



**International Pharmaceutical Federation
Fédération Internationale Pharmaceutique**

PO Box 84200, 2508 AE The Hague, The Netherlands

**FIP REFERENCE GUIDE ON
GOOD PHARMACY PRACTICE IN COMMUNITY AND HOSPITAL SETTINGS
FIRST EDITION 2009**

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Preface

In recent years the term "pharmaceutical care"¹ (1) has established itself as a philosophy of practice, with the patient and the community as the primary beneficiaries of the pharmacist's actions. The concept is particularly relevant to special groups such as the elderly, mothers and children, and chronically ill patients, as well as to the community as a whole in terms of, for example, cost containment. While the basic concepts of pharmaceutical care and good pharmacy practice (GPP) are largely identical, it can be said that good pharmacy practice is the way to implement pharmaceutical care.

When developing quality assurance systems for GPP, important differences between countries have to be recognized. All countries should be working towards establishing a long term vision for pharmacy practice. The first steps in such strategic planning usually involve determining the functions of pharmacists² that are desired by patients, physicians, policy makers, insurers, payers, and other health care practitioners and then to determine who should have accountability for these functions. It is also considered important to describe key competencies that the pharmacy profession brings to the continuum of health care delivery in each country, in all settings and health care environments.

Therefore, the purpose of this reference guidebook serves to define good pharmacy practice by contemporary standards of practice and thinking; it also aims to emphasize that GPP offers a system, whereby pharmacists can provide pharmaceutical care. Patients are at the focus of attention of pharmacists and patients can be treated better by optimizing their use of medicines through receiving pharmaceutical care.

Finally, this document is also intended to encourage national policy makers to focus the attention of pharmacists working in community and hospital pharmacies when establishing national GPP guidelines. The conditions of practice vary widely from country to country and each national pharmaceutical organization is best able to decide what can be achieved and within what time-scale.

The information contained reflects the preliminary research done from 2008 to 2009 and the information received by and recorded discussions of the FIP Working Group on GPP. Selected text has been adapted from the FIP/WHO guidelines on GPP in the community and hospital settings, with additional literature research information available online and from FIP National Member Associations.

¹ Pharmaceutical care is a patient centered practice in which the practitioner assumes responsibility for a patient's drug related needs and is held accountable for this commitment. (1)

² Pharmacists are health care professionals whose professional responsibilities include seeking to ensure that people derive maximum therapeutic benefit from their treatments with medicines. This requires them to keep abreast of developments in pharmacy practice and the pharmaceutical sciences, professional standards requirements, the laws governing pharmacy and medicines and advances in knowledge and technology relating to use of medicines. (41)

Box reference 1: Historical developments of good pharmacy practice guidelines

Following the adoption of WHO'S revised drug strategy by the Thirty-ninth World Health Assembly in 1986, WHO organized two meetings on the role of the pharmacist - in New Delhi in 1988 (2) and in Tokyo in 1993 (3). These meetings were followed by the adoption by the Forty-seventh World Health Assembly of resolution WHA47.12 on "The role of the pharmacist in support of the WHO revised drug strategy" in May 1994 (4).

Subsequently, WHO organized two more meetings on the role of the pharmacist – in Vancouver in 1997 (5) and in The Hague in 1998 (6). These meetings reinforced the need for pharmacy curricular reform and the added value of the pharmacist in self-care and self-medication.

In 1992, the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading "Good pharmacy practice in community and hospital pharmacy settings". The text on good pharmacy practice was also submitted to the meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations held in Geneva from 28 November to 2 December 1994. Following the recommendations of the WHO Expert Committee and the endorsement of the FIP Council in 1997, the FIP/WHO joint document on Good Pharmacy Practice was published in the thirtieth fifth report, WHO technical report series No.885 in 1999. (7) (8)

In collaboration with the WHO, the first edition of a practical handbook "Developing Pharmacy Practice – A Focus on Patient Care" (9) was launched in 2006. This handbook is designed to meet the changing needs of pharmacists, setting out a new paradigm for pharmacy practice and presents a step-by-step approach to pharmaceutical care.

With the overall aim to improve standards and practice of drug distribution and drug utilization, using the FIP/WHO Guidelines for Good Pharmacy Practice (GPP) as the framework, FIP had also taken the initiative to explore the possibilities for providing technical assistance to its Member Organizations in Thailand, Uruguay, Vietnam, Moldova, Mongolia, Paraguay and Cambodia in developing national standards for GPP, in a pilot study from 2005 to 2007 (10).

In 2007, the "Bangkok declaration on good pharmacy practice in the community pharmacy settings" (11) in the South East Asia region was adopted by the FIP South East Asia Pharmaceutical Forum and sets the commitment of its member associations towards raising standards of pharmacy services and professional practice.

Since 1993, significant changes in practice, applied science and technology, and pharmaceutical policy have occurred, including the relevance of subsequent WHO resolutions, WHA54.11 (WHO Medicines Strategy), WHA54.13 (Strengthening health systems in developing countries), WHA55.14 (Ensuring accessibility of essential medicines), WHA55.18 (Quality of care: Patient safety), WHA57.16 (Health promotion), and WHA60.16 (Rational use of medicines). Hence, an updating of the FIP/WHO joint Good Pharmacy Practice document is necessary to reflect contemporary standards of practice and thinking.

In 2008, the FIP working group on Good Pharmacy Practice organized an expert consultation in Basel. The meeting report identified key issues that need to be considered in the revision of the guidelines (12) (See Appendix 2).

Box reference 2: Regional priority areas on GPP policy and plans in the South East Asia region

The first regional conference on GPP policy and plans was organized by SEARPharm Forum with support from the FIP Foundation, WHO-SEARO, WR Thailand, Thai FDA and the Thailand Pharmaceutical Association to discuss Good Pharmacy Practice (GPP) development, policy and plans in the SEA Regional countries with Thailand as the project country. A few Western Pacific Pharmaceutical Forum (WPPF) countries were also invited to share their experiences. The objective of the Conference was to promote the development of GPP in the Region since GPP is an important component for raising standards of pharmacy services and practice as well as professional attitudes and the behavior of pharmacists in improving health in the community.

At the end of the conference, the following six priority areas emerged:

1. Changing the perception of the role of pharmacists within the profession.
2. Improving the quality of pharmacy practice
3. Documentation and dissemination of the value and benefits of pharmacy in the supply chain for society and for patients
4. Raising public awareness of the added value of the role of the pharmacist/pharmacy
5. The role of the pharmaceutical associations and Regional Forums
6. Education and continuing education

The recently concluded 2nd regional conference in Indonesia in August 2008 looked at the progress made by countries and focused on the development of quality management and implementation plans.

Acknowledgements

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Introduction

Good Pharmacy Practice (GPP) is at the very heart of the profession of Pharmacy; indeed it is the very essence of the profession. Moreover, it expresses our covenant with the patient not only to 'do no harm' but also to facilitate good therapeutic outcomes with medicines.

This reference guidebook is aimed primarily at the two main branches of the profession whose focus is the direct care of patients, namely community pharmacy and hospital pharmacy, although it is recognised that these two branches of the profession are becoming less clearly defined as the profession evolves and the two branches become more integrated through efforts to resolve discontinuities of care.

Whilst the document is aimed at the two main branches of the profession, nevertheless the principles enunciated in the document should be equally applicable to other branches of the profession.

It is recognised that pharmacy practice varies enormously from one country to another and from one continent to another, incorporating developing, transitional and developed countries. The flexibility of this document is intended to take these variations in practice into account.

The profession is currently advancing at a considerable pace and new roles are being proposed and promulgated, not only by the profession itself but also by other healthcare professions and by national and international authorities and agencies. This document is intended to be far reaching and sufficiently flexible in its approach that it should remain relevant as these new roles become established.

We would emphasise that this document is, first and foremost, a Reference document and is for the use of FIP Member Organisations (national pharmacy/pharmaceutical associations) together with their national authorities and other relevant bodies responsible for drawing up GPP documentation and related laws and regulations in their individual countries. It does **not** establish standards nor does it provide a template for such GPP documentation.

Professional concerns and attitudes are emphasised throughout the document and the patient's welfare and well being is of paramount importance. However it will be noted that economic matters are also referred to frequently and this is right and proper given the considerable worldwide debate on the economics of medicines, the provision of care services and application of healthcare skills in modern practice; wherever appropriate published research and practical recommendations based on the experiences of national pharmacy associations are also highlighted.

This reference guidebook serves as the precursor to the creation of a policy document within the International Pharmaceutical Federation whose focus will be on updating the Good Pharmacy Practice Statement of 1991.

Underlying philosophy

Convenient and timely access to care, patient safety and health outcomes, financial sustainability, and scopes of practice of health professionals are the major issues challenging governments and health care leaders. Pharmacists, as medication experts, have an important role to play in the debate and resolution of these issues. (13)

A pharmacy professional body needs to consider a vision to succeed as a unifying force for pharmacy professionals throughout their careers; it must support education, innovation, best practice and professional development from initial training all the way to retirement and beyond; it must support both generalists and specialists within pharmacy and enable its members to be fulfilled professionally. (14)

The mission of pharmacy practice is to provide medications and other health care products and consistent professional services and to help people and society to make the best use of medicines

The practice of pharmacy has been regarded as the custody, preparation, dispensing and provision of medicines, together with systems and information to assure quality of use. Pharmacists utilise their expertise in medicines and treatment therapy to optimise health outcomes. (15)

A comprehensive pharmacy service involves activities both to secure good health and to avoid ill-health in the population. A pharmacy takes care of the patient's health, the public health and the environment. When ill-health is treated, it is necessary to assure quality in the process of using medicines in order to achieve maximum therapeutic benefit and to avoid untoward side-effects.

Pharmacy practice is or should be managing patient care and assuring appropriate drug therapy outcomes. Health promotion and health maintenance are key components of pharmacy practice and effective drug therapy management. The pharmacist, as the trained medication management specialist, has a leadership role to play in the collaborative effort to help patients better manage their health care and to help other health care practitioners address the complexities of drug therapy. (16)

Pharmacists should move from behind the counter and start serving the public by providing pharmaceutical care instead of merely supplying medicines. There is no future in the sole act of dispensing - that activity can and will be taken over by the internet, machines, and/or trained technicians or assistants. The fact that pharmacists have an academic training and act as health care professionals puts a burden upon them to better serve the community than they currently do. (17)

It is also important to recognise that socio economic conditions in different parts of the world vary, and may result in unfavorable conditions for optimal patient care. In these settings, the practice of pharmacy becomes very much product orientated rather than patient focused. However, it needs to be emphasized that despite of such economic challenges, national pharmacy associations and their Governments must take steps and make best efforts to ensure that pharmacists put the patient first notwithstanding external social pressures.

Box reference 3: Economic effects of clinical pharmacy interventions: A literature review (18) (19) (20) (21)

Clinical pharmacists' interventions in hospital inpatient settings to improve patient outcomes reduced and avoided expenditures, according to a June 15, 2008, review article in the American Journal of Health-System Pharmacy.

In a review of 21 studies published between 1996 and 2007, clinical pharmacists' fiscal value became apparent as they engaged in cost-saving interventions such as discontinuing unnecessary drugs and switching patients to a less expensive agent. Review authors also found that drug costs were reduced when pharmacists participated in rounds as part of a health care team. During rounds, pharmacists "gathered patient information, evaluated patients' drug therapy, and made therapeutic recommendations."

Pharmacists also avoided costs by preventing adverse drug events and reduced costs by optimizing patients' antibiotic therapy. Other general clinical pharmacist interventions reduced costs, such as by reviewing patients' charts and drug profiles.

Cost savings among the studies reviewed ranged widely, from \$1,977 during a 24-week period (extrapolated to \$9,135 in savings a year) to \$251,764 over 22 days (extrapolated to \$4.3 million in savings a year). The savings ranged from \$12 to \$11,444 per day.

The authors recommended future clinical pharmacy economic studies have a comparative design, such as comparing the results before and after clinical pharmacy is introduced. Future studies also should include "the incremental cost-effectiveness or cost-benefit ratio of clinical pharmacy interventions from a societal perspective."

Further reading:

The Iowa Continuity of Care study: Background and methods. Barry L. Carter, Karen B. Farris, Paul W. Abramowitz, David B. Weetman, Peter J. Kaboli, Jeffrey D. Dawson, Paul A. James, Alan J. Christensen, and John M. Brooks. 2008, Am J Health-Syst Pharm, Vol. 65, pp. 1631-46.

Pharmacist-led program to improve venous thromboembolism prophylaxis in a community hospital. Jered B. Bauer, David S. Chun, and Todd A. Karpinski. 2008, Am J Health-Syst Pharm, Vol. 65, pp. 1643-7.

Box reference 4: The contribution of community pharmacy to improving the public's health (22) (23)

This report presents a summary of findings from a review of evidence published in peer-reviewed journals between 2004 and 2007 on the contribution of community pharmacy to improving the public's health. This current review adds to the evidence identified from the two previous reviews covering the periods 1990-2001 and 2001-2004. It was commissioned by the Department of Health. This Management Summary focuses on evidence of effectiveness, quality, costs/cost-effectiveness and skill mix where available. Key findings relating to pharmacists' attitudes and practice are also summarised.

Conclusions

The review found a substantial number of studies and their findings have strengthened the evidence base of effectiveness for community pharmacy based services in smoking cessation, CHD management and prevention, diabetes screening and management, hypertension – although most of the studies were conducted abroad in settings that might vary from those in the UK and therefore further research is required within the UK. Some evidence of effectiveness was found relating to osteoporosis risk assessment and weight management. These areas remain promising and should also be tested in pilot studies and further research.

Earlier studies (24) (25) reviewed generally showed pharmacists to be positive about their potential contribution to health development, although the constraining effects of current working practices of pharmacists, existing remuneration arrangements and some community pharmacy premises are well-described. Training appears to be a key factor in changing community pharmacists' practice to incorporate health development activities and embedding a more holistic approach. Research suggests that pharmacists are currently more likely to engage in health improvement activities that are linked to medicines use in some way. Furthermore, the literature indicates that, at present, pharmacists tend to take a reactive rather than proactive approach to health.

