the safety of medicines at the point of administration by the patient at home. The true nature and extent of medicines safety issues in the home are not well understood or quantified and further research is required in this area particularly with the increasing complexity of care being delivered for patients at home. We recommend that this agenda should be prioritised with the funders of research in order for us to understand the nature and extent of the problem and track improvements over time.

Recommendation 3
Medicines safety issues in the patient’s home are not well understood and should be made a research priority.

7.1.3 Pharmacovigilance
Knowledge about the ADRs associated with newly licensed drugs emerges very slowly. Pharmacists, particularly in hospitals, have great potential to form a pharmacovigilance network to rapidly identify how the drugs are being used, and their adverse events. In UK hospitals, pharmacists already visit wards, often daily, to monitor prescribing and use of medicines. This is a tremendous resource which could be used to a far greater extent. We recommend that the new professional body for pharmacy works with the Medicines and Healthcare products Regulatory Agency (MHRA) to establish a national pharmacovigilance network of hospital pharmacists in key hospitals to document and report the early use and effects of new medicines. The same approach can also be applied to those groups who are not adequately represented in clinical trials. There could be pharmacovigilance networks set up, which need not be based in hospitals, for paediatrics, the elderly and pregnant women, capturing vital information about the safety of medicines now and in the future.

Recommendation 4
A pharmacovigilance network of hospital pharmacists should be established to monitor and report on ADRs associated with newly-licensed medicines.

Recommendation 5
Pharmacovigilance networks should be established for patient groups not adequately represented in clinical trials.

7.2 Encouraging and developing a safety culture
7.2.1 Supporting pharmacists to speak up
For medicines safety to improve, pharmacists must be able to speak up about their concerns and to report safety incidents and near misses in an environment where this is encouraged and where action is taken to learn and improve. Not all organisations have a safety culture that is open and fair and pharmacists can find themselves in a very difficult position particularly when reporting concerns about another clinician (for example picking up persistent prescribing errors by a well-respected local doctor). In other circumstances the pharmacist themselves may have made an error and need help and advice in the aftermath.

The Community Pharmacy Research Consortium (a joint venture between the major national pharmacy bodies) commissioned research on errors in community pharmacy which highlighted concerns regarding
‘a prevailing blame culture’ which deters pharmacists and support staff from reporting incidents and prevents organisational learning. Important factors to encourage voluntary incident reporting included ‘a non-punitive environment, simplicity in reporting, and timely and valuable feedback’ (Ashcroft et al, 2005).

Some advisory and counselling services are currently available to all pharmacists (e.g. the RPSGB’s Legal and Ethical Advisory Service⁵, Pharmacist Support³) or to pharmacists who are members of particular organisations (e.g. the Pharmacists’ Defence Association⁴, or the Guild of Healthcare Pharmacists⁵) but there is no single service or organisation which supports pharmacists in speaking up in their own organisations when things go wrong.

7.2.2 Supporting pharmacists to tackle error-provoking working conditions
An area where we believe priority should be focussed is that of pharmacists working in error-provoking conditions, working long hours, without breaks, with an unacceptably high workload, or working in cramped and under-lit conditions. There is a particular issue with high workload and few breaks for some community pharmacists. The RPSGB is undertaking policy work on pharmacy workload to identify the nature and extent of workload problems in the profession, and the types of measures that other regulators and professional bodies for health professionals have used successfully to combat excessive workload.

7.2.3 Professional regulation
RPSGB’s regulatory functions also contribute to patient safety by monitoring compliance with the requirements for practitioners to be registered to practise and to remain registered; by providing guidance and advice to help registrants to continue to meet the required standards of competence, conduct and practice; and by taking disciplinary action, where appropriate, against registrants who are no longer fit to practise. The RPSGB also registers and inspects pharmacies.

Implementation of the RPSGB’s new fitness-to-practise procedures in 2007-2008 has provided an excellent foundation for the future of pharmacy regulation and it is anticipated that the General Pharmaceutical Council will continue to build on that foundation long into the future.

7.2.4 Moving medication safety to the top of the agenda
Medicines safety should be a key priority for the new professional body: it should support its members to maximise the safe use of medicines in their own practice and to promote medicines safety in the organisational systems and multidisciplinary teams they work with. At the strategic level, the professional body should speak with authority on all issues related to the safe and effective use of medicines.

Recommendation 6
The new professional body for pharmacy should prioritise medicines safety in its support for members and in its strategic influencing role.

