VALIDATION INSTRUMENTS
FOR
COMMUNITY PHARMACY

Pharmaceutical Care for the Third Millennium

Handbook

Lilian M. Azzopardi, Department of Pharmacy,
University of Malta, Msida, Malta

Sam Salek, Medicines Research Unit, Welsh School of Pharmacy
University of Wales, Cardiff, Wales

Anthony Serracino Inglott, Department of Pharmacy,
University of Malta, Msida, Malta

Maurice Zarb Adami, Department of Pharmacy,
University of Malta, Msida, Malta
PREFACE

This handbook is intended to present a practical approach to the validation of community pharmacy method. It is meant to present enough detail and material so that one may actually practise the process itself. The main book provides background information enabling one to develop specific validation tools in a scientific manner. The handbook provides the practical basis for the student, validator, instructor and researcher to develop a more hands-on approach which should result in producing a scientifically tested validation process with excellence.
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References
ACKNOWLEDGMENTS

The authors would like to thank all those who contributed to the development and evaluation of the validation tools. Special mention has to be made of:

- Professor Roger Ellul Micallef, Rector, University of Malta
- Professor Mark Brincat, Dean, Faculty of Medicine & Surgery, University of Malta
- Professor Anton Buhagiar, Biostatistician, Department of Mathematics, University of Malta
- Mr Leslie Agius, Professor Albert Borg, Professor Charles Farrugia, Dr. Saviour Gauci and Professor Kenneth Wain, colleagues from the University of Malta
- FIP Foundation for Education and Research
- European Society of Clinical Pharmacy and the German Research and Education Foundation
- Mr Peter Kielgast, President, International Pharmaceutical Federation
- Dr Michel Buchmann, President FIP Community Pharmacy Section
- Dr Olivier Bugnon and his team at the Department of Quality and Development, Swiss Pharmaceutical Society.

We cannot but not mention our colleagues at the Faculty of Medicine and Surgery of the University of Malta and the team members.
TEAM MEMBERS

Statistician
Professor Anton Buhagiar

Expert Panel Members
Ms Marianne Bonanno
Dr George Buttigieg
Mr Joseph Camilleri
Dr Anthony Felice
Prof Godfrey Laferla
Mr Eric Santucci
Ms Mary Rose Zammit

Raters for Reliability Testing
Jeantide Abela
Tracy Falzon
Doreen Farrugia
Alfred Naudi

Community Pharmacists who participated in Reliability Testing
Marianne Bonanno
Marisa Dalli
Marthese Dalli
Andre Delicata
Denise Ellul
Cecilia Galea
Joseph Gatt
Mark Sciberras
Imelda Serracino Inglott
Malcolm Soler
Doris Zerafa

Secretarial Assistance
Dorothy Fenech
Maria Pirotta
Mary Rose Zammit
Agnes Zerafa
GLOSSARY

Validation Tool
any one of the seven Validation Tools which have been developed for the purpose of this exercise namely, *The setting of the community pharmacy, Dispensing a prescription, Responding to symptoms. Communicating with the patient, Equipment and professional services available in a community pharmacy, Consumer Services Tool, Health Professionals Tool.*

Tool
a copy of one of the seven Validation Tools.

Set of Tools
made up of a copy of tools 1 and 5 and ten copies of tools 2, 3 and 4; and the two external validation tools namely Consumer Services Tool and Health Professionals Tool.

Mark
mark assigned to a statement

Total Mark
sum of marks obtained for a section in a tool.

Total Score
sum of total marks obtained in a tool.

Internal Validation
validation study using validation tools 1 to 5. This study considers services provided by the pharmacist.
**External Validation**

performed with members of the public and other health professionals to discern their perception of the services provided by the pharmacist.

**Validation Grade**

grade obtained from the internal validation study. The grade is worked out by adding the total score obtained in tools 1, 5 and the averages of the total scores obtained in tools 2, 3, 4.

**Validation Study Result Sheet**

a sheet used to work out the validation grade, a separate sheet for each community pharmacy is used.

**Minimum Validation grade**

this has been set at 350.

**Pink Recommendations**

these are suggested areas where the pharmacist may improve his services to achieve a validation grade which is above the minimum validation grade.

**Green Recommendations**

these are suggested areas where the pharmacist may improve his services to achieve a higher validation grade.
### Internal Validation

<table>
<thead>
<tr>
<th>Tool No.</th>
<th>Validation Tool</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The setting of the community pharmacy</td>
<td>200</td>
</tr>
<tr>
<td>2</td>
<td>Dispensing a prescription</td>
<td>100</td>
</tr>
<tr>
<td>3</td>
<td>Responding to symptoms</td>
<td>100</td>
</tr>
<tr>
<td>4</td>
<td>Communicating with the patient</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>Equipment and professional services available in a community pharmacy</td>
<td>100</td>
</tr>
</tbody>
</table>

**Maximum validation grade**: 600

### External Validation

<table>
<thead>
<tr>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer Services tool</td>
</tr>
<tr>
<td>Health Professionals Tool</td>
</tr>
</tbody>
</table>

INTRODUCTION

The Purpose and Scope of Validation of Community Pharmacy

Foundations of community pharmacy, not exceedingly different from present time practice, date back to the early 9th century in Baghdad.\(^1\)