Further reading:

The contribution of community pharmacy to improving the public's health: Evidence from the peer-reviewed literature of 1990-2001. Anderson, C, Blenkinsopp, A, and Armstrong, M. 2003, PharmacyHealthLink and Royal Pharmaceutical Society of Great Britain.

The contribution of community pharmacy to improving the public's health. Evidence from the peer reviewed literature 2001-2004. Anderson C, Blenkinsopp A, Armstrong M. 2005, PharmacyHealthLink and Royal Pharmaceutical Society of Great Britain.

Libby Roughead, Susan Semple, Agnes Vitry. *The value of the pharmacist in the community: a systematic review of the literature 1990-2002.* University of South Australia, Quality use of medicines and pharmacy research centre

Box reference 5: Remodeling pharmaceutical care in Sub-Saharan Africa (SSA) amidst human resources challenges and the HIV/AIDS pandemic (26)

Summary abstract:

Pharmaceutical care, meant to complement a proper drug supply system, is a key component of a robust health care system and is the direct, responsible provision of medication-related care designed to achieve definite outcomes that improve a patient's quality of life. Beyond simply dispensing medicine, pharmaceutical care promotes adherence to therapeutic regimens and addresses problems such as over dosage, sub-therapeutic dosage, adverse drug reactions, medication errors, and untreated indications. The dearth of health care workers trained in pharmaceutical care coupled with inadequate access to medications creates multiple disease management challenges in Sub-Saharan Africa (SSA), which has 25% of the world's disease burden but only 1.3% of the world's health workforce. To prevent and treat HIV/AIDS, TB, malaria, and other maladies, the need is urgent to train and integrate the contributions of current workers who handle medications for major and minor health problems, especially those in licensed pharmacies and drug shops. On the aggregate in SSA, pharmaceutical care is in a nascent stage in most countries but needs to grow as a discipline as well as be tailored to specific country needs. The SSA solution lies in establishing health care system components where cadres of workers engage in pharmaceutical care practices, as well as store and distribute medications. Curriculum changes in pre-service education, more continuing education for the health workforce in place, and training pharmacists to supervise a lower cadre of assistants and others are among the elements in a pharmaceutical care paradigm shift which is the focus of this article.

Key messages

This article highlights and discussed factors discussed that are contributing to the immediate need to rethink the application of the current paradigm in pharmaceutical care delivery in SSA: inadequate number of training institutions, brain drain, low density of pharmacists per country population, maldistribution of pharmacists in rural/urban areas, low numbers or improperly trained pharmacy technologists/assistants, low-resourced pharmacy regulatory authorities, widespread use of counterfeit and adulterated drugs and the handling of medicines by untrained or inadequately trained health workers and others. Mainstream pharmaceutical care in SSA requires a paradigm shift which includes adding pharmaceutical care to the pharmacy pre-service curriculum, developing training modules or lectures for nursing and medical schools, continuing education for pharmacists, doctors, and nurses on pharmaceutical care, developing strategies to retrain staff in various countries and most critically, formalizing and training a lower cadre of personnel such as pharmacy technologists or assistants and drug shop attendants.

Therefore, the solution in SSA requires refining the traditional scope of practice for pharmacists. The research further proposes a new model for the provision of pharmaceutical care across four generally recognized levels, that is, pharmacists, dispensing doctors, and nurses, pharmacy technologists as well as drug shop attendants.

Further reading:

The 2009 FIP Global Pharmacy Workforce Report. Available online at <http://www.fip.org/hr> (27)

"The global pharmacy workforce: a systematic review of the literature". (28) The article aims to explore contemporary issues surrounding expansion of the global pharmacy workforce. The journal is open access and the article can be downloaded at: <http://www.human-resources-health.com/content/7/1/48>.

Box reference 6: Pharmacists combating counterfeit medical products for patient safety

There are numerous reports of an unacceptable prevalence of substandard and counterfeit pharmaceutical products in international trade. Developing countries are the ones most frequently exposed to such products which may be inefficacious or toxic and which threaten to erode confidence in the health care system. It was for this reason that in May 1994 the Forty-seventh World Health Assembly, in adopting resolution WHA47.12 on the role of the pharmacist in support of the WHO revised drug strategy, drew attention to pharmacists' responsibilities in assuring the quality of the products they dispense. The resolution also recognized that the pharmacist can play a key role in public health and particularly in the field of medicines, and that the rational use of drugs is contingent upon the availability to the whole population at all times of essential drugs of good quality at affordable prices (4). Patients and care-providers must make sure that they only buy from legal outlets, such as pharmacies and appropriate trained personnel such as pharmacists.

Affluent countries usually have effective drug regulatory systems that are based on legislation. These monitor and assure the quality of industrially produced pharmaceutical products by several means: the issuance of product licenses or marketing authorizations; the licensing and inspection of pharmaceutical manufacturers, wholesale and other distributors, community and hospital pharmacies and other drug outlets; and occasional quality control in a government laboratory. Many developing countries lack an effective drug regulatory system, which puts the main responsibility and accountability for the quality of pharmaceutical products on the pharmacists. These then have to rely on their own, or their pharmacists' associations, quality assessment and must make sure that they procure medicines only from reliable sources. The FIP has developed special guidelines for drug procurement. (29)

One should be aware of the specific nature of medicines since their purpose is to cure patients of diseases - counterfeit medicines endanger patients' safety. The legitimate pharmaceutical supply chain as the secure channel to distribute medicines to patients around the world needs to be strengthened in order to be maintained in the long run.

All stakeholders in the pharmaceutical supply chain should endeavor to protect the integrity of the supply chain. (30) There is a need to consider traceability of medicines and medical devices from their production to their administration to patients. Therefore a stronger role for pharmacists at every step of the supply chain could reduce the risks of medicine counterfeiting and improve patient safety.

Further reading:

FIP's framework for establishing a national guide for pharmacists in combating counterfeit medicines. International Pharmaceutical Federation (FIP) 2009, The Hague

Trading in False Hopes: A review of medicines counterfeiting as a world-wide threat and the need for strengthened international collaboration to reduce pharmaceutical crime and promote global health. Taylor D and Craig T. 2009, The School of Pharmacy, University of London

The definition of GPP

Good Pharmacy Practice (GPP) is the practice of pharmacy that responds to the needs of the people who use the pharmacists' services by providing optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines.

The requirements of Good pharmacy practice

1. Good pharmacy practice requires that a pharmacist's first concern in all settings is the welfare of patients.
2. Good pharmacy practice requires that all processes in supplying medicines and assuring appropriate use take into consideration the patient's health, the public health and the environment. (31)
3. Good pharmacy practice requires that the core of the pharmacy activity is the supply of medicines and other health care products of assured quality, appropriate information and advice for the patient, and monitoring of the effects of use.
4. Good pharmacy practice requires that an integral part of the pharmacist's contribution is the promotion of rational, cost effective, economic prescribing and of appropriate use of medicines.
5. Good pharmacy practice requires that the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved.
6. Good pharmacy practice requires that successful drug therapy management involves the collaboration of a team of pharmacists, physicians, nurses, and other health care practitioners. (16)
7. Good pharmacy practice requires that, as readily accessible health professionals, pharmacists provide primary health care including education and advice to promote good health and to reduce the incidence of illness. (15)

In satisfying these requirements, the following conditions are necessary:

- Professionalism should be the main philosophy underlying practice, although it is accepted that economic factors are also important.
- Pharmacists should have input into decisions about the use of medicines. A system should exist that enables pharmacists to report adverse events, medication errors, defects in medicines quality or detection of counterfeit medical products. This reporting may include information about medicines use supplied by patients or health professionals, either directly or through pharmacists.

- The ongoing relationship with other health professionals, particularly physicians, should be seen as a therapeutic partnership that involves mutual trust and confidence in all matters relating to pharmacotherapeutics. The pharmacist should be in the position to make his professional judgment in autonomy.
- The relationship between pharmacists should be as colleagues seeking to improve pharmacy service, rather than as competitors.
- All pharmacists should accept a share of responsibility and accountability for the definition, evaluation and improvement of quality in their professional practice.
- The pharmacist should have access to essential medical and pharmaceutical information about each patient.
- The patient-pharmacist relationship can be strengthened if the patient chooses to use only one pharmacy. The pharmacist needs independent, comprehensive, objective and current information about therapeutics and medicines in use.
- Pharmacists in each practice setting should accept personal responsibility and accountability for maintaining and assessing their own competence throughout their professional working lives.
- Pharmacists should be aware of the fact that pharmaceuticals may have an environmental impact and should always consider the possibilities to minimize this impact, especially when disposing of pharmaceutical waste.
- For pharmacy managers, it is important to determine and to ensure required levels of competency and responsibilities for different tasks undertaken by the pharmacy support staff. These personnel can be pharmacy technicians or assistants working in the pharmacy.
- Educational programmes for entry to the profession should appropriately address both current and foreseeable future changes in pharmacy practice.
- National standards of good pharmacy practice should be specified and should be adhered to by practitioners.

Box reference 7: American Society of Health-System Pharmacists (ASHP) – vision for pharmacists (32)

Pharmacists will:

1. Will significantly enhance patients' health-related quality of life by exercising leadership in improving both the use of medications by individuals and the overall process of medication use.
2. Will manage patient medication therapy and provide related patient care and public health services.
3. Will be the primary individuals responsible for medication use and drug distribution systems.
4. Will be recognized as patient care providers and sought out by patients to help them achieve the most benefit from their therapy.
5. Will take a leadership role to continuously improve and redesign the medication-use process with the goal of achieving significant advances in (a) patient safety, (b) health-related outcomes, (c) prudent use of human resources, and (d) efficiency.
6. Will lead evidence-based medication use programs to implement best practices.
7. Will have an image among patients, health professionals, administrators, and public policy makers as caring and compassionate medication-use experts.

Box reference 8: Key guiding principles adopted by the Canadian Pharmacists Association in achieving The Vision for Pharmacy – Blue Print for Pharmacy (13)

- 1) Pharmacists and pharmacy technicians practice to the full extent of their knowledge and skills, and are integral to emerging health care models.
- 2) Pharmacists and pharmacy technicians protect the safety, security and integrity of the drug distribution system through the enhanced role of regulated pharmacy technicians and greater automation of dispensing.
- 3) Pharmacists and pharmacy technicians lead the development of and participate in medication safety and quality improvement initiatives.
- 4) Pharmacists manage drug therapy in collaboration with patients, caregivers and other health care providers.
- 5) Pharmacists identify medication use issues, take responsibility for drug therapy decisions and monitor outcomes.
- 6) Pharmacists initiate, modify and continue drug therapy (e.g., through collaborative agreements, delegated or prescriptive authority) and order tests.
- 7) Pharmacists empower patients in decision-making about their health, and play a prominent role in health promotion, disease prevention and chronic disease management.
- 8) Pharmacists conduct practice research and contribute to evidence based health care policy and best practices in patient care.

Box reference 9: Areas unique to Community and Hospital Pharmacy Practice

Community pharmacy

- Direct patient contact – some long term, some very short term
- Compliance and consistent use of medicines
- Self care
- Cognition / literacy of patient
- Product and service aspect packaged together
- Customer services
- Contact with internet patients
- Contact with patients through a third party
- Extemporaneous preparation
- Health information in the community
- Isolation as a professional, not part of a team
- Lack of clinical patient information
- External influences affecting practice
- Cost issues impinging on professional matters
- Confidentiality issues
- Medication reconciliation/comprehensive medication record (community/hospital/nursing home)
- Health promotion
- Legal framework within which to work
- Home delivery of medicines
- Home visits by pharmacists
- Medical supplies/oxygen/renal dialysis
- Contact with drug addicts
- Screening for diseases eg. diabetes/BP/cholesterol

Hospital pharmacy

- Parenteral Solutions, IV admixtures
- 'Bedside' clinical care, ward rounds
- Hospital Formulary
- Drugs & Therapeutics Committee
- Medical Gases
- Manufacturing
- TPN
- Satellite Pharmacies
- Emergency/life threatening situations
- Complex therapy
- Rapid turnover of patients
- Clinical trials and investigative drugs/work
- Cytotoxics
- Radiopharmaceuticals and diagnostics
- Medical devices and IV pumps
- Sterile materials, handling distribution and preparation
- Complexity of the organisation
- Infections
- Individualised medicines
- Access to laboratory data and biomarkers
- Procurement – through tenders
- Specialized softwares – informatics, Drug Information Centre
- Proteomics, Genomics and other "omics", gene therapy
- Biochips, biosensors and MEMS (micro electro mechanical systems)
- Poisoning/intoxication

Applying good pharmacy practice

Whom are our pharmacists serving in society?

Our “customers” may include patients, nurses, physicians, pharmacist employers, academicians, government officials, health plan administrators, pharmaceutical manufacturers.

If these are our “customers”, what do they expect of us?

Pharmacy customer expectations appeared to be grouped into some common themes (16):

- Patients will achieve appropriate drug therapy outcomes.
- Drug related problems will be identified, resolved, and prevented.
- Care is coordinated and practitioners are competent.
- There is value in the care that patients receive and it is affordable.
- The system is accessible and is looking out for the patient’s best interest.
- There is a professional covenant between the patient and practitioner.
- The system will provide adequate and appropriate information and education regarding appropriate drug use.

We need to recognize that there are at least three ways that pharmacists can define their functions or roles, in accordance to:

1. The medicines management pathway (Box reference 10) – in this way, our functions relate closely to the use of medicines and how our actions improve medication/patient safety.
2. With the patient in focus (Box reference 11) – in this way, our functions are organized in a sequence that follows a patient’s care process if they were to progress logically through the health care system.
3. With the pharmacist in focus (Box reference 12 and 13) – in this way, our functions relate the full range of knowledge, skills, attitudes and values a pharmacist might have to deploy on day one.

