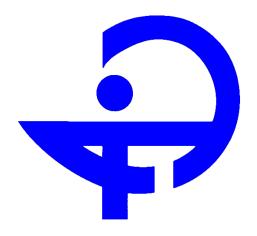
Quality Care Standards in Community Pharmacy



Community Pharmacy Section

International Pharmaceutical Federation

Quality Care Standards in Community Pharmacy

Report of a Working Group



Community Pharmacy Section

International Pharmaceutical Federation

Quality Care Standards in Community Pharmacy Report of a Working Group September 2005

Community Pharmacy Section International Pharmaceutical Federation

Secretariat:

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Foreword

From the days of the first apothecaries, the profession of pharmacy has worked to develop new products and new systems.

The International Pharmaceutical Federation (FIP) has always recognised the need for progress and, from its inception, has been actively involved in leading the way forward in many areas of practice.

In meeting the challenge of its Strategic Planning Objectives "To Raise Professional Standards", the Community Pharmacy Section decided, in 1999, to establish a Working Group "Quality Care Standards in Community Pharmacy Practice" with the stated aim of further developing guidelines which member organisations could use to assist in the development and implementation of their own Pharmacy Standards projects.

The Working Group first met in September 2000 and consisted of Frans van de Vaart from The Netherlands, Olivier Bugnon from Switzerland, Lilian Azzopardi from Malta, Greg Hodgson from Australia, Anita Martini from Sweden, and Bob Grant, an Australian Executive Committee member of the Community Pharmacy Section, acting as Chairman. The Working Group was later joined by Graham Bridge and Tim Logan from Australia and by Pia Ungvari from Sweden.

Each of the members of the group has been involved in their own countries in the Quality Standards area.

The Executive Committee of the Community Pharmacy Section wishes to acknowledge and thank the members of the Working Group for their participation and time so generously given, and to thank member organisations for their responses to our survey letter.

On the basis of the report the Executive Committee recommends that all member organisations embrace the adoption of a Quality Care Standards Programme by considering the recommendations made in this report. We hope the recommendations can be an inspiration for beginning, or continuing, the process.

Executive Committee of the Community Pharmacy Section September 2004

Avi Moshenson, President

Introduction

The Working Group was established with the aim to give recommendations for the development and implementation of Quality Care Standards for community pharmacy practice and to make them available for all FIP members. The ultimate aim was to improve the professional standards of pharmacy worldwide.

To commence the task, the Working Group discussed the elements, which would need to be examined, and the information, which would need to be gathered in order to make progress.

In looking at the elements involved we recognised:

- The need to have clarity in terminology with different quality systems in use
- The different pharmacy practice systems throughout the world
- Not to be prescriptive in developing a "one-size-fits-all" solution
- That there are many ways of practicing pharmacy in different economic and political systems.

We agreed that we would present a report outlining what we saw as the essential elements to be included in a system along with examples of other elements which could be included if desired or useful.

We decided to develop a questionnaire to be sent to FIP's member organisations of which 23 national organisations participated in the investigation.

In collecting data, the Working Group took into consideration:

- The purpose and the background for the development of standards
- To what extent the standards are being used
- Possible legislative backing for the standards
- The pharmacy system under which the standards are developed and used.

In September 2003 the Working Group presented an analysis of these responses to the Executive Committee as well as systems from Switzerland, Sweden and Australia were demonstrated.

I wish to thank my colleagues in the Working Group for the time and efforts they have brought to this important initiative from the Executive Committee of the Community Pharmacy Section of FIP.

September 2004

Bob Grant
Member, Executive Committee of

Member, Executive Committee of the Community Pharmacy Section of FIP 1996-2004

Quality Care Standards Analysis By Lilian Azzopardi

Quality in health care presents a range of interpretations including accreditation and certification, compliance with rules and regulations, meeting established levels, use of modern equipment, efficiency, and performing inspections. When taking into account a patient-oriented approach, quality of pharmacy services represents optimum patient care to meet patient's needs. So, structures and processes are necessary to measure the patient care provided and, therefore, measure quality.

These systems are presented in Quality Care Standards, the presentation of which could vary depending on the interpretation of a quality care standard.

Rationale

- Quality Care Standards confirm the effectiveness of the pharmacist intervention in patient care.
- Quality Care Standards present a process that will assist the pharmacy profession to gain confidence in the services it provides.
- Quality Care Standards can be used to demonstrate the good standard professional services provided by community pharmacists.
- Any process where there is no form of quality assessment may constitute a threat to society and to the profession. Quality Care Standards present processes which monitor professional pharmacy services.

Recommendations

- The profession is now in a position to implement the process of Quality Care Standards.
- Quality Care Standards should be developed by national pharmacy organisations so as to provide a system that reflects standards of professional services provided by community pharmacists.

Development of Quality Care Standards

- The Quality Care Standards should be viewed as a process that will benefit the profession to determine a confirmation of the pharmacists' participation in patient care.
- Practicality should be the main focus of development of the standards whilst maintaining acceptable robustness.

Recommendations

- Pharmacists practising in the community pharmacy setting, other health professionals, consumers and representatives of the payers should be included in the discussions for the development of the Quality Care Standards.
- Quality Care Standards should be regularly reviewed and updated.
- Quality Care Standards should be developed as a generic approach taking into consideration the various activities undertaken by community pharmacists when providing professional services.

Recommendations for the Implementation of Quality Care Standards Programmes

This document presents guidelines, which could be followed by different countries to begin or continue the process of developing and implementing Quality Care Standards. The guidelines are presented as a step-wise approach, and each country could consider moving from one stage to another depending on the particular situation and on the needs of the profession in the country.

- The Quality Care Standards programme should be established as a process of continuous quality improvement. It is advisable that the implementation of Quality Care Standards is based on a step-by-step process of quality improvement.
- The elements of a Quality Care Standards programme are divided into three stages (stage I, II, III). National pharmacy organisations should promote the development of Quality Care Standards based on this stepwise approach to achieve continuous service improvement.
- Quality Care Standards at the level of stage I of the programme should be promoted amongst national pharmacy organisations.