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3.  Pharmacist Support (formerly the Benevolent Fund) provides a number of services to pharmacists including the Listening Friends service which offers free listening services to pharmacists suffering from stress. The service provides the opportunity to talk to a pharmacist trained to offer support regarding the particular pressures that apply to the pharmacy profession; www.pharmacistsupport.org


5.  NHS-employed pharmacists can join the Guild of Healthcare Pharmacists which is part of the Unite trade union. Unite provides its members with free legal advice on work related problems (such as personal injury, unfair dismissal, discrimination and harassment) and a 24 hour legal hotline for advice on non-work related issues. See http://www.ghp.org.uk and http://www.unitewithus.org.uk/legal/
7.3 Knowledge and resources to improve medicines safety

7.3.1 Professional education and development

If Britain is to become a safer place to take medicines, all pharmacists will need to have an understanding of the factors underpinning safe systems of work – the ‘science of safety’. This includes understanding human error and systems thinking; safety culture and the role of the pharmacist; supporting colleagues in the event of an error; the role of patients and carers; the role of technology; design and human factors. Pharmacists already have a good understanding of the practical aspects of safe system design (from ‘Good Manufacturing Practice’); they need the theory to support these pragmatic approaches, and go beyond them.

Pharmacists also deliver a unique ‘world view’ into medicine, that focuses on medicines as a precious but potentially dangerous intervention – what has been called the ‘Pharmaceutical Gaze’. Their education needs to retain this unique contribution into the health care system.

Medicines safety should therefore remain a core element in the undergraduate curriculum, an essential part of the requirements for continuing professional development and be central to revalidation. The future professional body should bring influence to bear to help ensure that medicines safety remains at the forefront of professional education and development in pharmacy.

Recommendation 7
The new professional body for pharmacy should use its influence to ensure that medicines safety remains at the forefront of professional education and development in pharmacy.

7.3.2 The changing nature of the workforce

Pharmacy technicians form an important part of the workforce and play a key role in medicines safety.

The changing nature of the workforce is such that increasingly, particularly in community pharmacy, pharmacists are choosing to work flexibly. This means that locum pharmacists are being relied upon in many sectors. In order for medicines safety to prevail, locum pharmacists and technicians, and those employing them need to be cognisant of the safety issues relating to temporary working. Again this is an area where there is insufficient knowledge to share, particularly about good practice and where more work is needed to understand the issues.

Recommendation 8
Further research is needed on the implications for medicines safety of the increasing role of pharmacy technicians in the pharmacy workforce, and the increasing use of locum pharmacists.

7.3.3 The RPSGB as a source of information to pharmacists

There is currently no single source of information about medicines safety in the UK. For a pharmacist to find further information about a medicines safety issue identified in their local organisation, they currently have to search the internet and conduct their own literature search. It would be more difficult still for them to find information about interventions and initiatives that have been shown to be effective, especially since many in-house studies are never published or presented only in abstract form. The future professional body for pharmacy should work with other stakeholders to establish a repository or portal for information and knowledge sharing about medicines safety and effective interventions. Not only will this assist pharmacists locally but it will also inform the professional body about the range and nature of concerns about medicines safety and about the range and nature of interventions being tested, helping to shape the professional body’s agenda in the medium to long term.
Recommendation 9
The future professional body for pharmacy should work with other stakeholders to establish a repository or portal for knowledge sharing about medicines safety and effective interventions.

7.3.4 Technology
Technology plays an important role in improving medicines safety throughout the drug journey and in all settings. However, implementing new technology for maximum benefit is not always straightforward and lessons need to be captured and shared. For example, implementing a new dispensing robot or a new computerised prescribing system can introduce the potential for new errors. There is currently no central repository for the lessons learnt from implementing new technology nor is there advice available from the early adopters of this technology for others following on to consider. This area of knowledge would be a key component of the knowledge repository on medicines safety discussed above. It would provide information of benefit to pharmacists locally and also to the professional body in influencing and advising national bodies and industry. It would also complement the system run by NICE for assessing the risks of new interventional procedures.

Recommendation 10
Experience with implementing new technology should be a key component of a knowledge repository on medicines safety.