Consider the notion of “a patient-focused medication use system to improve quality of care” as a fundamental principle for a pharmacy practice framework.

Competency based approaches to setting pharmacy practice standards

Given the increasingly complex and diverse nature of pharmacists’ role in the health care system and public health, there is a need to empathize the importance of maintaining the competence of pharmacists as health care professionals who have relevant and up-to-date skills and expertise (33). National associations need to work together with their appropriate governing bodies to support pharmacists in their country through providing continuing professional development activities and establishing a national pharmacy competency framework that defines minimum national standards of pharmacy services and practice objectives.

Characteristics of a pharmacy practice framework

1. Provide an overview of all aspects of pharmacy practice
2. Incorporates minimum standards and establishes goals
3. Aims to be non-setting specific, non-disease specific but with the ability to adapt roles and procedures to meet the needs of various practice environments
4. Aims to achieve universal applicability, with focus placed on fundamental elements of drug therapy management, and with a focus on populations while still maintaining the attention to patients as individuals (16)
5. Includes all aspects of the medication-use process and provides explicit descriptions of the necessary performance elements (34)

Recent studies identified that the profession lacked an over-arching, generic framework that enables differentiation between levels of practice, as the majority of existing pharmacy competency frameworks only apply to specific areas of work such as in pediatrics or oncology. In the UK, there are extensive researches in areas relating to the development and validation of a generic General/Advance level practice competency framework (35)

For more information and example of pharmacy competency frameworks, please see Box References 10 to 14 and Appendix 1 on background of 37 national GPP standards among FIP Member Organisations.

Box reference 10: Short list of pharmacy related competency frameworks (mainly UK). See also Appendix 1 for information of national competency and GPP standards developed by national pharmacy associations

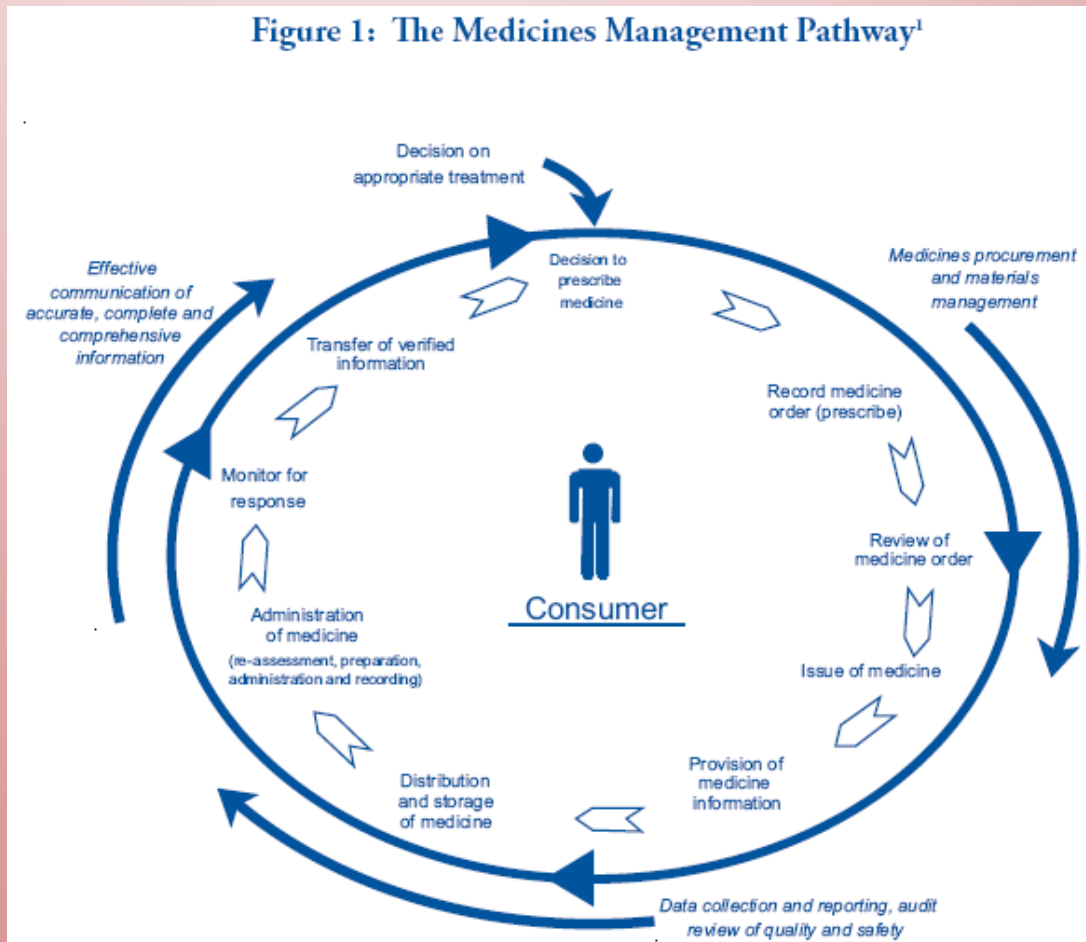
Country	List of pharmacy competency framework	Source
UK	Competencies for Pharmacists Working in Primary Care, 2nd edition 2003	National Prescribing centre www.npc.co.uk/publications
	A Competency Framework for Community Health Pharmacy Services, June 2003	Primary & Community care Pharmacy Network www.pccpnetwork.org/publications
	Maintaining Competency in Prescribing - an outline framework to help pharmacist supplementary prescribing, 2003	National Prescribing centre www.npc.co.uk/publications
	General Paediatric Competencies, Sept 2002	College of Pharmacy Practice Faculty of Neonatal and Paediatric Pharmacy www.collpharm.org.uk/FNPCC
	A Competency Framework for Pharmacy Practitioners to Provide Minimum Standard of Pharmaceutical Review: The General Level Framework Handbook First Edition October 2006	Safe Medication Practice Unit Queensland Health http://www.codeg.org/fileadmin/codeg/pdf/SMPU_GLF_Handbook.pdf
	Outline Competencies for Mental Health Pharmacists, 2001	College of Mental Health Pharmacists, the UK Psychiatric Pharmacy Group www.ukppg.org.uk/cmhp-competencies
	A Competency Framework for Pharmacy Practitioners <i>General level, 2003</i> <i>Advanced level, 2003</i>	London, Eastern & South East Specialist Pharmacy Services, Clinical Pharmacy In collaboration with Brighton School of Pharmacy & London School of Pharmacy In consultation with the Guild of Healthcare Pharmacists www.londonpharmacy.nhs.uk/clinical/competency
	Competency Framework for the Assessment of Pharmacists providing the Medicines Use Review (MUR) and Prescription Intervention Service	NHS Community Pharmacy Contractual Framework http://www.wales.nhs.uk/sites3/Documents/498/Advancedservicecompetencyframework.pdf
	A Competency Framework for Medicines Information Pharmacists, 2001	United Kingdom Medicines Information (Pharmacists Group) www.ukmi.nhs.uk
	A new professional framework for developing future chief pharmacists, Sept 2008	http://www.pjonline.com/fileproxy/1134
Canada	Model Standards of Practice for Canadian Pharmacists - April 2003	National association of pharmacy regulatory authorities http://www.napra.ca/docs/0/95/123.asp
New Zealand	The Competence Standards for the pharmacy profession	Pharmacy council of NZ http://www.pharmacycouncil.org.nz/cms_show_download.php?id=38
United States	Academy of Managed Care Pharmacy: Framework of quality drug therapy	http://www.fmcenet.org/index.cfm?p=132D8447
	Minimum Standard for Home Care Pharmacies	American Health-System Pharmacists http://www.ashp.org/DocLibrary/BestPractices/ASHPGuidelinesMinimumStandardforHomeCarePharmacies.aspx
	Minimum Standard for Pharmaceutical Services in Ambulatory Care	American Health-System Pharmacists http://www.ashp.org/DocLibrary/BestPractices/ASHPGuidelinesMinimumStandardforPharmaceuticalServicesinAmbulatoryCare.aspx
	Minimum Standard for Pharmacies in Hospitals	American Health-System Pharmacists http://www.ashp.org/DocLibrary/BestPractices/ASHPGuidelinesMinimumStandardforPharmaciesinHospitals.aspx
Australia	Competency Standards for Pharmacists in Australia 2003	http://www.psa.org.au/site.php?id=1123
	Professional Practice Standards 2006	http://www.psa.org.au/site.php?id=1094

Box reference 11: The Medicines Management Pathway (36)

The medicines management pathway describes the cognitive and physical steps involved in the use of medicines, with a focus on the consumer. There are 9 steps and 3 background processes. The steps and processes are interdependent and influence each other. Documentation of the pathway provides a framework to identify how the steps are related, the potential for any errors and safety system improvements. The pathway is applicable to all medicines, independent of the setting, health professionals involved and funding source. An understanding of the pathway and human factors associated with each step are necessary to ensure safe, effective and efficient use of medicines. The pathway can assist consumers and health professionals to understand their role and how their actions can improve medicine safety. Hospital pharmacists have an established role at all steps. With more professional services being offered via community and other pharmacy practice settings, the medicines management pathway concept will play an increasingly greater role across the continuum of care. Follow ups and outcomes of medication is a responsibility for all pharmacists.

Based on this concept, the Pharmaceutical Society of Australia developed the Professional Pharmacy Standards (Version 3) in 2006.

Figure 1: The Medicines Management Pathway¹



Box reference 12: Framework of quality drug therapy of the United States AMCP (16)

The Academy of Managed Care Pharmacy (AMCP) created a task force early in 1999 to design *Pharmacy's Framework for Drug Therapy Management in the 21st Century*. To fulfill this objective, a strategic plan was developed to create a model for drug therapy management. This model would support a long-term vision for pharmacy practice. The first steps in the strategic plan involved determining what functions are desired by patients, health care practitioners, payers, insurers, employers, physicians, policy makers, and academicians, and then to determine who should have responsibility for that component. What sets the *Framework* project apart from previous studies of pharmacy is the listening to large numbers of customers/patients in planning drug therapy management services for the future that are setting or environment-independent. The *Framework* broadly describes key competencies that the profession of pharmacy brings to the continuum of health care delivery in the United States, in all settings and health care environments. It does not attempt to define specific roles and tasks of pharmacists or pharmacy itself.

There are seven core areas of focus in the Grid and Self-Assessment Tool. The first core area of focus addresses components that are applicable whenever a health care practitioner is interacting with patients. Core focus areas two through seven are organized in a sequence that follows a patient's care process if they were to progress logically through the health care system.

US Academy of Managed Care Pharmacy - Frame of quality pharmacy services

<p>Employ fundamental skills, tasks, and functions for effective drug therapy management.</p> <ul style="list-style-type: none"> 1.1 Interpersonal communication skills 1.2 Credentials — skill documentation and maintenance 1.3 Patient Education 1.4 Patient and Work Safety 1.5 Leadership 1.6 Patient rights and responsibilities 1.7 Continuous quality improvement 	<p>Patient response to drug therapy is monitored for effectiveness, adherence, avoidance of adverse effects, and drug therapy is adjusted to achieve optimal outcomes.</p> <ul style="list-style-type: none"> 5.1 Patient monitoring and documentation 5.2 Drug therapy adjustments and changes 5.3 Patient education 5.4 Continuous quality improvement
<p>Health management, health promotion, and disease prevention programs and services are offered.</p> <ul style="list-style-type: none"> 2.1 Program design 2.2 Outreach and accessibility 2.3 Program delivery 2.4 Continuous quality improvement 	<p>Health benefits are provided through a system that has an appropriate drug use policy and benefit design.</p> <ul style="list-style-type: none"> 6.1 Selection of optimum therapy 6.2 Access to health benefits 6.3 Patient education 6.4 Drug utilization review 6.5 Continuous quality improvement
<p>The patient is effectively assessed, accurately diagnosed, and appropriate drug therapy is selected</p> <ul style="list-style-type: none"> 3.1 Patient assessment and diagnosis 3.2 Drug selection 3.3 Drug prescribing 3.4 Transmission of orders 3.5 Coordination of care 3.6 Continuous quality improvement 	<p>The health system performs ongoing assessment to ensure that the results of drug therapy management lead to healthy individuals and populations.</p> <ul style="list-style-type: none"> 7.1 Drug therapy evaluation 7.2 Collection and dissemination of information 7.3 Continuous quality improvement
<p>The patient is served by a distribution system that provides accurate drug therapy and understandable health information in a timely manner.</p> <ul style="list-style-type: none"> 4.1 Security and storage 4.2 Drug preparation and dispensing to patients 4.3 Patient medical records 4.4 Patient education 4.5 Coordination of care 4.6 Continuous quality improvement 	<p>Note: The “component” tasks, skills and functions in each of the core areas of focus are categorized under “functional areas” of drug therapy management. The components under a given functional area are building blocks that interact to permit the health care practitioner or the system to achieve successful patient care.</p>

Box reference 13: The Royal Pharmaceutical Society of Great Britain Practice Framework (RPSGB) (37)

Since 2007, the RPSGB in developing “The Practice Framework” that will define what pharmacists do and what they therefore need to know, what skills they must acquire and how they need to behave. The Practice Framework is not a number of things: it is not a pharmacist’s job description; it is not a national curriculum; it is not a description of advanced or specialist practice; and it is not a description of the first day of every single pharmacist. It is a statement of the full range of knowledge, skills, attitudes and values a pharmacist might have to deploy on day one.