Quality Care Standards Programme: Stage I (Minimum requirements)

Areas to be included	Domains	
Setting of the pharmacy	 Appearance of the pharmacy Accessibility of the pharmacy Window dressing Dispensing area Counselling area/Pharmacist consultation area Staffing 	
Handling of stock and preparation of medicines	 Purchasing of stock Storage of stock Maintenance of quality of stock (identification of expired products, recalled medications) Availability of standard operating procedures for extemporaneous dispensing Documentation of extemporaneous preparations Storage of raw materials 	
Provision of prescription medicines	 Prescription receipt and patient identification Prescription checking Provision of information on the use of medication(s) Dispensing of medication(s) 	
Supply of non- prescription medicines for self-care	 Advice on the selection of medicines Advice on the use of non-prescription medicines Responding to minor ailments 	
Interaction with patients	 Communication skills (verbal and non-verbal messages) of pharmacists and pharmacy staff Provision of advice on the safe use of medicines and on the management of disease conditions Promotion of good health Provision of written information (labels, leaflets) 	
Documentation systems	 Patient medication profiles Formulary systems Policies and standard operating procedures Documentation of pharmacist interventions 	

Quality Care Standards Programme: Stage II

Areas to be included	Domains	
Equipment	Cleanliness and good state	
	Routine maintenance/ validity	
	 Availability of refrigerator, counting devices, and other dispensing equipment 	
	 Reference drug information systems (e.g. pharmacopoeia) 	
Health promotion	Distribution of leaflets	
activities	Display of health promotion advertisements	
	 Participation in health promotion campaigns 	
Diagnostics	Provision of diagnostic tests e.g. blood pressure monitoring, blood cholesterol testing, blood glucose testing, monitoring of peak expiratory flow rate, urinalysis and pregnancy testing, body weight monitoring	
	Documentation of diagnostic tests carried out	
Pharmacotherapy	Development of pharmaceutical care plans	
monitoring	Patient monitoring	
	Identification of medication-related problems	
	Interaction with prescribers	
Research and professional	Participation in research projects	
development	 Participation in continuing professional development activities 	
Audit	Development of quality manuals for the pharmacy system	
	 Running audit exercises for services provided (self- audit) 	

Quality Care Standards Programme: Stage III

Areas to be included	Domains	
Domiciliary services	 Provision of pharmaceutical services to house-bound persons, nursing homes Procedures 	
On-line services	 Provision of on-line pharmacy services System maintenance and update Handling requests Website 	
Pre-registration training	 Acceptance of pre-registration trainees Monitoring and documentation requirements Activity description for trainees 	
Parapharmaceuticals	 Availability of medical devices, homeopathic products, and other parapharmaceutical and non-pharmaceutical items Display of parapharmaceuticals Information on parapharmaceuticals 	
Customer perceptions (external audit)	 Views of patrons on service provided Expectations of patrons from pharmacists 	

Presentation

- Quality Care Standards should be developed where statements reflect the domains pertaining to the area considered. Statements should be clear, concise and specific.
- Quality Care Standards should <u>initially</u> be presented in the *Guidelines format*, whereby they are intended to create a quality environment, promote responsibility for quality and provide information on the standards required. The *Guidelines format* consists of the areas considered with details on domains pertaining to the service considered.
- Within the step-by-step process of quality improvement, consideration should be made to <u>subsequently</u> develop the Quality Care Standards programme in an *Audit format*. In the Audit format there is a quantitative approach towards the domains that are followed and, therefore, presents a tangible outcome when the Quality Care Standards are implemented.

Dissemination of the Quality Care Standards

- Quality Care Standards should be made available to practising pharmacists and should be widely promoted by the national pharmacy organisations and collaborating institutions.
- Quality Care Standards should be presented as a hard copy to all pharmacists and summarised versions may be presented to consumer organisations and other health care professionals.
- Consideration should be given to the availability of the Quality Care Standards electronically via a website and on CD-ROM.

Conclusion

Community pharmacists are obliged to ensure that the services they are providing to society are of the appropriate quality. Quality Care Standards are the tools with which to measure the quality of the service provided. Quality Care Standards should not be viewed as a necessary evil but as a process that will aid the profession to determine a confirmation of the pharmacists' participation in patient care.

This document provides leadership in the development and implementation of Quality Care Standards programmes amongst national pharmacy organisations in different countries.

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Appendix A: Terminology

Audit format

Framework whereby scores are assigned for each statement within a standard

Continuous quality improvement

A process by which shortcomings are identified, recommendations issued and activity is, again, monitored within an established timeframe

Domains

Indicator variables

External audit

Process performed with members of the public and health professionals other than pharmacists

Generic standard

Standard which takes into account different activities within the professional services offered

Guidelines format

Presentation of standards whereby statements explain the requirements for each domain

Quality assurance

Identification of standard of professional services provided

Quality manual

Compilation of standards required

Self-audit

Process which could be undertaken by the community pharmacist

Specific standard

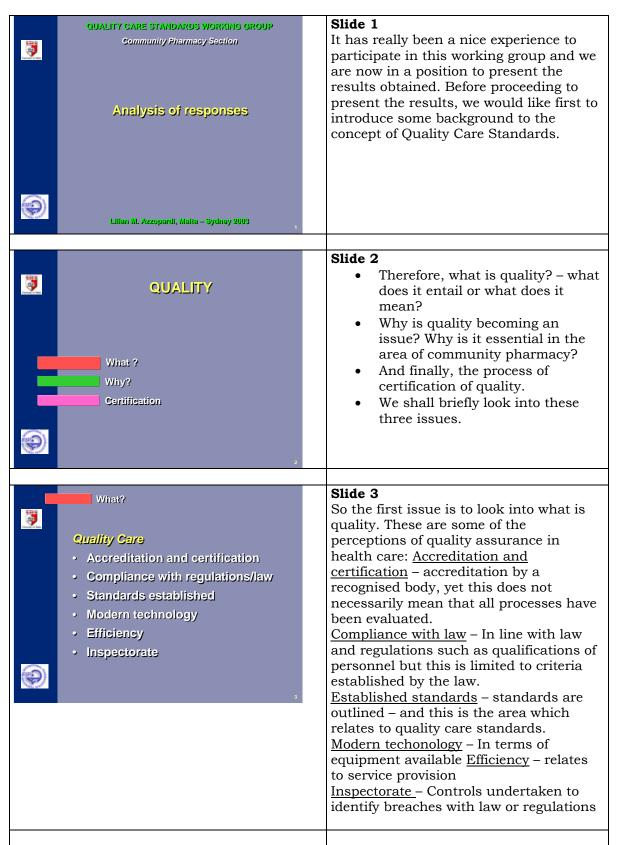
Standard developed for a specific activity carried out by the pharmacist

