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
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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 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 step-wise 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)

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

<table>
<thead>
<tr>
<th>Areas to be included</th>
<th>Domains</th>
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<tbody>
<tr>
<td>Equipment</td>
<td>• Cleanliness and good state</td>
</tr>
<tr>
<td></td>
<td>• Routine maintenance/ validity</td>
</tr>
<tr>
<td></td>
<td>• Availability of refrigerator, counting devices, and other dispensing equipment</td>
</tr>
<tr>
<td></td>
<td>• Reference drug information systems (e.g. pharmacopoeia)</td>
</tr>
<tr>
<td>Health promotion activities</td>
<td>• Distribution of leaflets</td>
</tr>
<tr>
<td></td>
<td>• Display of health promotion advertisements</td>
</tr>
<tr>
<td></td>
<td>• Participation in health promotion campaigns</td>
</tr>
<tr>
<td>Diagnostics</td>
<td>• 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</td>
</tr>
<tr>
<td></td>
<td>• Documentation of diagnostic tests carried out</td>
</tr>
<tr>
<td>Pharmacotherapy monitoring</td>
<td>• Development of pharmaceutical care plans</td>
</tr>
<tr>
<td></td>
<td>• Patient monitoring</td>
</tr>
<tr>
<td></td>
<td>• Identification of medication-related problems</td>
</tr>
<tr>
<td></td>
<td>• Interaction with prescribers</td>
</tr>
<tr>
<td>Research and professional development</td>
<td>• Participation in research projects</td>
</tr>
<tr>
<td></td>
<td>• Participation in continuing professional development activities</td>
</tr>
<tr>
<td>Audit</td>
<td>• Development of quality manuals for the pharmacy system</td>
</tr>
<tr>
<td></td>
<td>• Running audit exercises for services provided (self-audit)</td>
</tr>
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</table>
Quality Care Standards Programme: Stage III