In order to corral all the various different things that pharmacists do into a coherent whole, we have divided them up as follows:

- Roles – 7 broad clusters of related functions
- Functions – a slightly more detailed description of what the roles comprise (between 2 and 6 Functions per Role)
- Activities – the basic building block descriptions of what pharmacists do (between 2 and 5 activities per role) Each Activity also has some Indicators of good practice, to give a better indication of what we see each Activity to be

Royal Pharmaceutical Society of Great Britain – The Practice Framework

Contribute to the effectiveness of the health care system and public health

- 1) Comply with professional obligations and guidelines.
- 2) Contribute to the safe, rational and cost – effective use of medicines
- 3) Promote, evaluate and improve health in the community
- 4) Advocate and support policies that promote improved health outcomes
- 5) Medicines are designed with leading edge knowledge of compound pharmacology, medicines chemistry and pharmaceuticals and in response to patient needs/ requirements
- 6) Contribute to the education, training and mentoring of students and health professionals

Contribute to the safe and effective operation of the pharmacy or other work place

- 1) Contribute to the maintenance of a productive, healthy and safe working environment
- 2) Contribute to the management of staff and other resources within the workplace
- 3) Contribute to systems to provide products and high quality services
- 4) Contribute to the viability of the organisation or service
- 5) Minimise practice errors and omissions, unsafe practices and professional misconduct

Implement, monitor and modify therapeutic approaches

- 1) Support the patient to implement the care plan
- 2) Support and monitor the patient progress with the care plan
- 3) Document findings, follow-up, recommendations, information provided and patient outcomes

Professional and therapeutic decision making

- 1) Assess the patients health status and needs
- 2) Agree the appropriate course of action with the patient

Dispense medicines

- 1) Evaluate and advise on prescribed medicines
- 2) Assess prescriptions
- 3) Supply prescribed medicines

Maintaining and improving professional performance

- 1) Plan and implement personal development strategies to improve current and future performance
- 2) Play an active role in the pharmacy-based and multi-disciplinary systematic monitoring and review of the quality of service provision, and the implementation of service improvement measures

Produce, obtain, store, and distribute products

- 1) Produce drug preparations and products
- 2) Obtain and store drug preparations and products
- 3) Distribute drug preparations and products
- 4) Dispose of drug preparations and products

Box reference 14: Framework of professional practice (College of pharmacists of British Columbia)

The Framework of Professional Practice is a blueprint of good pharmacy practice. It describes what British Columbia pharmacists do in their daily work and how they know they are doing it well. It is the foundation for all College of Pharmacists of British Columbia programs and services. (38)

How the Framework of Professional Practice was developed (extract version only)

Pharmacists experienced in many types of pharmacy practice developed this framework. Through a systematic process called functional analysis they described:

- What pharmacists do
- Why and when they do it
- How they do it
- How they know when they perform well
- What they need to know to perform all aspects of their work

Through this process, they drafted a core statement that describes the primary reason the profession of pharmacy exists. They described why pharmacists do what they do, how they do it and whom they do it for. Based on this statement of purpose, they defined the:

- Key roles pharmacists perform
- Broad functions that enable pharmacists to fulfill each role
- Daily practice activities that contribute to each function
- Indicators of good practice for each activity
- Specifications for the knowledge and skills pharmacists need

The objective of the Framework of Professional Practice is to describe the components of good pharmacy practice. It is not a description of any one pharmacist's job. Some components are most relevant to pharmacists involved in direct patient care, while others are more relevant to pharmacists engaged in research, management, education or consulting. B.C. pharmacists validated the Framework of Professional Practice, confirming it reflects contemporary pharmacy practice.

"The primary purpose of the profession of pharmacy is to help people achieve their desired health outcomes. Pharmacists do this by providing current, rational, safe and cost-effective pharmaceutical services, information, and products, in collaboration with clients and others in the health care community."

Pharmacists, who contributed to a functional analysis process that describes why the profession of pharmacy exists, developed this purpose statement. Much like a mission statement, the purpose statement is fundamental to understanding the Framework of Professional Practice. It is the starting point for each component and it relates to everyone who contributes to the profession.

To maintain good standards of pharmacy practice, and meet the standards described in this Framework of Professional Practice, B.C. pharmacists identified five key roles that require direct pharmacist involvement or supervision.

- 1) Provide pharmaceutical care
- 2) Produce and distribute drug preparations and products
- 3) Contribute to the effective operation of the pharmacy
- 4) Maintain professional development and contribute to the professional development of others
- 5) Contribute to the effectiveness of the health care system

Setting standards for pharmacy practice

Box reference 15: Definitions of role, function and activity

A role is defined as an expected behavior of pharmacists by society and the people they serve

A function is defined as a focus area for which pharmacists have direct responsibility and accountability for ensuring it is performed well

An activity is defined as a set of actions designed to achieve a particular function.

This reference document is not meant as a technical guide to develop a comprehensive framework for pharmacy practice but aims to bring together key information that needs to be considered by national pharmacy associations when embarking on work to develop their own national frameworks (39) (40) (41) (42) (43). This is especially important when setting national standards for pharmacy practice or accreditation schemes.

In the context of this document, there are 4 main roles where pharmacists' involvement or supervision is required.

Role 1: Provide effective medication therapy management (see Table A)

Role 2: Prepare, obtain, store, distribute and dispose of medical products (see Table B)

Role 3: Maintain and improve professional performance (see Table C)

Role 4: Contribute to improve effectiveness of the health care system and public health (see Table D)

Based on the preliminary research conducted by the Working Group on GPP, a description of fundamental roles, functions and activities of pharmacists is provided as a reference to all national pharmacy associations. FIP recommends all national pharmacy associations adapt these components in accordance with their own requirements. For each activity, they should further develop indicators of good practice that need to be relevant and defined appropriately to the local needs of the pharmacy practice environment and national professional aspirations. See Box reference 16 for an example of goals, objectives and indicators used to benchmark pharmacy practice improvement goals in the hospital and health-system setting.

National pharmacy associations should also identify and clarify the other personnel working in the pharmacy, their importance, and the role played by them. It is not enough that only pharmacists know about GPP. There is a need to educate GPP concepts to other personnel in the pharmacy also, because most of the times, a large number of tasks in the pharmacy are performed by these personnel.

Table A: Role 1 - Provide effective medication therapy management

Function 1.1: Assess patient health status and needs	Activity 1.1.1: Pharmacists should ensure that health management, disease prevention, and healthy lifestyle behavior are incorporated into the patient assessment and care process.
	Activity 1.1.2: Pharmacists should acknowledge unique patient considerations such as education level, cultural beliefs, literacy, native language, and physical and mental capacity in all patient assessments.
Function 1.2: Manage patient medication therapy	Activity 1.2.1: Pharmacists should utilize a medicine formulary system (local, regional and/or national) linked to standard treatment guidelines, protocols and treatment pathways based on the best available evidence.
	Activity 1.2.2: Pharmacists should have a key role in educating prescribers on the access to and evidence for optimal and appropriate use of medicines including the required monitoring parameters and prescribing adjustments.
	Activity 1.2.3: Pharmacists should provide continuity of care by transferring patient medicines information as patients move between sectors of care.
Function 1.3: Monitor patient progress and outcomes	Activity 1.3.1: Pharmacists should consider patient diagnosis and patient-specific needs when assessing patient response to drug therapy.
	Activity 1.3.2: Pharmacists should have access to and use all necessary clinical and patient data to coordinate effective drug therapy management, especially when multiple health care practitioners are involved in the patient's drug therapy.
	Activity 1.3.3: Pharmacist should establish a standard operating procedure for referrals to health care professionals, specialists or other care providers, where appropriate.
Function 1.4: Provide patient education	Activity 1.4.1: Pharmacists should ensure that patient education takes place in an environment conducive to patient involvement, learning and confidentiality, where feasible.
	Activity 1.4.2: Pharmacists should provide sufficient health and disease and drug-specific information to patients for their participation in the decision-making process regarding a comprehensive care management plan.

Table B: Role 2 - Prepare, obtain, store, distribute and dispose medical products

<p>Function 2.1: Prepare extemporaneous drug preparations and medical products</p>	<p>Activity 2.1.1: Pharmacists should ensure that drug preparation areas are appropriately designed to permit ease of extemporaneous preparation and are maintained in a manner that minimises the potential for medication errors and assures the cleanliness and safety of medical products.</p>
	<p>Activity 2.1.2: Pharmacists should ensure that compounded medicines are consistently prepared to comply with written formulae and quality standards for raw materials, equipment and preparation processes, including sterility where appropriate.</p>
<p>Function 2.2: Obtain and store drug preparations and medical products</p>	<p>Activity 2.2.1: Pharmacists who are responsible for procurement should ensure that the procurement process is transparent, professional and ethical so as to promote equity, access and to ensure accountability to relevant governing and legal entities.</p>
	<p>Activity 2.2.2: Pharmacists who are responsible for procurement should ensure that procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system.</p>
	<p>Activity 2.2.3: Pharmacists who are responsible for procurement should ensure that procurement must be supported by a reliable information system which provides accurate, timely and accessible information.</p>
	<p>Activity 2.2.4: Pharmacists should establish contingency plans for medicines shortages and purchases in emergencies.</p>
	<p>Activity 2.2.5: Pharmacists should assure that proper storage conditions are provided for all medicines used in the hospital.</p>
<p>Function 2.3: Distribute drug preparations and medical products</p>	<p>Activity 2.3.1: Pharmacists should ensure that all medical products, including medicine samples, are handled and distributed in a manner that assures accountability and safety of the drug supply.</p>
	<p>Activity 2.3.2: Pharmacists should establish an effective distribution system which includes a written procedure, to recall promptly and effectively pharmaceutical products known or suspected to be defective or counterfeit, with a designated person(s) responsible for recalls.</p>
	<p>Activity 2.3.3: Pharmacists should develop with manufacturers and wholesalers an access plan for uninterrupted supply of essential medicines as part of a disaster or pandemic preparedness strategy</p>
<p>Function 2.4: Dispose of</p>	<p>Activity 2.4.1: Pharmacist should ensure that drug inventory monitoring</p>

drug preparations and medical products	includes drug samples in the process of periodic inspection for expiration dates and removal of out-dated stock.
	Activity 2.4.2: Pharmacists should ensure that recalled drugs, including drug samples, are removed from all inventory sources.
	Activity 2.4.3: Pharmacists should establish a safe way of drug waste disposal at the pharmacy so that patients and the public can be encouraged to return their expired or unwanted medicines and medical devices

Table C: Role 3 - Maintain and improve professional performance

Function 3.1: Plan and implement continuing professional development³ strategies to improve current and future performance	Activity 3.1.1: Pharmacists should perceive continuing education as lifelong and be able to demonstrate evidence of continuing education or continuing professional development to improve practice skills and performance.
	Activity 3.1.2: Pharmacists should take steps to update their knowledge and skills about both “mainstream” therapies, complementary and alternative therapies such as herbal therapy, homeopathy, naturopathy, and other non-traditional health management options.
	Activity 3.1.3: Pharmacists should take steps to update their knowledge and be engaged in implementation of new technology and automation in pharmacy practice, where feasible.

³ The concept of Continuing Professional Development (CPD) can be defined as “the responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional, throughout their careers.” (47)

Table D: Role 4 - Contribute to improve effectiveness of the health care system and public health

<p>Function 4.1: Comply with national professional obligations, guidelines and legislations</p>	<p>Activity 4.1.1: Pharmacists should take steps to ensure that they comply with the provisions of the Code of Ethics for pharmacists.</p>
<p>Function 4.2: Contribute to the safe, rational and cost-effective use of medicines</p>	<p>Activity 4.2.1: Pharmacists should maintain access to an appropriate evidence base relating to the safe, rational and cost effective use of medicines such as drug information reference books/journals, national essential medicines lists and standard treatment guidelines.</p>
<p>Function 4.3: Advocate and support national policies that promote improved health outcomes</p>	<p>Activity 4.3.1: Pharmacists should contribute to public and professional groups to promote, evaluate and improve health in the community</p>
	<p>Activity 4.3.2: Pharmacists should collaborate with other health care professionals in their efforts to improve health outcomes</p>
<p>Function 4.4: Disseminate evaluated information about medicines and various aspects of self care</p>	<p>Activity 4.4.1: Pharmacists should ensure that the information provided to patients and the public is objective, understandable, non-promotional, accurate and appropriate.</p>
	<p>Activity 4.4.2: Pharmacists should develop educational materials for health management, health promotion, and disease prevention programs that are applicable to a wide range of patient populations, age groups and health literary levels.</p>
	<p>Activity 4.4.3: Pharmacists should educate patients on how to evaluate and use web-based health-care information (including medicines information) and to strongly encourage them to speak to a pharmacist regarding information they find online.</p>
	<p>Activity 4.4.4: Pharmacists should assist patients and their care providers to obtain and critically analyse information to meet their individual needs.</p>

Box reference 16: ASHP’s Health-System Pharmacy 2015 Initiative –hospital pharmacy practice indicators

Health-system Pharmacy 2015 is ASHP’s landmark initiative to significantly improve the practice of pharmacy in health systems. The project includes six key goals and 31 objectives to be achieved by the year 2015, evolved from the "ASHP Vision Statement for Pharmacy Practice in Hospitals and Health Systems." The principal themes in the statement (and therefore in the goals and objectives) are that health-system pharmacists will help make medication use more effective, scientific, and safe and will contribute meaningfully to public health in their communities.

Goal 1	Increase the extent to which pharmacists help individual hospital inpatients achieve the best use of medications.
Goal 2	Increase the extent to which health-system pharmacists help individual non-hospitalized patients achieve the best use of medications.
Goal 3	Increase the extent to which health-system pharmacists actively apply evidence-based methods to the improvement of medication therapy.
Goal 4	Increase the extent to which pharmacy departments in health systems have a significant role in improving the safety of medication use.
Goal 5	Increase the extent to which health systems apply technology effectively to improve the safety of medication use.
Goal 6	Increase the extent to which pharmacy departments in health systems engage in public health initiatives on behalf of their communities.