7.4 The informing and influencing role of the RPSGB

7.4.1 The European Union
With the global nature of the pharmaceutical industry and with the free movement of professions across borders, the EU now plays a key role in the medicines safety agenda. Patient safety is also high on the agenda of the Commission’s Health Directorate (DG Sanco). It is therefore important that the RPSGB is active in influencing the EU agenda through:

- The European Medicines Agency
- EU organisations representing hospital and community pharmacists
- Keeping MEPs informed on the medicines safety agenda
- The European Network for Patient Safety: EUNetPas (www.eunetpas.eu)

Recommendation 11
The new professional body for pharmacy should consider joining EUNetPas.

7.4.2 Westminster and the devolved governments
With the national campaigns to improve patient safety and with the high media and public interest in areas such as hospital acquired infection levels, it is important that parliamentarians are well informed about the topic and have access to robust, evidence based information. Medicines safety needs to maintain a high political profile to be retained as a key government priority. The new professional body will be well placed to inform members of the parliaments in Westminster, Wales and Scotland about the medicines safety agenda and we recommend that this forms part of the new professional body’s strategy to make Britain a safer place to take medicines.

Recommendation 12
The new professional body should ensure that parliamentarians are well informed about the medicines safety agenda.
7.4.3 Patients and the public

It is clear from the evidence set out in this report that patients and the public are central to making Britain a safer place to take medicines. The RPSGB has an active Public Liaison Group (PLG), comprising a wide range of national patient and consumer organisations plus individual patient members, which advises the Council on policy issues. The new professional body is expected to retain some form of patient and public involvement. The PLG (or any successor structure in the professional body) should become actively involved in future work on promoting medicines safety. The future professional body should also actively engage with organisations giving direct advice to the public about their medicines, such as NHS Direct and NHS24 in Scotland.

**Recommendation 13**

Representatives of patients and the public should be actively involved in the professional body’s work on promoting medicines safety.

**Recommendation 14**

The future professional body should actively engage with organisations giving direct advice to the public about their medicines.

7.4.4 The national agenda across the UK

It is clear from the considerable work underway across the UK that patient safety is a high priority and within this tackling medication safety is firmly on the agenda and pharmacists are actively involved in this. The future professional body will be well placed to influence the national agenda by drawing on the experience and expertise of its members and developing its role to be seen as the organisation to go to for advice about improving medication safety. It is therefore important that the professional body:

- Develops its role so that it is in a position to advise the Chief Pharmacists in each GB country on medication safety;
- Works with national bodies including the MHRA, NPSA and NICE;
- Continues to be actively involved in the national campaign;

**Recommendation 15**

The future professional body should develop its role and expertise in medicines safety so that it can influence the national policy agendas and patient safety campaigns in the three GB countries.

7.4.5 Influencing the Pharmaceutical Industry

The pharmaceutical industry has a central role in improving medicines safety through initiatives such as the design of the labelling and packaging of drugs; the naming of medicines; and the information given to patients in the packs. These initiatives can help reduce dispensing errors, drug administration errors and non-adherence. Nationally and through the European Union, the government has tremendous opportunity to influence these vital areas for medicines safety. There may be merit in setting up a national working group bringing together experts in medicines safety to report to the government on what more could be done by the pharmaceutical industry to improve medicines safety in the next five years.

Purchasing policies in the NHS are increasingly being used to ensure medicines are safe and are of suitable quality; increasingly purchasing is driving safety within the pharmaceutical industry by favouring manufacturers who provide safer products (safer packaging, clear use instructions etc).
Recommendation 16
Consideration should be given to setting up a national working group to identify whether any additional measures by the pharmaceutical industry are needed to improve medicines safety.

7.4.6 Influencing the Research Agenda
Research is fundamental to improving medicines safety from understanding the reasons why safety is compromised to finding new ways to improve safety in all areas of the drug journey. To make Britain a safer place to take medicines, it will be necessary to take an overview of the research to date into medicines safety in the UK and internationally and to identify where there are gaps and where new research could benefit patients. This information would enable the new professional body and other stakeholders to influence research funders to prioritise research that will have the most impact in improving medicines safety.

Recommendation 17
The future professional body should work with other stakeholders to prioritise the areas for research where there are currently gaps in the literature relating to medication safety in the UK and influence research funders to fund these areas.

8. Conclusions
In this report we have set out what we know about medicines safety in the UK, from the extent of the problem across the medicines journey to areas for action and improvement. It is clear from the considerable work underway in the EU and across the UK that patient safety is a high priority and within this, tackling medication safety is firmly on the agenda and pharmacists are already actively involved in this. Medicines safety has traditionally fallen into three distinct areas: the safety of the medicine itself; the safe and appropriate use of medicines by healthcare professionals and carers (‘medication errors’ are failures in this area); and non-adherence to medicines by patients. All these cause harm and place a large burden on the NHS. In reality these three aspects are related and an integrated approach is likely to improve patient safety. The pharmacy profession is ideally placed to lead this integration and to deliver safer medicines, taken in a safer way.