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

References

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Organisation</th>
<th>Contact information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>The Pharmacy Guild of Australia</td>
<td>Tel.: +61 2 6270 1888&lt;br&gt;Fax: +61 2 6285 1800&lt;br&gt;E-mail: guild <a href="mailto:nat@guild.org.au">nat@guild.org.au</a></td>
</tr>
<tr>
<td>Australia</td>
<td>Pharmaceutical Society of Australia</td>
<td>Tel.: +61 2 6283 4777&lt;br&gt;Fax: +61 2 6285 2869&lt;br&gt;E-mail: psa <a href="mailto:nat@psa.org.au">nat@psa.org.au</a></td>
</tr>
<tr>
<td>Canada</td>
<td>Canadian Pharmacists Association</td>
<td>Tel.: +1-613-523-7877&lt;br&gt;Fax: +1-613-523-0445&lt;br&gt;E-mail: <a href="mailto:executive@pharmacists.ca">executive@pharmacists.ca</a></td>
</tr>
<tr>
<td>Croatia</td>
<td>Croatian Pharmaceutical Society</td>
<td>Tel.: +385-1-4872-849&lt;br&gt;Fax: +385-1-4827-853&lt;br&gt;E-mail: hfd fg ap@zg tel hr</td>
</tr>
<tr>
<td>Denmark</td>
<td>Danmarks Apotekerforening</td>
<td>Tel.: +45-33-76 76 00&lt;br&gt;Fax: +45-33-76 76 99&lt;br&gt;E-mail: <a href="mailto:hs@apotekerforeningen.dk">hs@apotekerforeningen.dk</a></td>
</tr>
<tr>
<td>Finland</td>
<td>Association of Finnish Pharmacies</td>
<td>Tel.: +358-9-228-711&lt;br&gt;Fax: +358-9-647-167&lt;br&gt;E-mail: reijo <a href="mailto:karkkainen@apteekariliitto.fi">karkkainen@apteekariliitto.fi</a></td>
</tr>
<tr>
<td>France</td>
<td>Conseil National de l’Ordre des Pharmaciens</td>
<td>Tel.: +33 1 5621 3434&lt;br&gt;Fax: +33 1 5621 3469&lt;br&gt;E-mail: <a href="mailto:dap@ordre.pharmaciens.fr">dap@ordre.pharmaciens.fr</a></td>
</tr>
<tr>
<td>Germany</td>
<td>ABDA, Bundesvereinigung Deutscher Apothekerverbände</td>
<td>Tel.: +49-30-4000 40&lt;br&gt;Fax: +49-30-4000 0125&lt;br&gt;E-mail: <a href="mailto:abda@abda.aponet.de">abda@abda.aponet.de</a></td>
</tr>
<tr>
<td>India</td>
<td>Indian Pharmaceutical Association</td>
<td>Tel.: +91-22-612-2401&lt;br&gt;Fax: +91-22-614-0480&lt;br&gt;E-mail: <a href="mailto:jpscentt@jmpl.net.in">jpscentt@jmpl.net.in</a></td>
</tr>
<tr>
<td>Israel</td>
<td>Pharmaceutical Association of Israel</td>
<td>Tel.: +972-3-566-0475&lt;br&gt;Fax: +972-3-560-5085&lt;br&gt;E-mail: <a href="mailto:pol@interpage.co.il">pol@interpage.co.il</a></td>
</tr>
<tr>
<td>Japan</td>
<td>Japan Pharmaceutical Association</td>
<td>Tel.: +81-3-3406-1171&lt;br&gt;Fax: +81-3-3406-1499&lt;br&gt;E-mail: <a href="mailto:gaku@nichiyaku.or.jp">gaku@nichiyaku.or.jp</a></td>
</tr>
<tr>
<td>Malta</td>
<td>Department of Pharmacy University of Malta</td>
<td>Tel.: +356 13437645/5&lt;br&gt;Fax: +356 21340427&lt;br&gt;E-mail: <a href="mailto:phcy@um.edu.mt">phcy@um.edu.mt</a></td>
</tr>
<tr>
<td>The Netherlands</td>
<td>KNMP</td>
<td>Tel.: +31-70-373-7373&lt;br&gt;Fax: +31-70-310-6530&lt;br&gt;E-mail: <a href="mailto:knmp@knmp.nl">knmp@knmp.nl</a></td>
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<tr>
<td>Nordic countries</td>
<td>Nordic Pharmacy Association</td>
<td>Tel.: +45 33 76 76 00&lt;br&gt;Fax: +45 33 76 76 33&lt;br&gt;E-mail: <a href="mailto:hj@apotekerforeningen.dk">hj@apotekerforeningen.dk</a></td>
</tr>
<tr>
<td>Norway</td>
<td>Norwegian Association of Pharmacists</td>
<td>Tel.: +47-21-023-300&lt;br&gt;Fax: +47-21-023-350&lt;br&gt;E-mail: <a href="mailto:nff@farmaceutene.no">nff@farmaceutene.no</a></td>
</tr>
<tr>
<td>Portugal</td>
<td>Ordem dos Farmaceuticos</td>
<td>Tel.: +351-21 319 1370&lt;br&gt;Fax: +351-21 319 1399&lt;br&gt;E-mail: <a href="mailto:dirmacional@ordemfarmaceuticos.pt">dirmacional@ordemfarmaceuticos.pt</a></td>
</tr>
<tr>
<td>Sweden</td>
<td>Apoteket AB</td>
<td>Tel.: +46-8-466 10 00&lt;br&gt;Fax: +46 8 466 11 42&lt;br&gt;E-mail: thony bjork@apoteket se</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Swiss Pharmaceutical Society</td>
<td>Tel.: +41-31-978-5858&lt;br&gt;Fax: +41-31-978-5859&lt;br&gt;E-mail: <a href="mailto:sav@sphin.ch">sav@sphin.ch</a></td>
</tr>
<tr>
<td>Uganda</td>
<td>Pharmaceutical Society of Uganda</td>
<td>Tel.: +256-41-3487 96&lt;br&gt;Fax: +256-41-340 385&lt;br&gt;E-mail: <a href="mailto:psupe@infocom.co.ug">psupe@infocom.co.ug</a></td>
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<tr>
<td>United Kingdom</td>
<td>Royal Pharmaceutical Society of Great Britain</td>
<td>Tel.: +44 20 7735 9141&lt;br&gt;Fax: +44 20 7735 7629&lt;br&gt;E-mail: <a href="mailto:enquiries@rpsgb.org.uk">enquiries@rpsgb.org.uk</a></td>
</tr>
<tr>
<td>USA</td>
<td>American Pharmacists Association (APhA)</td>
<td>Tel.: +1-202-628-4410&lt;br&gt;Fax: +1-202-783-2351&lt;br&gt;E-mail: <a href="mailto:gen@mail.aphanet.org">gen@mail.aphanet.org</a></td>
</tr>
</tbody>
</table>
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.