Example of qualitative monitoring of progress for Goal 1:

Goal 1	Increase the extent to which pharmacists help individual hospital inpatients achieve the best use of medications.
Objective 1.1	Pharmacists will be involved in managing the acquisition, upon admission, of medication histories for a majority of hospital inpatients with complex and high-risk medication regimens* in 75% of hospitals.
Objective 1.2	The medication therapy of a majority of hospital inpatients with complex and high-risk medication regimens will be monitored* by a pharmacist in 100% of hospitals.
Objective 1.3	In 90% of hospitals, pharmacists will manage medication therapy for inpatients with complex and high-risk medication regimens*, in collaboration with other members of the health-care team.
Objective 1.4	Hospital inpatients discharged with complex and high-risk medication regimens* will receive discharge medication counseling managed by a pharmacist in 75% of hospitals.
Objective 1.5	50% of recently hospitalized patients (or their caregivers*) will recall speaking with a pharmacist while in the hospital.
Objective 1.6	In 90% of hospitals, pharmacists will ensure that effective medication reconciliation* occurs during transitions across the continuum of care.

For more information on the objective indicators for each goal, please visit: <http://www.ashp.org/2015>

Strengthening the legal foundations for pharmacy practice: national drug policies and others

Introduction

The 2008 UN report Delivering on the Global Partnerships for Achieving the Millennium Development Goals highlights the existence of large gaps in the availability of medicines in both the public and private sectors, as well as a wide variation in prices which render essential medicines unaffordable to poor people (44). The report also highlighted that generic substitution by pharmacists is a key policy for ensuring access to affordable essential medicines which should be adopted by more countries.

New World Health Organization (WHO) estimates show that public sector availability of essential medicines covers only one third of needs, while private sector availability covers about two thirds. (45)

Even people who have access to drugs may not receive the right medicine in the right dosage when they need it. Many people buy, or are prescribed and dispensed, drugs that are not appropriate for their needs. Some use several drugs when one would do. Others use drugs that carry unnecessary risks. In the recent progress report on the rational use of medicines presented at the 60th World Health Assembly in 2007, WHO data show that, at the primary health-care level in Africa, Asia and Latin America, only about 40% of all patients were treated in accordance with clinical guidelines for many common conditions, and that there has been no improvement over the past 15 years (46). In May 2007, WHO Member States subsequently passed a resolution WHA60.16 on rational use of medicines, calling for the following actions, among many others:

Box reference 17: Extracts from the WHA 60.16 resolution on rational use of medicines

“1. Urges Member States:

- to consider establishing and/or strengthening, as appropriate, a national drug regulatory authority and a full national programme and/or multidisciplinary body, involving civil society and professional bodies, to monitor and promote the rational use of medicine;
- to develop and strengthen existing training programmes on rational use of medicines and ensure that they are taken into account in the curricula for all health professionals and medical students, including their continuing education, where appropriate, and to promote programmes of public education in rational use of medicines;
- to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, non promotional information about medicines;
- to develop and implement national policies and programmes to improve medicine use, including clinical guidelines and essential medicines lists, as appropriate, with an emphasis on multifaceted interventions targeting both the public and private health systems, and involving providers and consumers; to consider developing, and strengthening where appropriate, the capacity of hospital drug and therapeutic committees to promote the rational use of medicines;”

These are important global callings for the pharmacy profession to have an impact on the rational use of medicines at national levels. More importantly, these can form fundamental principles for establishing

good pharmacy practice standards within the context of a national drug policy (37) in achieving better access (*equitable availability and affordability of essential drugs*), quality (*safety, efficacy and quality of all medicines*) and rational use (*the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers*) of medicines.

Strengthening the legal foundation for pharmacy

In some countries, Good Pharmacy Practice guidelines are an essential component of the national drug/medicines policy. One of the reasons is that pharmacists, pharmacy assistants and prescribing nurses are in a good position to promote the rational use of drugs, and their roles should receive increased attention. In developing countries, the training and supervision of pharmacists, pharmacy technicians and assistants should be emphasized. The appropriate skills and training needs must be identified first (47). National pharmacy associations should therefore be engaged with their governments on developing, updating and implementing a national drug policy, where appropriate.

Box reference 18: Pharmacy practice and the law (48) (49)

Pharmacy laws describe for pharmacists the basic requirements of day-to-day practice. Pharmacy laws also define the relationship pharmacists have with the public they serve. As health professionals, pharmacists are highly regulated because the slightest misstep in drug distribution or pharmaceutical care could cost a life. As custodians of the nation's drug supply, pharmacists are subjected to extensive regulation because the products pharmacists control are held to the most exacting standards of any consumer product. Pharmacists study the law because through the law society has described what is considered acceptable conduct for pharmacists and pharmacists who fail to meet this level of acceptability will be held accountable for their failure.

Further reading:

Abood, Richard. *Pharmacy Practice and The Law, Fifth Edition*. US : Jones & Bartlett, 2008. ISBN 0763749788.

Pharmacists, pharmaceuticals, and policy issues shaping the work force in pharmacy. Manasse HR Jr, Speedie MK. 12, 2007, Am J Health Syst Pharm, Vol. 64, pp. e30-48.

Box reference 19: Key policy issues relevant to pharmacists in the national drug policy making process (47)

- Throughout the drug policy process (and not only in the development phase) there will be consultation, dialogue and negotiations with all interested groups and stakeholders. These include other ministries (higher education, trade, and industry), doctors, pharmacists and nurses, local and international pharmaceutical industries, drug sellers, academia, nongovernmental organizations (NGOs), professional associations and consumer groups.
- National institutions, such as the drug regulatory agency, the pharmacy department in the ministry of health, the central medical stores, and district or provincial health offices, are key players in drug policy implementation.
- Legislation and regulations ensure that the responsibilities, qualifications, rights and roles of each party are defined and recognized (including those of medical practitioners, pharmacists and the drug regulatory authority).
- Pharmaceutical legislation is mostly concerned with ensuring that effective and safe drugs of good quality are made available, and that correct information is provided about them. These tasks are covered in drug laws, pharmacy acts and drug regulations.
- The process by which drugs are selected is critical. A standing committee should be appointed to give technical advice. This committee should include people from different fields, such as medicine, nursing, clinical pharmacology, pharmacy, public health, consumer affairs as well as health workers at grass-roots level.
- There is a need to engage the private sector. In most countries the majority of the population is serviced by private-sector drug supply systems, which include private wholesalers, distributors, pharmacists and informal drug sellers.
- Improving the basic training of health professionals is an important strategy for achieving rational drug use. The essential drugs concept and its practical application should be included in the curriculum of all health workers.
- In countries where there is a shortage of trained pharmacists and pharmacy assistants, prescription drugs are sold by drug sellers with no formal qualifications or training. Basic in-service training could be provided to them. Practical training based on checklists and simple written information can help them to do their job well and to communicate effectively with patients.
- The combination of prescribing and dispensing functions in one professional usually leads to overprescribing, as there is a financial incentive to sell more or more expensive drugs. It is therefore recommended that these two functions are separated as much as possible, except in rural areas where there is insufficient market for separate pharmacies.
- The government could consider regulatory measures to separate prescribing and dispensing functions, in order to remove a perverse incentive. For example, both dispensing doctors and prescribing pharmacists have a tendency to overprescribe.
- Generic policies, pricing policies and the dispensing fee structure could be used to encourage the use of essential drugs and promote generic prescribing and substitution.
- Development and implementation of a drug policy require highly qualified and experienced professionals, including policy-makers, doctors, pharmacists, pharmacy technicians, clinical pharmacologists, paramedical staff, economists and researchers.
- Pharmacists, pharmacy assistants and prescribing nurses are also in a good position to promote the rational use of drugs, and their roles should receive increased attention. In developing countries, the training and supervision of pharmacists, pharmacy technicians and assistants should be emphasized. The appropriate skills and training needs must be identified first.

Core principles of a pharmacy practice quality management framework

Introduction

In the previous section on setting standards of good pharmacy practice, the general goals of the pharmacy services or activities are described. To be sure that these goals are achieved, there is a need to standardize the production of the services or activities. The standardization guarantees that the outcomes of the processes by which the desired services are produced in pharmacies are the wanted ones and that their quality is on the right level so that the needs of the customers can be met.

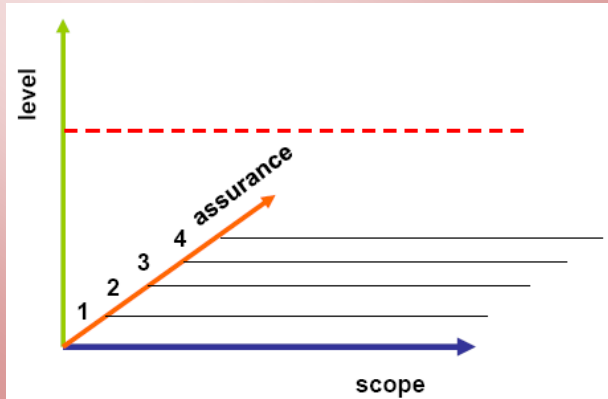
The “customer” in this context can be either the patient in a pharmacy or an institutional customer like society or an organization. As pharmaceutical services usually are organized on a national basis the analysis of the customer needs has to be made on the same level and the quality requirements on producing these services has to be set on the national level, too. There are some universal services for the whole pharmaceutical profession (like dispensing) but the level of the service production varies in different circumstances.

Usually the national legislation concerning the pharmacy profession and pharmacies gives some kind of minimum description of the pharmacy services. However, the legislation seldom gives any precise instructions about how the services should be produced to meet the requirements. For this the national pharmaceutical organizations have to build a quality management system for pharmacy use and have a strategic plan about the service development.

Needs assessment

The needs of the customers are different in different cultures and countries and the health care systems are built in different ways. The expectations concerning pharmacy services are different, too. Thus a needs assessment has to be made as the first task when starting the work with national standards and quality management systems. What is the role of pharmacists in drug supply, adherence, health promotion etc.? How could we develop the service production and raise the quality? Based on the needs assessment the national organizations and pharmacies can select the services which are provided and the appropriate level of the service. This can be described with the following diagram:

Box reference 20: Needs assessment framework



According to the Needs Assessment Framework (see Box Reference 18), the national pharmaceutical organizations have to define what are the elements of the pharmacy practice in the country, which quality levels may be achieved in every element and which level of quality assurance is required for every element. On these decisions the necessary standards and the system to manage the desired quality can be built.

Quality management systems

Quality management systems and standards like the ISO 9000 series and Total Quality Management (TQM) models have been developed to make the quality standards global. The ISO standards⁴ were originally developed for industrial production but they are today suitable for standardising service production, too.

Concerning standards of quality for pharmacy services it is recommended that the national organizations should use the international standards and adapt them to the local pharmacy environment.

An approach to developing and implementing a quality management system consists of several steps including the following:

1. Determining the needs and expectations of customers and other interested parties
2. Establishing the quality policy and quality objectives of the organizations
3. Determining the processes and responsibilities necessary to attain the quality objectives
4. Determining and providing the resources necessary to attain the quality objectives
5. Establishing methods to measure the effectiveness and efficiency of each process

⁴ The basic references are the standard ISO 9001-2000 "Quality management systems. Requirements" and the standard ISO 9000 "Quality management systems – fundamentals and vocabulary", together with the International Workshop Agreement IWA1, "Quality management systems – guidelines for process improvements in health service organizations".

6. Applying these measures to determine the effectiveness and efficiency of each process
7. Determining means of preventing nonconformities and eliminating their causes
8. Establishing and applying a process for continual improvement of the quality management system

Box reference 21: Certification of pharmaceutical services

In some countries, such as Portugal, there is increasing interest in the “certification of pharmaceutical services” rather than the certification according to the ISO 9000 series. The certification of services involves certifying that a certain service is rendered according to the specifications described in a Service Norm or Technical Specification (<http://www.sgs.com/>). In fact, while the ISO 9001 Certification is a certification of “means” applied to the organizational structure of the pharmacy, service certification is the certification of a certain service rendered/provided by the pharmacist/pharmacy to the patient/client. It is possible for the professional association to develop this using the “multi site” model, which is used by multinationals and franchising groups. It allows centralizing some processes in a unique central organizational structure, which takes care, for instance, of processes such as treating complaints, implementing corrective/preventive actions, managing the continuing education – allowing pharmacies, which sometimes have a very limited number of professionals to take care of the operational management of processes.

Quality management principles

In ISO-standards there are eight quality management principles. In this document they are briefly described as follows:

1. Customer focus

Pharmacies and pharmacists depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customers' expectations

2. Leadership

Pharmacy leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which the staff can become fully involved in achieving the organizations objectives.