Appendix B: List of Organisations that Presented Standards for Survey

Australia	Country	Organisation	Contact information
Australia Pharmaceutical Society of Australia Pharmaceutical Society of Australia Pharmaceutical Society of Australia Pharmaceutical Society of Australia Pharmaceutical Society Fax: +16.13-523-7877 Fax: +16.13-523-0445		The Pharmacy Guild of Australia	
Email: guild.nata@uild.org.au	1100010110		
Australia			
Fax: -612 6285 2869	Australia	Pharmaceutical Society of Australia	
Canada Canadian Pharmacists Association Canadian Pharmacists Association Croatia Croatian Pharmaceutical Society Croatia Croatian Pharmaceutical Society Croatia Croatian Pharmaceutical Society Croatia Croatian Pharmaceutical Society Pax: +1-613-523-0445 E-mail: seacutive@pharmacists.ca Pax: +385-1-4872-849 Fax: +48-53-76 76 90 B-mail: hss/aspotekerforeningen.dk Finland Association of Finnish Pharmaciets Finland Association of Finnish Pharmaciets France Conseil National de l'Ordre des Pharmaciens France Conseil National de l'Ordre des Pharmaciens France ABDA, Bundesvereinigung Deutscher Apothekerverbände Fax: +33 1 5621 3454 Fax: +49-30-4000 0125 E-mail: abadorabda aponet de Fax: +91-22-614-0480 E-mail: paceutivement planta in polorinetropate co.il Fax: +91-22-614-0480 E-mail: paceutivement planta in polorinetropate co.il Tel:: +972-3-566-60475 Fax: +972-3-566-6045 Fax: +972-3-566-6045 Fax: +972-3-566-0475 Fax: +972-3-3-666-0475 Fax: +972-3-3-7373 Fax: +1-611-70-737-7373 Fax: +1-611-70	1101011111111	Trialmace disease seerely of musicalia	
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Uganda Pharmaceutical Society of Uganda Tel.: +256-41-3487 96 Fax: +256-41-340 385 E-mail: psupc@infocom.co.ug United Kingdom Royal Pharmaceutical Society of Great Britain Tel.: +44 20 7735 9141 Fax: +44 20 7735 7629 E-mail: enquiries@rpsgb.org.uk USA American Pharmacists Association (APhA) Tel.: +1-202-628-4410 Fax: +1-202-783-2351 Fax: +1-202-783-2351			Fax: +41-31-978-5859
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Appendix C: Analysis of Responses

The following is a copy of the PowerPoint presentation made by Lilian Azzopardi on behalf of the Working Group on the occasion of the FIP Congress in Sydney in 2003.





The second issue is, why quality care standards in community pharmacy? Within quality care there is an established structure and processes have to be followed. If this chain is adopted then you have outcomes – results reflecting the standards of professional services provided.



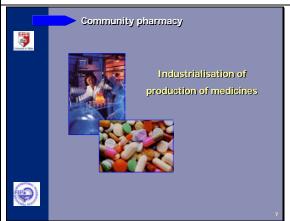
Slide 5

The results of the quality care process could lead to a certification of quality. For example, recently I was in Cannes in France and I noticed that a number of hair salons were displaying a label for quality service. Should we adopt similar systems for pharmacy after undertaking a quality care process?



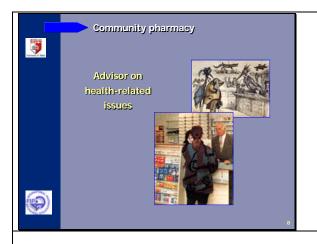
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Within the area of community pharmacy we have to develop quality care systems to evaluate whether the professional services provided from the pharmacies meet the required standards. But what are the required standards? How much has the process developed? Let's look at the developments in community pharmacy over the last fifty years.

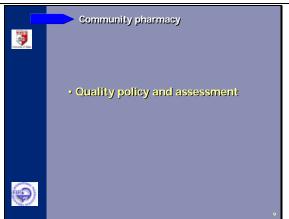


Slide 7

With the industrialisation of the production of medicines occurring in the late 50s there was a loss in the apparent traditional role of the dispensing pharmacist. Actually what the industrialisation brought about was the bringing to the forefront of the hidden role of the pharmacist – that of <u>an</u> advisor in health-related issues.

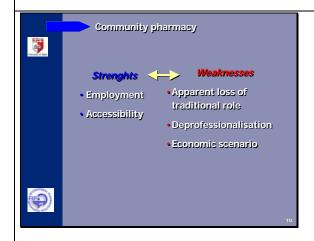


With the emphasis on the role of the pharmacist as an advisor on health-related issues, the analysis of the impact of the role of the pharmacist gained importance. Can the added value of the pharmacist intervention be demonstrated? Or what is the impact of the pharmacist advisory role on patient care?



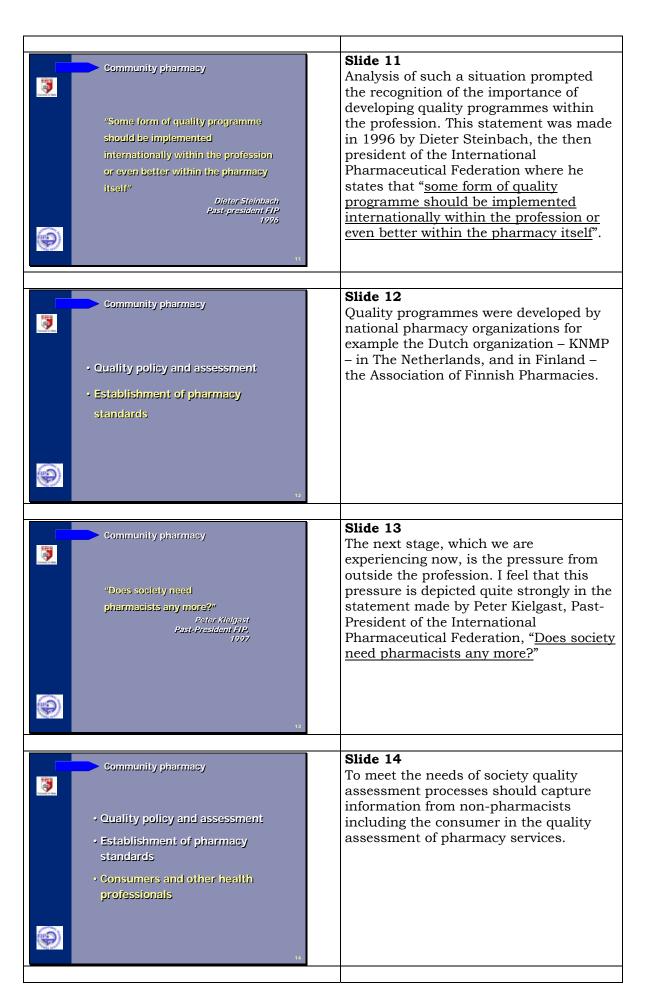
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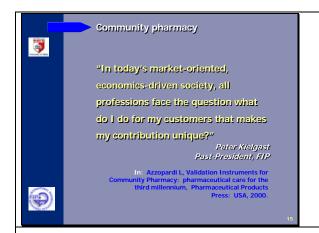
In this situation, <u>quality policy and</u> <u>assessment programmes</u> were implemented by government regulatory authorities in the form of inspections. Such practice was accepted for a number of years as the strengths and weaknesses of community pharmacy evolved.