Slide 1
It has really been a nice experience to participate in this working group and we are now in a position to present the results obtained. Before proceeding to present the results, we would like first to introduce some background to the concept of Quality Care Standards.

Slide 2
- Therefore, what is quality? – what does it entail or what does it mean?
- Why is quality becoming an issue? Why is it essential in the area of community pharmacy?
- And finally, the process of certification of quality.
- We shall briefly look into these three issues.

Slide 3
So the first issue is to look into what is quality. These are some of the perceptions of quality assurance in health care: Accreditation and certification – accreditation by a recognised body, yet this does not necessarily mean that all processes have been evaluated.
Compliance with law – In line with law and regulations such as qualifications of personnel but this is limited to criteria established by the law.
Established standards – standards are outlined – and this is the area which relates to quality care standards.
Modern technology – In terms of equipment available Efficiency – relates to service provision
Inspectorate – Controls undertaken to identify breaches with law or regulations.
Slide 4
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?

Slide 6
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 an 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?

In this situation, quality policy and assessment programmes 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.

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 under-utilised. 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 de-professionalisation 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.
Slide 11
Analysis of such a situation prompted the recognition of the importance of developing quality programmes within the profession. This statement was made in 1996 by Dieter Steinbach, the then president of the International Pharmaceutical Federation where he states that “some form of quality programme should be implemented internationally within the profession or even better within the pharmacy itself”.

Slide 12
Quality programmes were developed by national pharmacy organizations for example the Dutch organization – KNMP – in The Netherlands, and in Finland – the Association of Finnish Pharmacies.

Slide 13
The next stage, which we are experiencing now, is the pressure from outside the profession. I feel that this pressure is depicted quite strongly in the statement made by Peter Kielgast, Past-President of the International Pharmaceutical Federation, “Does society need pharmacists any more?”

Slide 14
To meet the needs of society quality assessment processes should capture information from non-pharmacists including the consumer in the quality assessment of pharmacy services.
In today's market-oriented, economics-driven society, all professions face the question what do I do for my customers that makes my contribution unique?

Peter Kielgast
Past-President, FIP


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?”

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.

Therefore, the quality care standards can be used to evaluate the provision of pharmaceutical care.
Slide 18
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.
The Quality Care Standards Working Group within the Community Pharmacy Section of FIP is working to identify status of quality care standards in community pharmacy in different countries.

The aims of this working group were to examine the availability of standards, identify areas for improvement and assess impact of implementation.

Following a number of meetings within the working group to discuss the concept of quality care standards from different perspectives, a letter was sent from the Community Pharmacy Section secretariat to National Pharmacy Organisations.

The different standards and data sent by the national organisations were evaluated.
Slide 25
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, the Association of Finnish Pharmacies prepared two area specific standards in addition to the generic standard:

- health promotion
- self-care

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.

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.

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.
Examples- Dutch Pharmacy Standard
Informing and advising the patient

1.1.0 The pharmacist's first concern is the welfare of the client. He will respect the client's own responsibility.

1.2.0 The pharmacist supports the client to make well considered decisions regarding the use of medicines and health care products.

Examples- USA
The pharmacist reviews, monitors, and modifies the therapeutic plan as necessary and appropriate, in concert with the patient and healthcare team.

Examples- Uganda
Work surface and shelving
Cupboards, work surfaces and shelves must be kept clean, tidy and in a good state of repair.
All work surfaces must be smooth, washable and impervious to liquids.

Quality Care Standards: Audit
- Procedures to be followed are presented
- Quantitative approach- scoring
- Tangible results

Standards that are developed as an audit process also present the procedures to be followed but the main difference is that there is a quantitative approach in terms of scoring or checking whether the procedure is carried out. Therefore after going through the standard, a tangible result is possible.
Slide 37

**Greeting the patient**

1. The pharmacist gives immediate attention to the patient in an orderly way 3
2. The pharmacist greets the patient with a friendly message 2
3. The pharmacist addresses the patient by name 2
4. The pharmacist is recognised by the patient or introduces himself to the patient 3

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Slide 38

Out of the 21 organisations that sent in their standards, 14 had developed their standards following the guidelines approach, whereas 7 developed the standards based on an audit process.