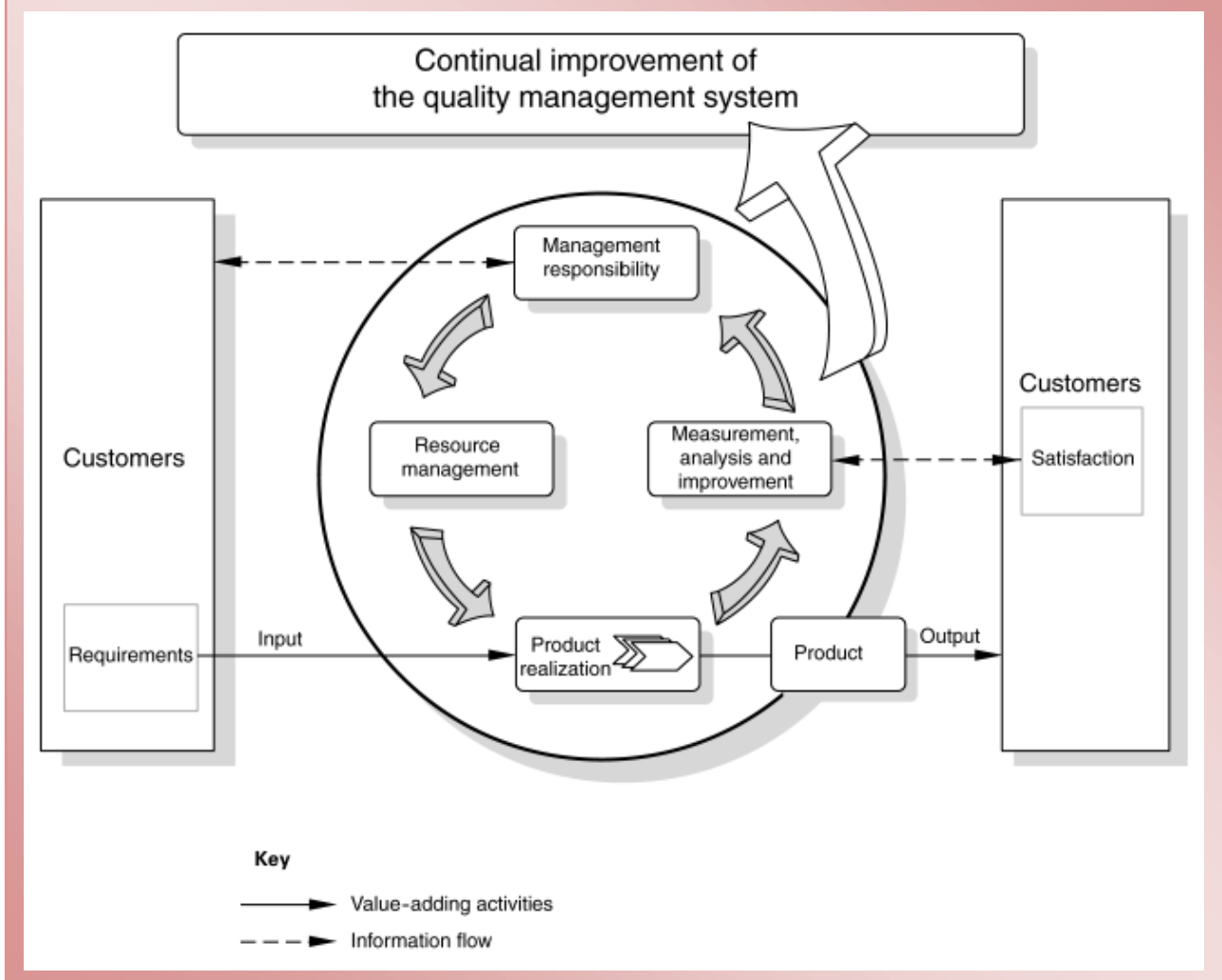
3. Involvement of staff

Staff in all levels is the essence of a pharmacy and their full involvement enables their abilities to be used for the pharmacy and professional benefit.

4. Process approach

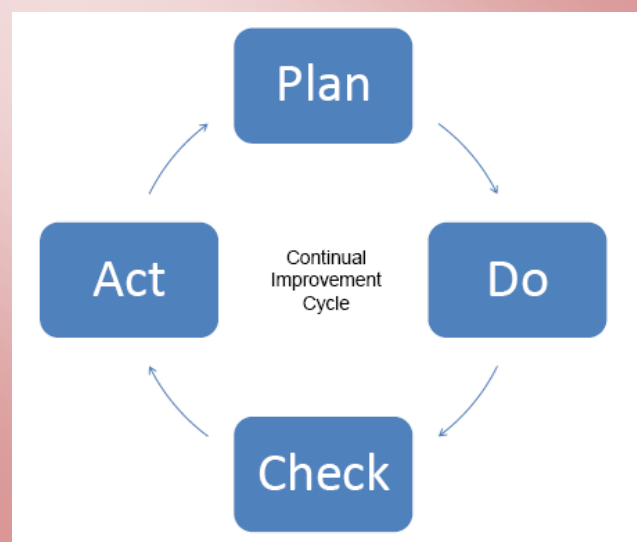
All the activities in the pharmacies can be described as processes. In these processes resources are used to transform inputs to outputs. There are two types of processes: main processes and supporting processes.

Box reference 22: Model of a process-based management system (50)



The main processes in a pharmacy setting may be “flow of materials” and “flow of information” and “health promotion”. A typical supporting process is cleaning or personnel management. The processes and the requirements for the process outcomes should be determined and evaluated regularly. In every process the Deming method “Plan-Do-Check-Act” should be used to guarantee the continuous follow up and development of the process.

Box reference 23: Deming's Plan-Do-Check-Act Cycle



5. System approach to management

Identifying, understanding and managing inter-related processes as a system contributes to the effectiveness and efficiency of a pharmacy in achieving its objectives.

6. Continual improvement

Continual improvement of the overall performance of pharmacies should be a permanent objective of the quality system.

7. Factual approach to decision making

Effective decisions are based on the analysis of data and information. The quality system has to be built so that it is producing reliable and up-to-date information about the processes and their outcomes on continuous basis.

8. Mutually beneficial supplier relationships

Pharmacies and their suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value. The relationships to the supply chain and to the health care team are of utmost importance and should be based on mutual respect and professionalism.

Appendix 1: Information on 37 national GPP standards

Country	Argentina
Dated	30/04/2008
Contact	Jose Ruggieri
Email	joseruggieri@cofa.org.ar
Source	National association in Argentina
Weblinks	www.cofa.org.ar
Summary of data available	There are three GPP documents from Argentina. Two of them regard good dispensing practice and good practices for the manufacture/preparation of medicines in community and hospital pharmacies, which will be included in the next version of the Argentinean Pharmacopoeia. These two documents were elaborated jointly by the national pharmaceutical organisation and the MoH. The third document is the guidelines for hospital pharmacy. They are currently working with the MoH in revising the current standards and creating pharmacies in all healthcare centres with in-patients

Country	Australia
Dated	04/05/2009
Contact	Kay Sorimachi
Email	kay.sorimachi@psa.org.au
Source	Pharmaceutical Society of Australia
Weblinks	http://www.psa.org.au/
Summary of data available	Competency Standards for Pharmacists in Australia 2003 – accessible at www.psa.org.au/site.php?id=1123 Professional Practice Standards 2006 – accessible at www.psa.org.au/site.php?id=1094

Country	Austria
Dated	30/04/2008
Contact	Sabine Horak-Harzhauser
Email	Sabine.Horak-Harzhauser@apotheke.or.at
Source	Österreichische Apothekerkammer
Weblinks	www.apotheke.or.at
Summary of data available	<p>Firstly national standards on Good Pharmacy Practice are in general regulated in the Austrian Regulation on the operation of pharmacies 2005 (“Apothekenbetriebsordnung 2005”), which is binding law in Austria. According to the fact, that pharmacies are responsible for the supply of pharmaceutical and medicinal products, the production and distribution of drugs and their storage and administration . All these functions are regulated.</p> <p>Because pharmacies also provide comprehensive customer counsel on general health issues, the Regulation on the operation of pharmacies 2005 secondly sets standards for pharmacists working in pharmacies and for the pharmaceutical care. The obligations of confidentiality, avoidance of incompatibilities as well as the obligation of continuing education are set national (minimum) standards. For further information the Regulation is enclosed. Unfortunately there is no English version available.</p> <p>Thirdly there exist guidelines on sales promotions and advertisements made by pharmacies. The national standards can be found on our website www.apotheke.or.at -> Themenbereiche -> Information der Rechtsabteilung -> Apothekerberufssitte as well as in the relevant law such as the Austrian Chamber of Pharmacists Act and Medicinal Products Acts.</p> <p>There is a disciplinary committee established at the Austrian Chamber of Pharmacists which observes these standards.</p>

Country	Bosnia and Herzegovina
Dated	15/04/2008
Contact	Sanja Stjepanovic
Email	sinapsa@bih.net.ba
Source	Pharmaceutical Association of FB&H
Weblinks	
Summary of data available	There is an electronic version of GPP booklet. "Professional Targets on Good Pharmacy practice for Bosnia and Herzegovina" which has established national standards for pharmacists working in community and hospital pharmacies. It was adopted at country level in 1999 by members of 3 existing national associations in Bosnia and Herzegovina. B&H Law on Health care states that pharmacists are obliged to work in accordance with GPP Standards.

Country	Brazil
Dated	15/04/2008
Contact	Jaldo de Souza Santos
Email	wanilda@cff.org.br
Source	National association in Brazil (CFF)
Weblinks	
Summary of data available	Reference to a national resolution (law) 357, the national association has established national standards for GPP. Last revised 20th April 2001. Only available in Portuguese

Country	Canada
Dated	17/04/2008
Contact	Barbara Scollick
Email	scollick@gmail.com
Source	Canadian Pharmacists Association/NAPRA
Weblinks	www.napra.org
Summary of data available	The Canadian Pharmacists Association (CPhA) is a national professional voluntary association and as such we do not develop standards of practice; however, the National Association of Pharmacy Regulatory Authorities (NAPRA) develops standards for pharmacists in Canada. NAPRA's website with some of standards is http://napra.org/docs/0/95.asp and you may wish to contact them for further information. Some of their documents you may be interested in are: Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice Guidelines to Pharmacy Compounding - October 2006 Supplemental Standards of Practice for Schedule II and III Drugs - June 2005 Model Standards of Practice for Canadian Pharmacists - April 2003

Country	Costa Rica
Dated	10/05/2008
Contact	María Lorena Quirós Luque
Email	direccionejecutiva@colfar.com
Source	National association in Costa Rica (COLEGIO DE FARMACEUTICOS)
Weblinks	www.colfar.com
Summary of data available	

Country	Croatia
Dated	22/04/2008
Contact	Maja Jakševac Mikša
Email	maja.jaksevac-miksa@zg.t-com.hr
Source	Croatian Pharmaceutical Society
Weblinks	
Summary of data available	The GPP guidelines are very old (from 1997) and they have only a printed version. It was issued by Croatian Chamber of Pharmacists and printed by Croatian Pharmaceutical Society as a supplement to our professional journal Farmaceutski glasnik (vol. 53, 7/8 1997). They intend to create a new version soon, after the revision of the Ethical Code which is in the course of preparation.

Country	Cuba
Dated	26/04/2008
Contact	Eneida Pérez Santana
Email	farma@hha.sld.cu
Source	Sociedad Cubana de Ciencias Farmacéuticas
Weblinks	
Summary of data available	The GPP guidelines are only available in Spanish. There is one specific to community pharmacy (revised 2005) and one specific to hospital pharmacy

Country	Czech Republic
Dated	29/04/2008
Contact	Stanislav Havlíček
Email	havlicek@lekarnici.cz
Source	Czech Chamber of Pharmacists
Weblinks	www.lekarnici.cz
Summary of data available	Czech Chamber of Pharmacists has new leadership since November 2007. We established a working group for standardization. This group is working on those standards right now. We hope we will finish it end of this year. Last year we just finished algorithm design (guidelines) for dispensing each pharmacotherapeutic group. Unfortunately those materials are only in Czech language

Country	Denmark
Dated	29/04/2008
Contact	Peter Jørgensen
Email	pj@apotekerforeningen.dk
Source	Association of Danish Pharmacies
Weblinks	
Summary of data available	<p>The philosophy of the FIP guidelines for Good Pharmacy Practice (GPP) has for a number of years been a central part of and implemented in the Danish legislation for the pharmacies (Pharmacy Act) and the drug legislation (Medicines Act). Therefore all in all most elements in the FIP guidelines for GPP are part of the daily work in Danish pharmacies. Let me give some examples:</p> <p>According to the Danish legislation for pharmacies and the drug legislation there are standards for:</p> <ul style="list-style-type: none"> * quality of prescribing data provided to the pharmacist * the preparation of formularies on medicines * educational programs for health professionals * confidentiality of data relating to individual patients * reporting of adverse events, medications errors, defects in products quality and diction of counterfeit products * manufacture of medicines * preparation and quality assurance of extemporaneous preparations * sources of supply of medicines and other items * disposal of unused pharmaceutical products and pharmaceutical waste * medication records <p>Furthermore the Association of Danish Pharmacies in 2006 approved an overall strategy for community pharmacies in Denmark with 3 visions: A professional, a customer-oriented and an ethical vision. The vision about professional competence is realised by pharmacists by</p> <ul style="list-style-type: none"> * always uncovering the need of the individual customer for counselling and information, * taking joint responsibility for the customer's drug treatment and patient safety, * offering a relevant selection of health promoting and disease preventing services and * cooperating with other actors in the health care sector. <p>Finally I would like to inform you briefly about our work in the Nordic Pharmacy Association where we together with our colleagues from Finland, Norway and Sweden have adopted several sets of professional "Guidelines for Pharmacies in the Nordic Countries" on patient safety, on medicines profiles and on information and counseling. These guidelines are to a large extent inspired by GPP and are even structured in the same way (society, patients, processes and staff)</p>

Country	Dominican Republic
Dated	01/05/2008
Contact	Lourdes Valenzuela
Email	lourdesvalenzuela_mateo@hotmail.com
Source	Pharmaceutical Association of the Dominican Republic
Weblinks	
Summary of data available	<p>In brief, there are regulations for hospital pharmacy and community pharmacy. In our country, the field of practice that is best organised is hospital pharmacy, since it has had its own professional society for a number of years. As for community pharmacy, the situation is a complete disaster: according to a study by the Ministry of Health and PAHO from 2005, 50% of community pharmacies in our country are illegal and this figure has not changed since then. Naturally, this causes a very bad impression on patients/users since medicines are not dispensed by competent professionals.</p> <p>Received attached the regulations in force, under the General Law on Healthcare, Law 42-01, regulation 246-06.</p>

Country	Eritrea
Dated	05/05/2008
Contact	Samuel Girmay
Email	gsamu4@yahoo.com
Source	Eritrea pharmaceutical association
Weblinks	
Summary of data available	Currently we don't have a separate document on Good Pharmacy Practice in our country Eritrea. But we do have other documents which we use as a guideline to practice our pharmaceutical services. Such documents include National Medicines Policy, guideline for Good Manufacturing Practice (GMP) and Logistic Management Manual. Please find attached the document for the National Medicines Policy; I think that is the most important one.