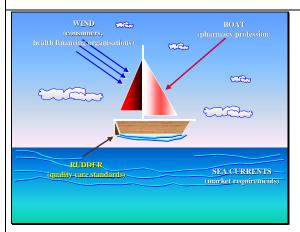
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The two major strengths of community pharmacy identified are that it is an area where a large percentage of pharmacists are employed and the accessibility of the pharmacist. Probably the community pharmacist is a readily available health professional whose services are underutilised. On the other hand the weaknesses of community pharmacy which emerged were the apparent loss of the traditional role as discussed earlier, the issue of de-professionalisation of community pharmacy and the fragility of to prove the valid contribution of the community pharmacist. The issue of deprofessionalisation developed mainly because of the business aspect within the setting and of the lack of control on medicines. With the increasing health expenditure, professionals are under scrutiny on the services provided. Community pharmacists are presently supported by the law, which requires that a pharmacist must be present in each pharmacy. In an ideal situation, the community pharmacist should be selected for health advice and dispensing of medicines independent of the legal requirement.



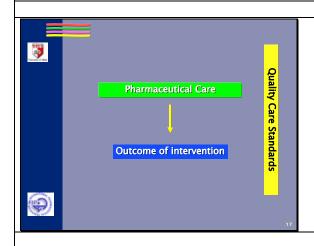


By including the perception of non-pharmacists in quality assessment, the profession is in a position to address the issue which is being presented again and again: "In today's market-oriented, economics-driven society, what do I do for my customers that makes my contribution unique?"



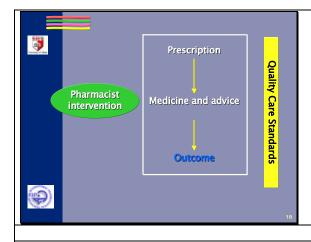
Slide 16

To discuss the impact of quality care standards on the practice of the profession I like to propose this comparison of the profession of pharmacy to a boat. The boat is in the sea facing forces of wind, sea currents which are the pressure experienced by the profession from consumers, governments and health financing organizations. If the boat is equipped with a rudder then it is able to determine its own course of travel. Similarly, if the profession of pharmacy has quality care systems, then it can determine its own participation in patient care.

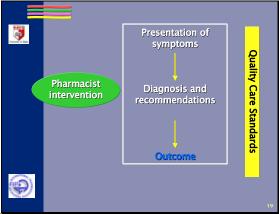


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Therefore, the quality care standards can be used to evaluate the provision of pharmaceutical care.



For example, when dispensing a prescription, the pharmacist intervention during the discussion of pharmacotherapy is monitored through quality care standards on this process.



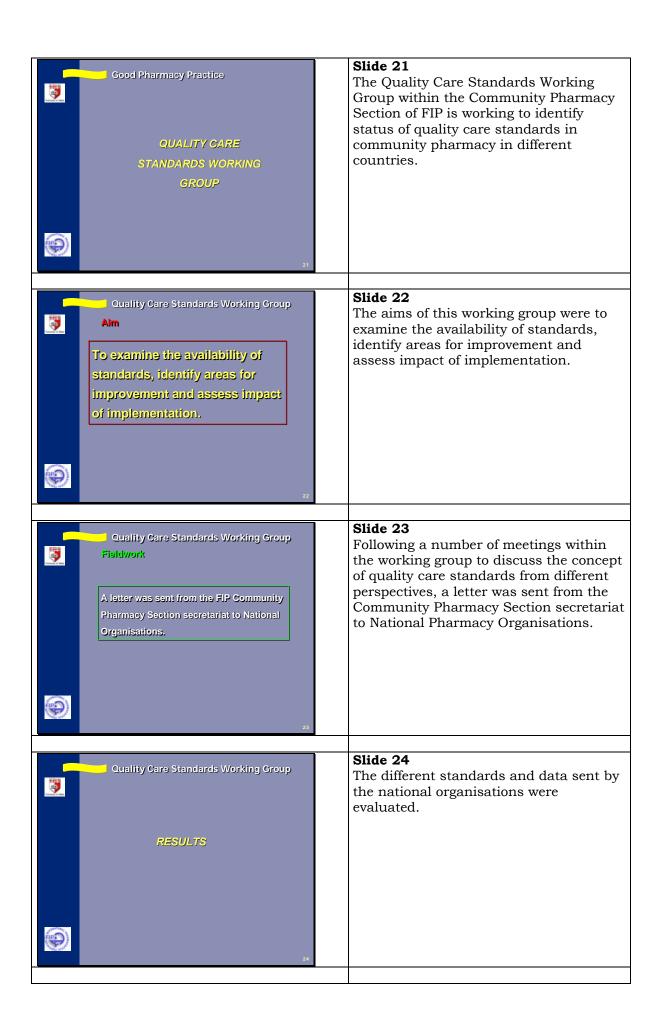
Slide 19

Similarly, when the patient presents a symptom the pharmacist intervention in the provision of pharmaceutical care – the diagnosis and recommended line of action could be monitored within the quality standards.



Slide 20

FIP has for the past decade been very much involved in the development of this concept in community pharmacy. FIP was very active in the establishment of baseline standards when in 1993 the Good Pharmacy Practice Guidelines were presented during the congress in Japan. This was the leadership to promote the initiation of the process in different countries. The guidelines were revised in 1997 and were endorsed by the WHO Expert Committee on Specifications for Pharmaceutical Preparations. In 1998 a report on Good Pharmacy Practice in Developing Countries was presented.