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Slide 39

This table relates to the data presented by the individual organisations. Out of the specific standards, the standard developed by the Pharmaceutical Society of Australia on non-prescription medicines was based on an audit exercise. Denmark, France, Malta, Portugal and Switzerland based their quality care standards on an audit approach.

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Slide 40

The language in which the standards were presented was English for 15 organizations, French for 1 organization, German for 1 organization, both French and German for 1 organization, and in other languages for Croatia, Denmark and Norway.
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.

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.

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.

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; Setting of the pharmacy also included in 13 standards; Documentation systems – included in 12 standards; Dispensing prescription medicines – included in 11 standards.
Extemporaneous preparations covers the preparation and storage of raw materials.

**Examples- Israel**
In extemporaneous dispensing it is imperative to reduce bacterial counts. This is achieved as follows:
1. Reduce or prevent the movement of people in the laboratory.
2. Provide positive air pressure using air conditioners and fans.

**Extemporaneous preparations**

**Quality Care Standards Working Group**

**Slide 45**

**Extemporaneous preparations**

**Examples- India**
Written standard operating procedures as well as standard formulations should be maintained for commonly made extemporaneous preparations.
Batch numbers of each medicine used for compounding should be recorded.

**Areas included in generic standards**

<table>
<thead>
<tr>
<th>Area</th>
<th>No. of organizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extemporaneous preparations</td>
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<tr>
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</table>

**Slide 46**

**Handling of stock** – maintenance of stock.

**Examples- Canada**
The pharmacist ensures the removal of outdated, mislabelled or deteriorated drugs, and those recalled from regular stock, for storage in a separate area for appropriate disposal.

**Slide 47**

**Handling of stock – expiry dates, recalls, storing and ordering.**
Examples – UK
Pharmacists must not purchase or supply any medicines, food supplement or health care related product where they have reason to doubt its quality or safety.

Handling of stock – acquisition of stock.

Interaction with patients – counselling and communication with patients.

Examples – India
The pharmacist must work out strategies to make time to provide professional counselling with regard to use of medicines and related products, so as to improve the quality of the patient’s life.

Non-prescription medicines and responding to symptoms.
Non-prescription medicines

Examples - Malta

Management of the condition - diarrhoea

i. The pharmacist recommends electrolyte replacement salts with or without medications to reduce diarrhoea

ii. The pharmacist recommends regular fluid intake

iii. The pharmacist recommends medications to reduce diarrhoea

Examples - Malta

Non-prescription medicines

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Responding to symptoms with a symptom-specific approach.

Non-prescription medicines

Examples - UK

Pharmacists or assistants asked for advice on treatment must obtain sufficient information to allow an assessment to be made that self-medication is appropriate, and to enable a suitable product or products to be recommended. Advice on the use of products must be provided.

General approach – which was the most common amongst the standards including this section.

No. of organizations (n=18)

Extemporaneous preparations 15 (83%)
Handling of stock 14 (78%)
Interaction with patients 13 (72%)
Non-presc medicines 13 (72%)
Setting of the pharmacy 13 (72%)
Documentation systems 12 (67%)
Dispensing presc medicines 11 (61%)

Setting of the pharmacy – layout, facilities, dispensing area, counselling area.

Examples - Israel

The pharmacy externally should have a professional appearance, in such a way that it can be easily distinguished as being a pharmacy.
A predominant sign should indicate it is a pharmacy in at least two of the major ethnic languages used in the location.
Areas included in generic standards

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</tr>
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</table>

Slide 57
Documentation systems – patient medication records, documentation of pharmacist interventions.

Documentation systems

Examples- France
L'historique des medicaments et produits delivres est-il systematiquement consulte pour verifier la bonne observance du traitement par les malades chroniques.

Slide 58
Patient medication records are kept to monitor patient's drug therapy particularly the chronic medication.