Country	Finland
Dated	30/04/2008
Contact	Ingrid Wiberg
Email	ingrid.wiberg@apteekkariliitto.fi
Source	Suomen Apteekkariliitto - The Association of Finnish Pharmacies
Weblinks	
Summary of data available	I submit The Ethical Guidelines as drawn up by The Association of Finnish Pharmacies and thus guiding the functions and work in the privately owned community pharmacies in Finland. The committee on pharmaceutical affairs at The Association of Finnish Pharmacies meets at the end of May, there we will discuss this matter further and after that submit our guidelines/strategies on: The Pharmacy and Health Promotion, Guidelines for a Professional Community Pharmacy in Finland and The Community Pharmacy – Expert on Health Care. These standards however are at the moment not available as electronic files.

Country	France
Dated	29/04/2008
Contact	Florence PETIT
Email	dap@ordre.pharmacien.fr
Source	Ordre national des Pharmaciens
Weblinks	www.ordre.pharmacien.fr
Summary of data available	<p>Further to your request for national standards for Good Pharmacy Practice, I am pleased to send you enclosed relevant documents and link on that topic:</p> <p>For hospital or community pharmacists: Bonnes pratiques de préparations</p> <p>For community pharmacists : Guide d'assurance qualité officinale http://www.ordre.pharmacien.fr/upload/Syntheses/90.pdf</p> <p>website EQO http://www.eqo.fr/accueil</p> <p>Guide de stage de pratique professionnelle en officine - Pharmacie générale - Officine - 6ème année http://www.ordre.pharmacien.fr/upload/Guidestage/guide-stage-6eme-annee.pdf</p> <p>Recommandations pour l'aménagement des locaux de l'officine http://www.ordre.pharmacien.fr/upload/Syntheses/219.pdf</p> <p>Information relative aux prix des médicaments http://www.ordre.pharmacien.fr/upload/Syntheses/151.pdf</p> <p>For hospital pharmacists: Bonnes pratiques de pharmacie hospitalière</p> <p>« Guide de pratiques professionnelles sur la prise en charge thérapeutique du patient hospitalisé : le circuit du médicament » élaboré sous l'égide de la DHOS (2004) et consultable à l'adresse : http://www.sante.gouv.fr/htm/dossiers/secumed/accueil.htm (mot de passe : dhosecumed1).</p> <p>Guide méthodologique rédigé par le SYNPREFH « sécurisation du circuit du médicament », version n° 2 de mai 2006 disponible sur le site du SYNPREFH à l'adresse : http://www.synprefh.org/documents/circmed_guide_synprefh_200605.pdf</p> <p>Le livre blanc "Pharmacie Hospitalière - Horizon 2012" édité par le SYNPREFH ne sera disponible qu'après le 22 mai 2008.</p> <p>Recommandations de bonnes pratiques appliquées au transport des produits de santé http://www.ordre.pharmacien.fr/upload/Syntheses/277.pdf</p> <p>Recommandations relatives aux bonnes pratiques de gestion des produits de santé soumis à la chaîne du froid entre 2 et 8° C http://www.ordre.pharmacien.fr/upload/Syntheses/216.pdf</p>

Country	Germany
Dated	28/04/2008
Contact	Christiane Eckert-Lill
Email	C.Eckert-Lill@abda.aponet.de
Source	ABDA
Weblinks	
Summary of data available	<p>The Ordinance on the Operation of Pharmacies (Apothekenbetriebsordnung), which is a federal ordinance, gives general standards on Good Pharmacy Practice, for example</p> <ul style="list-style-type: none"> – state, size and equipment of pharmacy premises – qualification and competences of the personnel – information sources – preparation and quality assurance of extemporaneous preparations resp. Drugs kept in stock in larger quantities – stockpiling – storage – delivery of drugs – information and advice – pharmaceutical risks and handling of non-marketable drugs – documentation – stand by duty <p>The Federal Chamber of Pharmacists has edited 18 Guidelines on Quality Assurance (including comments and SOP referring to the main topics</p> <ul style="list-style-type: none"> – information and advice, – pharmaceutical care, – preparation and quality assurance of drugs, – diagnostic testing. <p>They are recommendations and shall help to establish a quality assurance system focusing on pharmaceutical services. But they can be used in pharmacies without quality assurance system as well. The Guidelines on Quality Assurance and other relevant information are available on the website www.abda.de/bak_leitlinien.html</p>

Country	Ireland
Dated	30/04/2008
Contact	Damnait Gaughan
Email	Damnait.Gaughan@pharmaceuticalsociety.ie
Source	Senior inspector for the Ireland pharmaceutical Society
Weblinks	
Summary of data available	<p>The regulation of the practice and profession of pharmacy in this jurisdiction is undergoing a period of significant change. The legislative framework was significantly updated with the commencement of the Pharmacy Act 2007, and this provides for a more robust regulatory environment. This will necessitate and has instigated the commencement of work in the area of standards. I would refer you to www.pharmaceuticalsociety.ie where you will find under the Standards heading documentation which you may find of interest, specifically</p> <p>http://pharmaceuticalsociety.ie/Standards/upload/File/Standards%20Guidelines,%20FINAL.pdf and</p> <p>http://pharmaceuticalsociety.ie/Standards/upload/File/CodesOfEthics&Practice_01.05.doc</p>

Country	Israel
Dated	12/04/2008
Contact	Howard Rice
Email	howard@zahav.net.il
Source	National association in Israel
Weblinks	
Summary of data available	<p>Whilst our national organization has not implemented these guidelines, it is now a mandatory demand of the Ministry of Health for pharmacists to adopt the GPP standards as set out by FIP/WHO. These demands are particularly the case with preparation of medications (extemporaneous), labelling and recording. Physicians can only write prescription by computer or type writer or if not only in capital letters- to avoid mistakes. There is also a statutory requirement for all new pharmacies or those that undergo "shop fitting" renovations, that a consultation room be included. Whilst the amount of consultations is increasing rapidly in pharmacies, it has not reached 100% and it is difficult to inspect this.</p> <p>The national GPP document is in Hebrew and are available on the Ministry of Health website http://www.health.gov.il/forms/forms.asp?Category_Id=2&Element_type_id=2</p>
Country	
Country	Italy
Dated	24/04/2008
Contact	Giuseppe IMPELLIZZERI
Email	box@federfarma.it
Source	Federfarma
Weblinks	
Summary of data available	<p>Our Federation after the approval of GPP guidelines by FIP and consequently by PGEU, decided to set up a Quality Charter of our pharmaceutical services in 1994, where we began to ask to our members (only community pharmacists) to engage themselves in offering tailored services to their patients taking into account the model of pharmaceutical care.</p> <p>Other relevant points in our Charter concern the promotion of health, the help offered to patients in their self-care activity, the accurate control of the prescription, the continuous contact with the prescriber and so on.</p>
Country	
Country	Jordan
Dated	22/04/2008
Contact	Samira Goussous
Email	s_goussous@ads.com.jo
Source	Jordan pharmaceutical association
Weblinks	
Summary of data available	<p>The text is in Arabic it includes all the information and definition of GPP and the pharmaceutical care, Code of ethics etc</p>

Country	Republic of Macedonia
Dated	22/04/2008
Contact	Maja
Email	info@farmacevtskakomora.com
Source	Pharmaceutical Chamber of Macedonia
Weblinks	
Summary of data available	<p>The Republic of Macedonia hasn't yet established national standards for pharmacists working in community and pharmacy settings.</p> <p>The new Law of medicines and medical devices (2007) defines the necessity of establishment and implementation of such standards. Further more, the endorsed HEALTH STRATEGY OF THE REPUBLIC OF MACEDONIA, 2020, SAFE, EFFICIENT AND JUST HEALTH CARE SYSTEM, by the Government of RM, contains the whole chapter, explaining the pharmaceutical care and priorities for implementation. Therefore, a committee is formed by the Minister of Health, to set up these standards, and Pharmaceutical Chamber of Macedonia is actively involved in all the activities. Currently the Pharmaceutical Chamber of Macedonia runs a project sponsored by the World Bank, as training workshops, regarding these issues - promotion of GPP, health, patient self care, pharmaceutical care, improving prescribing and medicine use by pharmacist's activities. FIPs "GPP in developing countries" document is used as one of the reference materials.</p>
Country	Mongolia
Dated	29/04/2008
Contact	D.Dungerdorj
Email	dungerdorj@hsum.edu.mn
Source	Mongolian pharmaceutical association
Weblinks	
Summary of data available	<p>Mongolian Pharmaceutical Practice is using the Mongolian National Standards (MNS), which are based on the FIP/WHO GPP guidelines:</p> <ol style="list-style-type: none"> 1. Good Manufacturing Practices for pharmaceutical products – MNS 5524: 2005 (Mongolian GMP) (Since November 10, 2005). 2. General Principles for drug procurement organizations – MNS 5530: 2005 (Since December 01, 2005). 3. General Principles for Pharmacy – MNS 5260: 2006 (since January 10, 2007). <p>These National Standards not translated in English, so we could not send you above mentioned MNS copies.</p>

Country	The Netherlands
Dated	24/10/2008
Contact	F. (Frans) J. van de Vaart
Email	f.j.van.de.vaart@winap.nl
Source	KNMP Scientific Institute
Weblinks	www.knmp.nl
Summary of data available	<p>The quality care system in The Netherlands is based on the scheme of the Council for Quality Assessment in Healthcare (HKZ for community pharmacies, version 2003), the ISO 9001:2000 standards and their requirements relating to pharmacies, the Dutch GPP 2006 and its related guidelines.</p> <p>The Dutch model is derived from the EFQM model (European Foundation for Quality Management). The development and utilisation of the INK-model is supported by The Dutch Institute for Quality (INK).</p> <p>The quality care system has 9 chapters and follows the division of the INK model as is outlined below:</p> <ol style="list-style-type: none"> 1) Leadership 2) Staff 3) Strategy and management 4) Means and cooperation 5) Processes 6) Value of the organisation of the pharmacy for the fellow-workers 7) Value of the organisation of the pharmacy for the patients 8) Value of the organisation of the pharmacy for society (caregivers, healthcare insurance companies, suppliers, socially acceptable enterprising). 9) Value of the organisation of the pharmacy for the owner(s)

Country	Norway
Dated	25/04/2008
Contact	Trygve Fjeldstad
Email	Trygve.fjeldstad@apotek.no
Source	The Norwegian Pharmacy Association
Weblinks	http://www.apotek.no/sw21108.asp
Summary of data available	<p>In Norway we have introduced national guidelines for Good Pharmacy Practice based on the FIP/WHO document.</p> <p>Our first step was to develop common Nordic guidelines for GPP for the four Nordic countries (Denmark, Norway, Sweden, Finland) (2001) Based on these common guidelines we implemented adjusted national guidelines for Norway (Standards for Pharmacy Practice.) (2003)</p> <p>Our national Norwegian guidelines define the core activities for pharmacies as:</p> <ul style="list-style-type: none"> - prescriptions and requisitions - self-care - rational prescribing and medicine use - promotion of health and prevention of ill-health. <p>Both a Norwegian and an English version of our national guidelines are available on our website www.apotek.no</p> <p>In Norwegian: http://www.apotek.no/sw27069.asp</p> <p>In English: http://www.apotek.no/sw21108.asp</p> <p>A printed version of both the Nordic and the Norwegian guidelines will be sent you by mail. These documents are in Norwegian.</p>

Country	Panama
Dated	02/05/2008
Contact	Telva
Email	telvan@hotmail.com
Source	Ex-President of the Panamian Pharmaceutical Association/ President of FFCC
Weblinks	
Summary of data available	

Country	Paraguay
Dated	05/05/2008
Contact	Secretariat AQUIMFARP
Email	fedqui@conexion.com.py
Source	Federación de Químicos del Paraguay
Weblinks	
Summary of data available	<p>The curriculum of the Faculty of Pharmacy includes elements of GPP through the following subjects: Pharmaceutical Technology, Pharmaceutical Legislation and Deontology, Quality Management in pharmacy related fields. Moreover, the SAIDI-Paraguay programme proposes to train and certify pharmacists on GPP.</p> <p>Also, the Paraguayan Pharmacists Association sent a proposal to the Ministry of Health and Welfare regarding the accreditation of pharmacists based on GPP. At a different level, we also organised training courses on Pharmaceutical Care in which the concepts of GPP were also introduced. GPP guidelines in Spanish</p>

Country	Philippines
Dated	02/05/2008
Contact	Normita D. Leyesa
Email	philpharm@surfshop.net.ph
Source	Philippine Pharmacists Association
Weblinks	
Summary of data available	Received national GPP standards for community and hospital pharmacy. Guidelines cover 8 areas (Ethical practice, Work environment, Procurement, Storage and warehousing, Compounding, Dispensing, Monitoring of use and Professional development)

Country	Portugal
Dated	18/04/2008
Contact	Joana Viveiro
Email	joanaviveiro@ordemfarmaceuticos.pt
Source	Ordem dos Farmacêuticos/ Portuguese Pharmaceutical Society
Weblinks	
Summary of data available	<p>The Portuguese Pharmaceutical Society published the Good Pharmacy Practice in Hospital Pharmacy and collaborated in the publication of the Good Pharmacy Practice in Community Pharmacy.</p> <p>Unfortunately we just have these GPPs in our mother language (Portuguese). There is an internet link for the Good Pharmacy Practice in Community Pharmacy: http://e-formacao.anf.pt/courses/BPFpt1106/Livro_Azul.pdf.</p>

Country	Republic of Srpska
Dated	29/04/2008
Contact	Rada Amidzic
Email	farmacia@teol.net
Source	Pharmaceutical Society of the Republic of Srpska
Weblinks	
Summary of data available	<p>The Pharmaceutical Society of the Republic of Srpska is a young association, it was formed in 1996. We have the national guidelines (Guide for Good Pharmacy Practice) which includes recommendations for: promotion of health, the supply of medicines, patient self care etc.</p> <p>This document was established in our country in 1999. 1st revision of this document was in March 2003. The sponsor of this project was WHO and Task Force. The members of our association who were educated then, have been training other members ever since.</p> <p>The Organization Task Force for GPP from Sarajevo does not exist anymore. This document is not available in electronic files.</p> <p>Now we are working on a new revision of the Guide for GPP. The main part of this Guide should be to include advice for patients in Pharmacies.</p>