Twenty-three organizations sent their documentation. These organizations represented countries from five areas worldwide. Two organizations were from Australia. Of the responding organizations, two – Indonesia and Serbia – replied that they did not have quality care standards. Yet they stated that it is an area, which is being considered in the near future.



Slide 26

Quality care standards can be developed according to two intended purposes of use. The first purpose is an area specific standard where the standard developed is intended for a specific area such as, drug information. The second purpose is a generic approach where the standard comprises various sections covering different aspects of the professional service being evaluated.



Slide 27

Out of the 21 organizations that replied, three had produced an area specific standard.

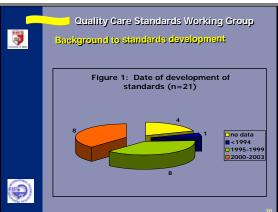


Slide 28

The specific areas considered were drug information and counselling by the Nordic Association, provision of pharmacist recommended medicines by the Pharmaceutical Society of Australia, and the prevention of errors in drug dispensing by the national association of Japan.



In Finland in addition to a generic standard, two area specific standards were prepared for health promotion and self-care activities.



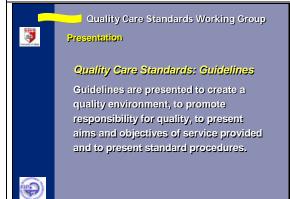
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The chronological development shows that the availability of standards increased over the past years. There were four standards where the date of development could not be identified. Sixteen standards were developed between 1995 to date. This development probably relates to the development by FIP in 1993 of the Good Pharmacy Practice Guidelines.



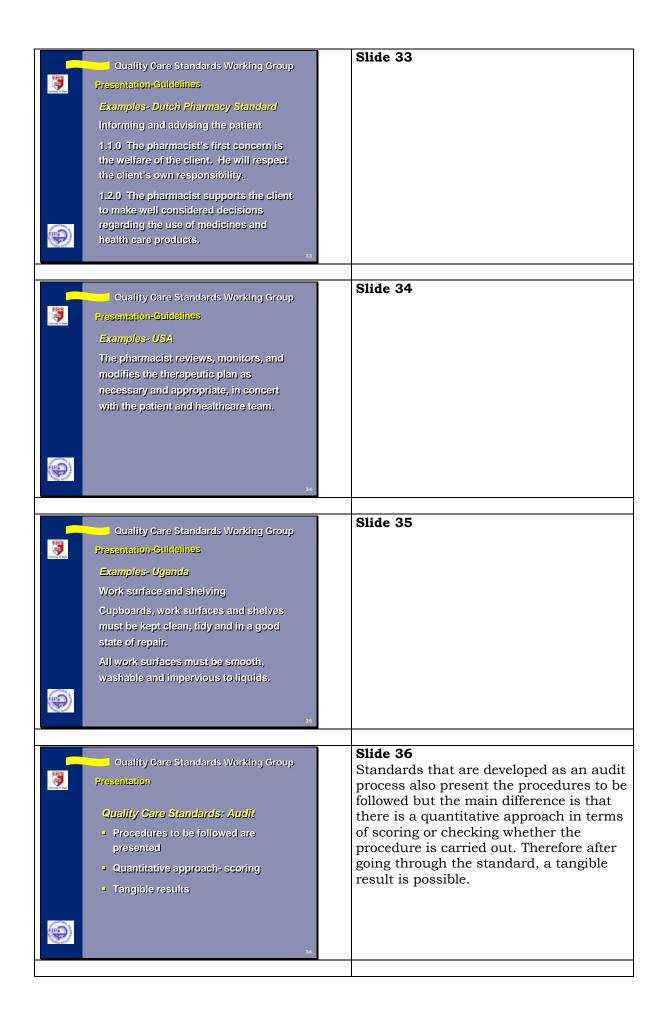
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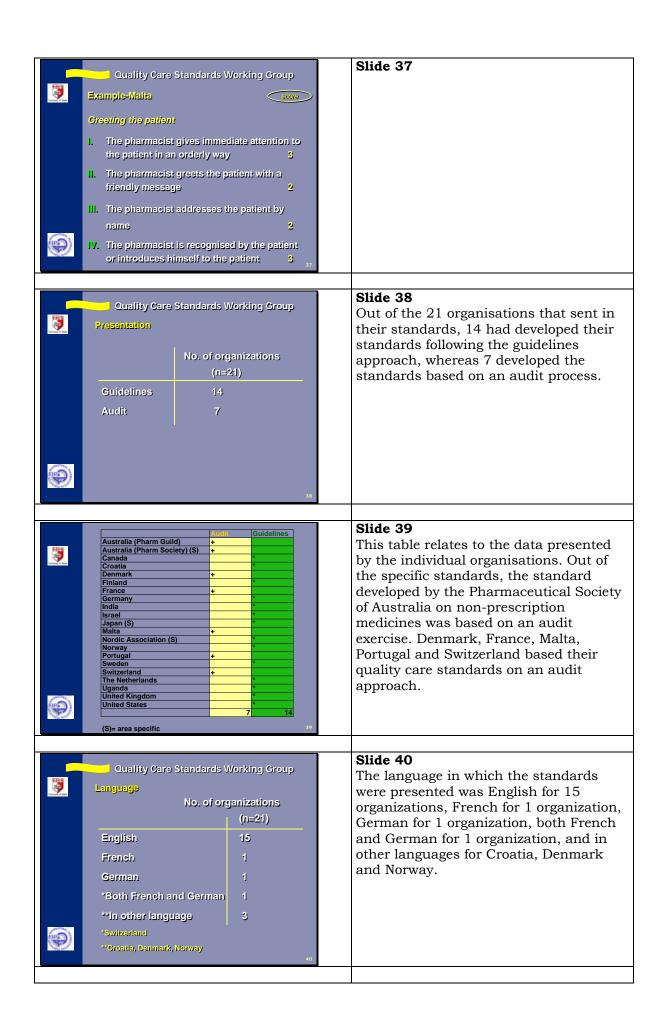
The presentation format of quality care standards could vary in two ways where the standards could be developed as guidelines or the standards could be developed for an audit exercise.