Dispensing prescription medicines

Examples- Uganda
A pharmacist or his/her designee must see every prescription for a medicine and make a judgement as to what action is necessary.
For each prescription, the date of issue, the quantity of drug supplied, the balance due and the signature of who dispenses the prescription must be indicated in red ink.

Slide 59
Dispensing prescription medicines – activity of prescription receipt and checking, dispensing medicines.

Slide 60
**Slide 61**

Equipment and Health promotion – included in 10 standards; research and professional development – included in 9 standards; and Undertaking audit exercises – Diagnostics – and; Pharmacotherapy monitoring and plan – included in 7 standards.

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**Slide 62**

Equipment available including refrigerator, balances, counting devices.

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**Slide 63**

As well as drug information services. The staff at the pharmacy has access to the French Pharmacopoeia, the Merck Index, the Medical Dictionary.

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**Slide 64**

Health promotion activities – leaflets and information.
Health promotion is an important aspect of the activity of a community pharmacy. Prevention of diseases and health promotion are among the central objectives of Finnish health policy.

Quality Care Standards Working Group

**Examples- Finland**

Health promotion

Health promotion is an important aspect of the activity of a community pharmacy. Prevention of diseases and health promotion are among the central objectives of Finnish health policy.

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Research and professional development – participation in research projects and continuing professional development activities; Undertaking audit exercises and development of quality manuals; Diagnostics – availability of carrying out diagnostic tests such as blood pressure monitoring; Pharmacotherapy monitoring and plan – discussion with patients on use of medication, identifying medication-related problems.

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Customer perceptions – evaluation of feedback from clients; Domiciliary services – provision of services to house-bound persons, homes for the elderly; On-line services – availability of e-mail communication, websites; Pre-registration training – pharmacy students traineeships; Parapharmaceuticals – use of medical devices, wound care products, homeopathy.

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Part of the herbal drugs and homeopathic products are sold exclusively from pharmacies. Therefore, the staff shall also get acquainted with the use of these products.
Examples - UK
Pharmacists providing on-line pharmacy services must advise patients to consult a convenient pharmacy whenever a request for a medicine or the symptoms described indicate that the patient’s interests would be better served by a face-to-face consultation.

On-line services

Areas included in generic standards (n=18)

<table>
<thead>
<tr>
<th>Audits</th>
<th>Customer perceptions</th>
<th>Diagnostics</th>
<th>Dispensing prescription medicines</th>
<th>Documentation systems</th>
<th>Domiciliary services</th>
<th>Equipment</th>
<th>Extemporaneous preparations</th>
<th>Handling of stock</th>
<th>Health promotion</th>
<th>Interaction with patients</th>
<th>Non-prescription medicines use</th>
<th>On-line services</th>
<th>Parapharmaceuticals</th>
<th>Pharmacotherapy monitoring/plan</th>
<th>Pre-registration training</th>
<th>Research &amp; professional development</th>
<th>Setting of the pharmacy</th>
<th>Total</th>
</tr>
</thead>
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<td>4</td>
<td>9</td>
<td>11</td>
<td>16</td>
</tr>
</tbody>
</table>

Slide 69

This slide shows the 18 areas as included in the standards produced by the organizations. The marked organizations represent a generic-audit system, which include a good number of the 18 areas considered.

DISCUSSION

The conclusions that can be drawn out of this overview of the current situation are:

Availability of standards

With regard to our first aim, availability of standards – we can see that this is increasing as organisations take up the challenge to develop quality care standards.
Slide 73
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 Quality 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.
Further considerations
- Who should run the method
- Cost of quality system
- Voluntary or mandatory
- Reward for improving quality

Slide 76
Once the implementation phase is more widespread, one could then start looking into further considerations such as: who should run the method – should it be run by the pharmacy association?, in conjunction with non-pharmacist members – consumers, payers?, what is the cost of the system – will the cost be included in the pharmacist professional fee? – should it be a voluntary or mandatory process?, and what is the reward for improving quality – a certificate, reimbursement that will have to be invested to improve the services of the pharmacy.

Slide 77
Quality care standards for community pharmacy practice is an area that has developed over the past decade and the profession is now in a position to implement this process. This process should not be viewed as a necessary evil but as a process that will benefit the profession to determine a confirmation of the pharmacists’ participation in patient care.

Slide 78
THANK YOU