Country	Serbia
Dated	29/04/2008
Contact	Dragana Sovtic
Email	pharmkom@verat.net
Source	Pharmaceutical chamber of Serbia
Weblinks	
Summary of data available	<p>Pharmaceutical chamber of Serbia finished the document for Good Pharmacy Practice in community and hospital pharmacy in January 2008. In March 2008 we sent this document to our Ministry of health, because they have jurisdiction in adopting this document. At present we are awaiting the answer and after that GPP will be an official document and after that we will send it to you.</p>

Country	Singapore
Dated	29/04/2008
Contact	Cheng Tiang NG
Email	ng.chengtiang@gmail.com
Source	Pharmaceutical society of Singapore
Weblinks	www.pss.org.sg
Summary of data available	<p>GPP guidelines published in 1997. Formerly known as the Guidelines on Good Dispensing Practice for Pharmacists, these guidelines have been revised and renamed Guidelines for Good Pharmacy Practice with additions on pharmaceutical care, sales of medicines, health promotion and relevant practice issues.</p>

Country	South Africa
Dated	18/04/2008
Contact	
Email	
Source	South African Pharmacy Council
Weblinks	http://www.pharmcouncil.co.za/documents/GPP%20in%20South%20Africa%20(2005).pdf
Summary of data available	GPP guidelines, second edition 2004

Country	Spain
Dated	21/04/2008
Contact	Consejo General de Farmacéuticos
Email	congral@redfarma.org
Source	Spanish pharmaceutical association
Weblinks	
Summary of data available	<p>The commitment to quality is one of the features that characterise the pharmaceutical profession. Therefore, one of the professional ideas set forth by the Spanish Pharmaceutical Organisation is the implementation of Quality Management Systems through the start up of the Complete Quality Plan by the General Council of Pharmacists of Spain (GCPS). In this way and through the corresponding National Pharmacy Departments, work is being carried out in the Pharmacy Office area for Clinical Analysis, Optical work and Hospital Pharmacy.</p> <p>In the community pharmacies field, the purpose of the Plan is to establish some basic parameters to be used in all the community pharmacies in Spain as a stamp of guarantee that allows the pharmacists to develop manage and provide some top quality pharmacy services that ensure top quality pharmaceutical care for the users of their community pharmacies.</p> <p>With this aim, a “Quality Standard for the Community Pharmacy” has been registered and coming soon it will be published, based on the UNE-EN-ISO 9001:2000 regulation and in which the all the legal and compulsory regulations, both from the State and from the Autonomous Communities on the subject of pharmacy are brought together, as well as the “Quality in Pharmacy” framework by the GCPS.</p> <p>Furthermore, documents complementing this regulation for the implementation of the QMS in the community pharmacies have been prepared, containing: A Quality Manual, describing the requirements established by the reference quality regulation. Operating procedures and Technical instructions, in which the processes characterising the pharmacy activity are described. Registers, which record how the functions defined in the procedures and instructions, have been performed.</p> <p>For the Implementation and Certification the community pharmacy may apply and adapt the documentary system offered, either using the help of a consultancy firm or not. Subsequently, in order to be able to obtain the “Quality in Pharmacy” trademark, the QMS implemented in the pharmacy office must be evaluated by the certifying body authorised by the GCPS, to ensure that it really fulfils the demands of the “Quality Standard for the Community Pharmacy”.</p> <p>The same methodology will be taken for the implementation of the QMS in the hospital pharmacy. Now, the General Council is working in the “Quality Standard for the Hospital Pharmacy”.</p>

Country	Sweden
Dated	29/04/09
Contact	Astrid Kågedal
Email	astrid.kagedal@apoteket.se
Source	Apoteket AB Sweden
Weblinks	
Summary of data available	<p>We have a Total Quality Management (TQM) concept where the Main processes, the Management processes and the Supportive processes are defined. The Main processes are . “Dispensing Prescriptions” and “Selling Non-Prescription Medicines”. The “main processes” are divided into “under processes” and the objective is that all customers should get high quality service every time at every pharmacy and most of the GPP concepts are taken care of. We also use the concept of Continuous Improvements. Staff members can go into the intranet and suggest improvements and then follow their suggestion to see how it is taken care of. The main processes have each a full time pharmacist in a central position with the objective to take care of suggestions and also be responsible for all kinds of development. When a change is decided the processes are changed and there is an implementation routine. The changes are of course communicated.</p> <p>The pharmacies in Sweden are inspected on a regular basis, reports are made from every inspection and a plan has to be elaborated on how to improve.</p>
Country	United Kingdom
Dated	18/04/2008
Contact	Yvonne Dennington
Email	yvonne.dennington@rpsgb.org
Source	The Royal Pharmaceutical Society of Great Britain
Weblinks	
Summary of data available	<ol style="list-style-type: none"> Code of Ethics for Pharmacists and Pharmacy Technicians http://www.rpsgb.org/pdfs/coeppt.pdf Professional Standards and Guidance Documents http://www.rpsgb.org/protectingthepublic/ethics/ Medicines, Ethics and Practice Document http://www.rpsgb.org/informationresources/downloadsocietypublications/#m
Country	Uruguay
Dated	11/04/2008
Contact	Marta Morkevicius
Email	marta.morkevicius@adinet.com.uy
Source	Pharmaceutical association in Uruguay
Weblinks	
Summary of data available	<p>In Uruguay we have established national standards that are available at our webpage www.aqfu.org.uy. “Buenas Prácticas de Farmacia”, some of them are in English: (1. Good dispensing practice 2. Pharmaceutical care 3. Self medication 4. Rational use of medicines)</p>

Country	Vietnam
Dated	21/04/2008
Contact	Xuan Hung
Email	xuanhung29@vnn.vn
Source	Vietnam pharmaceutical association
Weblinks	
Summary of data available	In Vietnam, based on the FIP-WHO guideline, 4 years ago we prepared a draft of GPP standards and published it for comments. In 24-1-2007, at last, the Guideline on GPP standards was approved by our Minister of Health. Until now near 100 pharmacies are accredited (received GPP certificates) by MOH.

Appendix 2: FIP Basel consultation on GPP

The following main key issues were discussed and expanded upon during the FIP expert consultation on standards in quality of pharmacy services, held during the 69th FIP Congress in Basel 2008.

Areas related to the GPP standards:

- There is a need to focus on self-care issues. Pharmacists helping people to use and comply with their medicines, whether prescription or non-prescription- “advising on use of medicines for best outcomes”.
- There is a need to incorporate aspects of leadership and management – encouraging mentoring and collaborating with colleagues
- There is a need to identify a framework that can be broken down in steps and where roles and responsibilities can be identified for each step of a process (e.g. from simple to complex levels).
- There is a need for clear indicators and measurements for both supply chain and clinical activities
- Monitoring the “right things.” Defining inappropriate indicators for standard setting or accreditation practice may skew practice inadvertently
- Challenge of measurement – defining outcomes for both major components of practice and establishing standards, indicators and measures can be a very challenging task
- Inter-professional collaborative practice in the health care team, incorporating concepts of practice such as “Comprehensive Pharmaceutical Care,” and “Medication Therapy Management Services (MTMS)” also known as Medicines Management.
- Antibiotic stewardship is a global concern. This relates closely to rational use of medicines.
- Managerial role of pharmacists, including skill sets relating to good leadership and mentorship, especially in the need for task-shifting in some settings
- Issues relating to information on drug pricing and access to medicines
- GPP standards need to address the availability of essential medicines
- There is a need to focus on the development of new technologies in pharmacy practice. With new technology there is a need to ensure quality control.

Discussion on using a step-wise approach for GPP implementation:

- Supported in general; however further work needs to be done to produce broad principles and standards first. More detailed, country specific guidelines or practical handbooks can then be used to assist in implementation. A proposal was made to break down the scope of pharmacy

service process into parts –ask the right Questions, give the right Advice and provide the right Treatment (QAT).

- May include aspirational goals that should be relevant to all (including developing countries) recognizing that not all of them will be achievable. Using a measurement tool to assess differences in ‘real life’ from ‘aspired practice’ should allow for organisations/practitioners to assess where they sit on the “evolutionary ladder” of implementing GPP.
- Given the spectrum across which different sizes and types of pharmacies, a “GPP grading system” does not need to be linear but can incorporate the scope, the level of quality and assurance of each component part of a pharmacy. The range and quality of pharmaceutical services may be very different but should be measurable.
- Should be formulated on evidence-based practice – research and experience from pilots – discussion about definition of evidence followed and need to incorporate/capture examples of good practice that are not traditional Randomized Control Trials (RCT)s .
- Global framework must be relevant to developing countries – and should aim to set aspirational standards for the profession globally – bearing in mind that one size will fit all
- GPP Quality management should look into setting scope of practice, levels of competence and assurance of quality services

Quality Assurance systems:

- Concerns with inclusion/implementation of ISO/American systems into pharmacies in Portugal (only 5% certified) and in Finland. There is a fear about setting standards too high and too far from pharmacy practice. A need for reality checks. Based on sound principles of GPP, developing countries need to adapt existing international standards to their specific needs and conditions of the region/country.
- Need to set up quality assurance as a step-wise process encouraging continuous improvement. Example basic level = there are pharmacists and medicines; next step = providing information; next step= having patient records available for clinical management ; finally, with a pro-active engagement of the pharmacist in managing treatment therapy
- The need to assure quality of pharmaceutical products throughout the distribution chain with particular attention to the current prevalence of substandard and counterfeit products in some national markets. This includes sales of medicines by persons who are not authorized.

Education and CPD:

- Quality of education and training both as initial practitioners and for continuing professional development should be included in guidelines.

- The roles, responsibilities and accountability of all key stakeholders, such as institutes, schools, pharmaceutical associations...etc need to be defined in the context of implementing an agreed framework of continuing professional development.
- Reinforce that there is a lack of training of interdisciplinary teams (e.g. physicians, nurses and pharmacists being educated and trained together)
- Need for curricular reform to close the gap for what we currently know to be competent in practice
- Requirement to re-train – need continuing professional development
- Strengthening the need for more comprehensive pharmaceutical workforce planning, especially in capacity building for education and training institutions for pharmacists, technicians and other pharmacy cadres. This may require a curricular reform of all levels of the workforce.

Implementation of GPP:

- Need for step-wise progression over time
- GPP Standard had the greatest impact when compared to other FIP documents in Portugal – 98% of pharmacies comply with GPP.
- Need to know about the difficulties faced in different countries and how these can be addressed. Example of difficulty faced is the lack of coordination between the different groups/agencies involved in provision of medicines – need to coordinate these agencies. Also need to recognize that although pharmacists give advice, many patients may not go through the standard system and do not receive advice. Need to think about how to manage and coordinate and relate to people at the country level.
- Need topic specific guidelines that are healthcare system specific. For example, GPP also require physicians and other medical personal to understand, respect and be involved in the process implementation of GPP, as part of their everyday work. National pharmaceutical associations need to collaborate with their counterparts in the medical associations and other health professions when implementing GPP.
- Setting measurable indicators for monitoring and evaluating the implementation of the guidelines. What is the role of the FIP member organizations and regional forums as key stakeholders?

Glossary

Term	Definition as used in this document only
National Standards	The standards, guidelines, recommendations and other pronouncements of professional organizations of pharmacy and in some countries, these are laws, regulations, standards, ordinances or other requirements enacted or promulgated by an official body at any level of government
Good Pharmacy Practice	The practice of pharmacy that responds to the needs of the people who use the pharmacists' services by providing optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines.
Pharmaceutical care	A patient centered practice in which the practitioner assumes responsibility for a patient's drug related needs and is held accountable for this commitment.
Medical product	For the purpose of this document, this includes, at least, medicines, medical devices and their accessories, active pharmaceutical ingredients and excipients which may be used in health care delivery, self-medication and/or clinical research, as defined in national legislation.
Pharmacists	Health care professionals whose professional responsibilities include seeking to ensure that people derive maximum therapeutic benefit from their treatments with medicines. This requires them to keep abreast of developments in pharmacy practice and the pharmaceutical sciences, professional standards requirements, the laws governing pharmacy and medicines and advances in knowledge and technology relating to use of medicines.
Qualified Pharmacy Technician/Dispensary Assistant	A person with formal dispensing training involved only in the dispensing of medicines. The training of this person would have taken place at a recognised training institution and a certificate or license would have been issued.
Unqualified Pharmacy Technician/Dispensary Assistant	A person who is involved in the dispensing of medicine, but who has only received "on the job" or "in house" training.
Community Health Care Worker	A person who is trained to provide simple, low level health care commensurate with the level of training
Continuous Quality Improvement	An internally driven management strategy and approach that aims to constantly improve quality by: identifying current and future desired outcomes; adopting relatively continuous assessments and evaluations of performance

	and achievement; identifying potential causes of quality defects; taking appropriate action to avoid or correct deficiencies; implementing process improvements and innovations; and evaluating the impact of all interventions.
Competence	The ability to perform one's duties accurately and confidently, make correct judgments, and interact appropriately with patients and with colleagues. Professional competence is characterized by good problem-solving and decision-making abilities, a strong knowledge base, and the ability to apply knowledge and experience to diverse patient-care situations.
Competencies	The knowledge, skills, behaviours and attitudes that an individual accumulates, develops, and acquires through education, training, and work experience.
Continuing Education	A structured process of education designed or intended to support the continuous development of pharmacists to maintain and enhance their professional competence.
Continuing Professional Development	The responsibility of individual pharmacists for systematic maintenance, development and broadening of knowledge, skills and attitudes, to ensure continuing competence as a professional throughout their careers
Scope of practice	The range of professional tasks and functions that a practitioner can perform as specified by legislation, rules, or regulations; the boundaries within which a practitioner may practice.

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