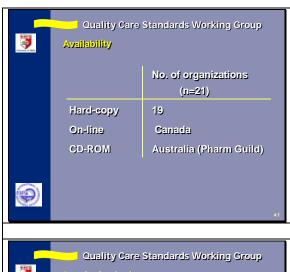


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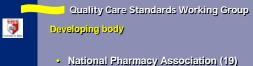
Standards that are developed as guidelines are rather general and are intended to create a quality environment, to promote responsibility for quality, to present aims and objectives of service provided, and to present standard procedures. Guidelines stipulate activities and processes that should be carried out.







19 standards were available as a hard copy whereas for Canada, the standards are available on-line and for Australia they are available on CD-ROM.



- Practice Research Group (1)- Malta
- Association of Pharmacy Regulatory Authorities (1)- Canada

Slide 42

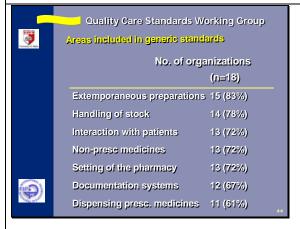
The standards were developed by a national pharmacy association except for Malta where a generic audit-based system was developed by a practice research group at the Department of Pharmacy at the University of Malta. In Canada, a generic guidelines-based system was developed by the national association of pharmacy regulatory authorities.



- India- FIP, WHO-SEARPHARM Forum
- Uganda- Ministry of Health

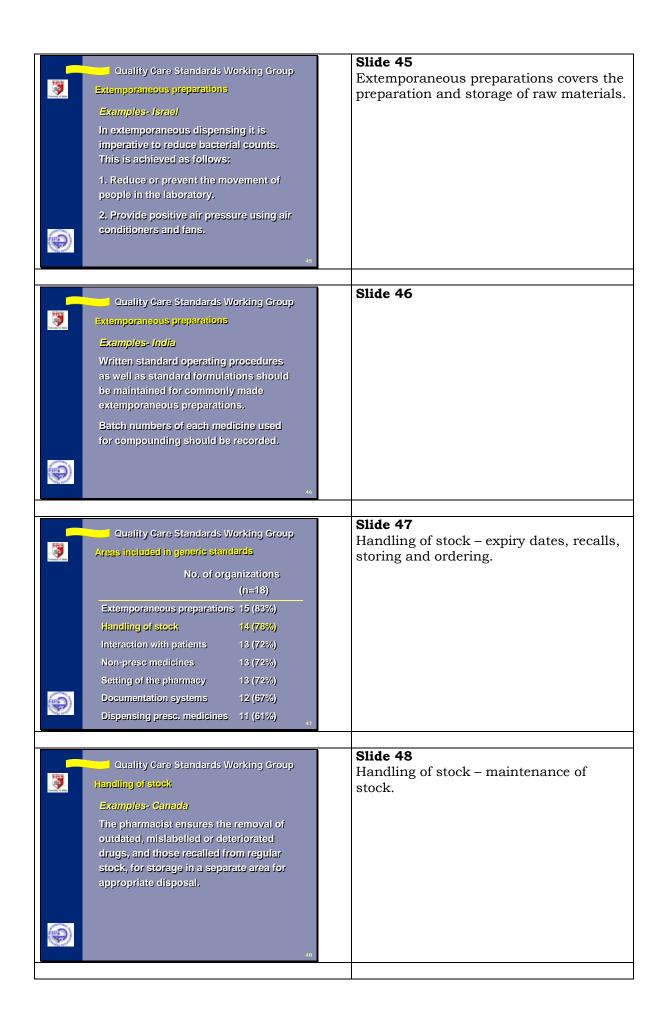
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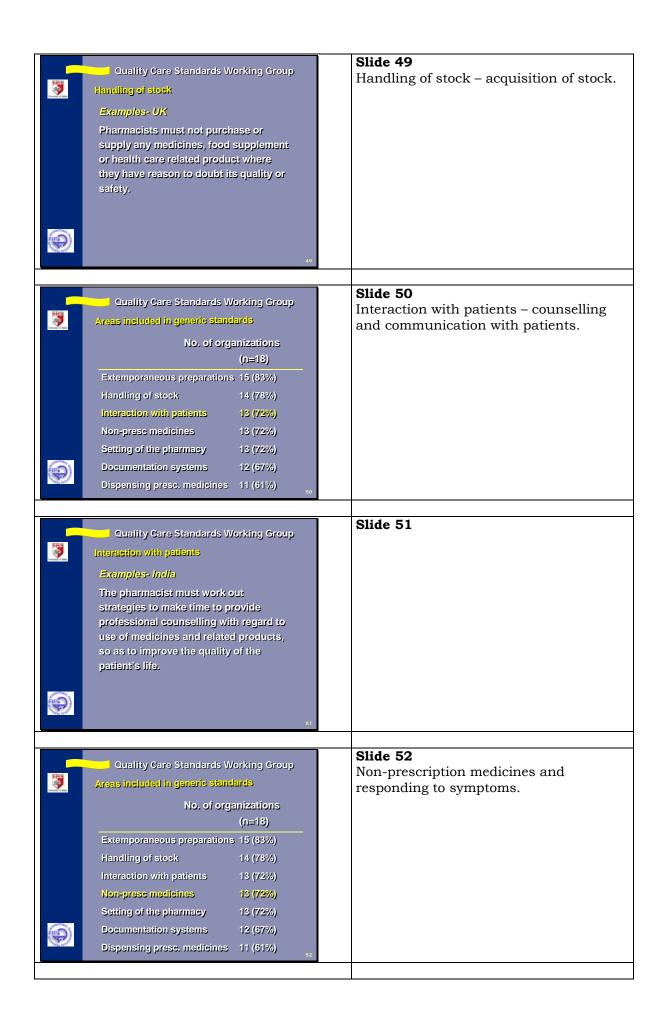
In India, the generic-guidelines based system was developed in collaboration with FIP and WHO whilst in Uganda the generic-guidelines based system was developed in collaboration with the Ministry of Health.