9. List of recommendations
We have translated the evidence into a set of recommendations for the new professional body for pharmacy to consider and take forward.

In developing the agenda for making Britain a safer place to take medicines, we recommend that the new professional body involves its members in considering the recommendations set out in this paper and in setting priorities for action in the short, medium and long term. This process should be updated regularly to ensure the professional body keeps patient safety high on its agenda and to ensure that its priorities meet the needs of its members.

The recommendations are as follows:

1. The new professional body in consultation with other key stakeholders should develop a 5-10 year plan for improving medication safety in GB with key milestones and with firm measures to track progress.

2. Specific UK-appropriate standard definitions are required to establish a baseline and track improvements in medicines safety.

3. Medicines safety issues in the patient’s home are not well understood and should be made a research priority.
4 A pharmacovigilance network of hospital pharmacists should be established to monitor and report on ADRs associated with newly-licensed medicines.

5 Pharmacovigilance networks should also be established for patient groups not adequately represented in clinical trials.

6 The new professional body for pharmacy should prioritise medicines safety in its support for members and in its strategic influencing role.

7 The new professional body should use its influence to ensure that medicines safety remains at the forefront of professional education and development in pharmacy.

8 Further research is needed on the implications for medicines safety of the increasing role of pharmacy technicians in the pharmacy workforce, and the increasing use of locum pharmacists.

9 The future professional body for pharmacy should work with other stakeholders to establish a repository or portal for knowledge sharing about medicines safety and effective interventions.

10 Experience with implementing new technology should be a key component of a knowledge repository on medicines safety.

11 The new professional body for pharmacy should consider joining EUNetPas.

12 The new professional body should ensure that parliamentarians are well informed about the medicines safety agenda.

13 Representatives of patients and the public should be actively involved in the professional body’s work on promoting medicines safety.

14 The future professional body should actively engage with organisations giving direct advice to the public about their medicines.

15 The future professional body should develop its role and expertise in medicines safety so that it can influence the national policy agendas and patient safety campaigns in the three GB countries.

16 Consideration should be given to setting up a national working group to identify whether any additional measures by the pharmaceutical industry are needed to improve medicines safety.

17 The future professional body should work with other stakeholders to prioritise the areas for research where there are currently gaps in the literature relating to medication safety in the UK and influence research funders to fund these areas.
References


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## Glossary

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<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADR</td>
<td>Adverse drug reaction</td>
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<tr>
<td>CCA</td>
<td>Company Chemists Association</td>
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<td>CPSSQ</td>
<td>Centre for Patient Safety and Service Quality</td>
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<td>EUNetPas</td>
<td>European Network for Patient Safety</td>
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<td>FMEA</td>
<td>Failure modes and effects analysis</td>
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<td>HOPE</td>
<td>European Hospital and Healthcare Federation</td>
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<td>IHI</td>
<td>US Institute for Health Improvement</td>
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<td>MEP</td>
<td>Member of the European Parliament</td>
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<td>MHRA</td>
<td>Medicines &amp; Healthcare products Regulatory Agency</td>
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<td>MRSA</td>
<td>Methicillin-resistant staphylococcus aureus</td>
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<td>MSSA</td>
<td>Methicillin-sensitive staphylococcus aureus</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<td>NPA</td>
<td>National Pharmacy Association</td>
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<td>NPSA</td>
<td>National Patient Safety Agency</td>
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<td>NSAIDs</td>
<td>Non-steroidal anti-inflammatory drugs</td>
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<tr>
<td>OTC</td>
<td>Over the counter</td>
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<tr>
<td>PDSA (methodology)</td>
<td>Plan, do, study, act</td>
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<tr>
<td>PGEU</td>
<td>Pharmaceutical Group of the European Union</td>
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<td>PLG</td>
<td>Public Liaison Group</td>
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<td>Pharmaceutical Services Negotiating Committee</td>
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<td>RFID</td>
<td>Radio frequency identification</td>
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<td>RPSGB</td>
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For further information, please contact:

Eileen Neilson
Head of Policy Development
Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street
London SE1 7JN
Tel: 0207 572 2217
Email: eileen.neilson@rpsgb.org