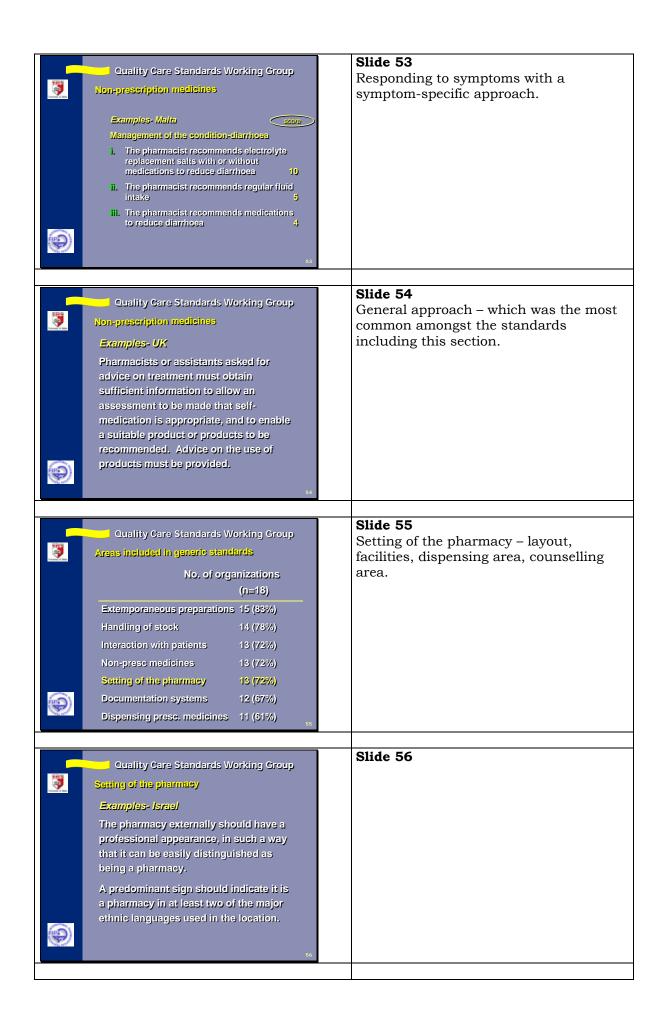


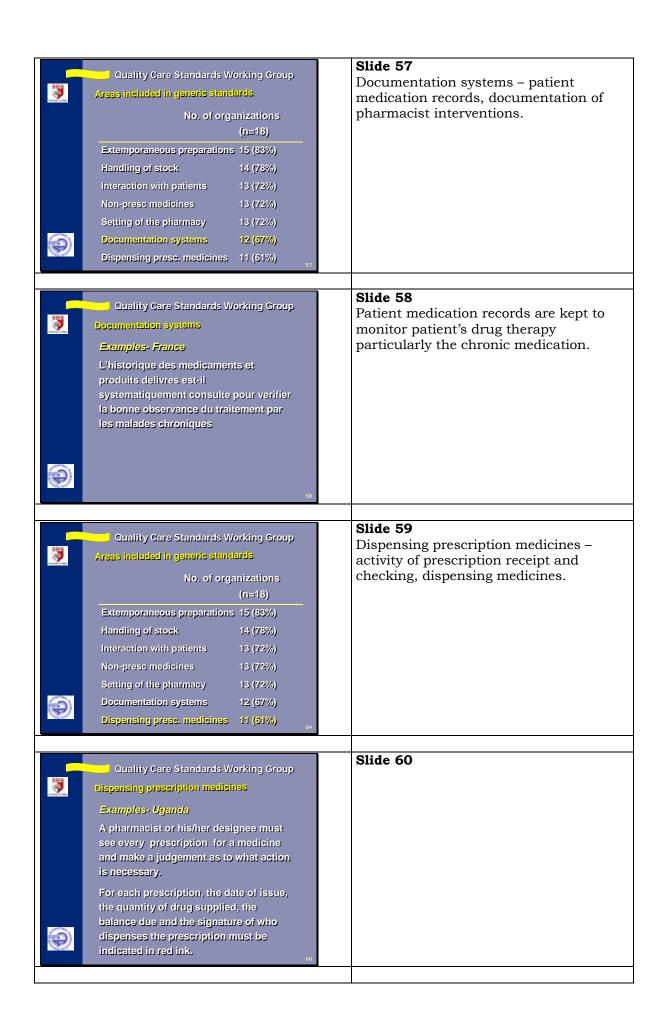
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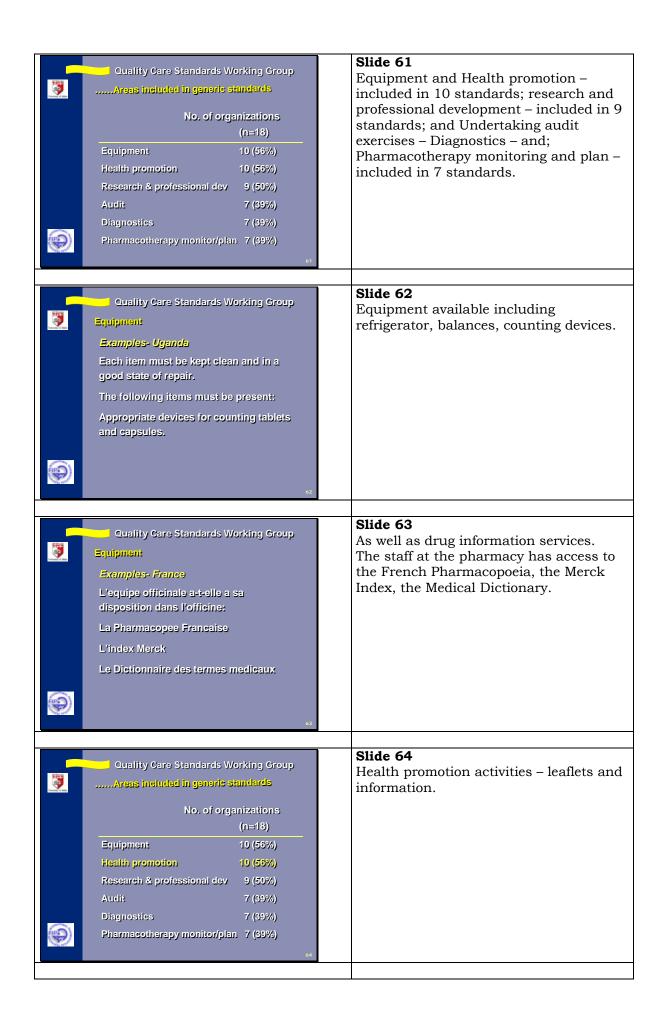
When looking at the 18 generic standards, there were 18 areas that were included in these standards. Over the next three slides we shall view these areas according to order of inclusion. The area of extemporaneous preparations was included in 15 standards. Handling of stock – included in 14 standards; Interaction with patients – included in 13 standards; Non-prescription medicines – included in 13 standards; Documentation systems – included in 12 standards; Dispensing prescription medicines – included in 11 standards.

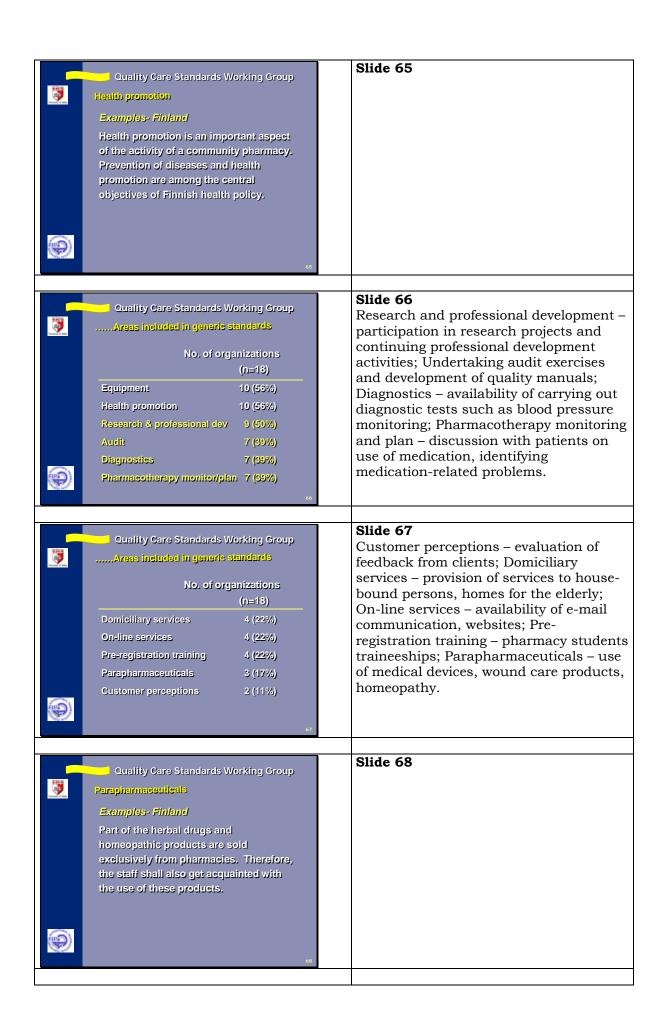


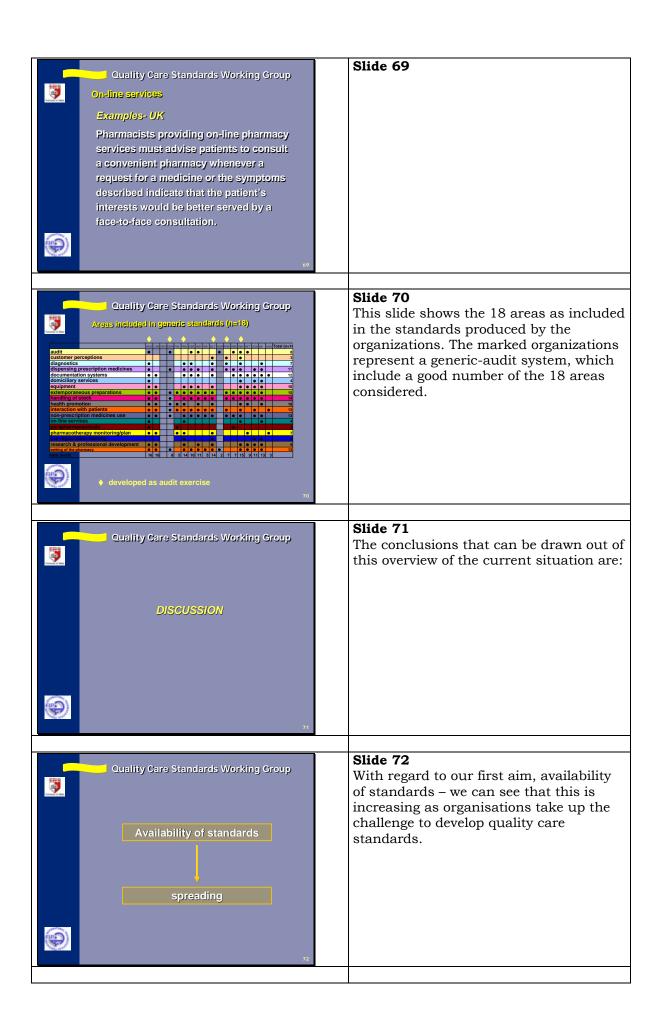


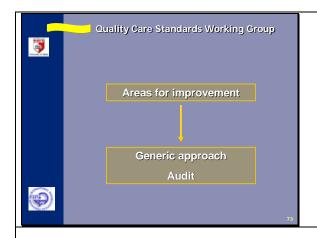




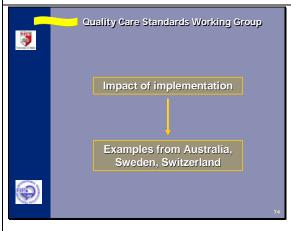






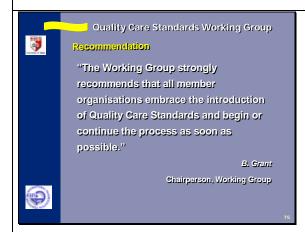


As for our second aim to identify areas for improvement – a generic approach is more robust and spans over the professional activities of a community pharmacist. The inclusion of all areas that have been identified in this analysis results in a comprehensive exercise. Developing the standards as an audit exercise would result in a more tangible outcome.



Slide 74

As for our third aim, the impact of implementation, my colleagues from Australia, Sweden and Switzerland will be discussing their experiences. The implementation of quality care standards in community pharmacy based as a legal requirement is still in its early stages. Pharmacists should take up this process and view such an activity is beneficial to the profession since it will help us confirm the effectiveness of the pharmacist in patient care. This will contribute to the continuous development of the pharmacy services provided.



Slide 75

The recommendation that emerges from this response analysis is that the Working Group strongly recommends that all member organisations embrace the introduction of Ouality Care Standards and begin or continue the process as soon as possible. This is a statement made by Bob Grant, Chairperson of the working group after reviewing the results obtained. The Community Pharmacy Section of FIP will provide whatever assistance it can and seeks the co-operation of member organisations in the provision of further assistance to those countries seeking such help.