Community pharmacy spread to the western civilization later and today the largest proportion of pharmacists across western Europe are employed in community pharmacies.\(^2\) In Malta 49% of Maltese active pharmacists are employed full time in the community.\(^3\)

Notwithstanding that the majority of pharmacists practise in community pharmacies, much debate has centred around the pharmacy profession during the last few years questioning the need for the professional services of pharmacists.\(^4\) One answer to this debate lies in demonstrating the value of the community pharmacist. The consultation paper "Pharmacy in a New Age" launched in 1995 in the UK aims to address this point and was intended to demonstrate "How many people were protected from harm last week by pharmacists?"\(^5\)

One way to quantify this is by showing that the practice of pharmacy is carried out to the greatest benefit of the patient. The concept of Validation of Community Pharmacy tries to confirm the intervention of the community pharmacist in patient care. Validation of community pharmacy is the process carried out to demonstrate that the services provided by a community pharmacist are needed.
SECTION 1

VALIDATION OF COMMUNITY PHARMACY: CONCEPTS AND METHODS

Meaning of Validation
The term validation is derived from the Latin word *validus* meaning "strong, powerful". The Virtue's English dictionary defines 'valid' as "sufficiently supported by actual fact, well grounded, just, good, not weak or defective, having sufficient legal strength or force". Subsequently the term to validate is defined as, "to make valid, to ratify, to confirm, to substantiate."\(^6\)

Development of Principles of Validation
The word *Validation* was introduced in the laboratory procedures jargon during the late 1960s to describe the process carried out to demonstrate that the instrument or the method under scrutiny is reliable for the intended application.\(^7\) The process of validation ensures confidence in the results obtained and minimizes consequences of error. Today validation is considered an essential procedure in the area of analysis.\(^8\)

Validation is also used in social and behavioural sciences to examine the usefulness and accuracy of questionnaires and measurement tools. Measurement tools involve the assignment of numerals, numbers or scores to properties or procedures.

Variation in the scores could be either due to 'real difference' in the property being measured or else due to the influence of the measure itself or the setting in which measurement is taking place. Differences due to 'real difference' are measurement errors. Validation of questionnaires and measurement tools prior to implementation in real situation minimizes measurement errors by ensuring that the instrument is measuring what it claims or what it is intended to measure.\(^9\)
**Characteristics of Validation of Community Pharmacy**

As the definition of 'validation' implies, three elements, namely scientific, measurement and confirmation make up any process of validation. These elements apply also to the concept of validation of community pharmacy.

- **Scientific** Validation involves scientific methodology which in turn is a system of explicit procedures on which research is based

- **Measurement** Validation involves quantification of the attributes of the instrument, service or data under scrutiny

- **Confirmation** Validation aims ultimately to provide supporting evidence

**Aims of Validation of Community Pharmacy**

- Scientifically confirm or 'deny' the accepted view that the community needs the community pharmacist

- Use scientific measuring instruments to quantify standards of pharmacy practice

**Validation Methods**

Validation tools are measurement instruments which involve the assignment of scores to properties or procedures. The method of Validation of Community Pharmacy is two-pronged. One aspect, the internal validation process, seeks to demonstrate that the services provided by a community pharmacist are needed by the community from within the profession itself. The validation tools address services provided by the community pharmacist. The other aspect, the external validation process, seeks to confirm the need of the intervention of the community pharmacist in patient care from outside the profession by studying consumer perception and views of other health professionals.
The internal validation process per se, quantifies the services provided by the community pharmacist. The external validation process can be used to confirm results obtained from the internal validation process.
SECTIION II

DEVELOPMENT OF THE INTERNAL VALIDATION TOOLS

Five internal validation tools were developed under the following headings:

• The setting of the community pharmacy
• Dispensing a prescription
• Responding to symptoms
• Communicating with the patient
• Equipment and professional services available in a community pharmacy

These validation tools were developed and then their measurement properties were established using standard psychometric techniques.

Baseline Data
All community pharmacies (n=189) in Malta were visited. Baseline data was collected from 184 community pharmacies. Services identified include dispensing of prescribed medication, dispensing of over-the-counter medicines, responding to symptoms, giving advice when selling non-pharmaceutical products and carrying out certain diagnostic tests such as pregnancy testing, urinalysis, blood pressure measurement, blood testing and weight monitoring.

Field Observation Studies
Ten community pharmacies were selected using stratified random sampling. Field observation studies were carried out in these pharmacies to quantify the division of time amongst the services offered by the community pharmacist. These data were then used to develop the validation tools.
**Psychometric Evaluation**

One aspect of psychometrics is validity which assesses how well the tool measures what it sets out to measure. Face and content validity were assessed by a group of expert panel members. Panel members included consumers, health professionals and academics.

Another aspect of psychometric evaluation is reliability which measures the reproducibility of the measuring instrument. Since the validation tools are intended to be administered by different raters this creates a subjective component during the rating exercise. To this effect it was considered important that the validation tools must possess acceptable degree of inter-observer reliability as part of their measurement properties. The validation tools were used in the ten pharmacies selected for the observation study. Each tool was used by two different raters in the same pharmacy. Results were analysed and the correlation coefficient obtained for the total score obtained by each rater for each tool was above the minimum accepted level representing good reliability for each tool.

**Validation Grades**

The Classification of the Validation Grades has been set after deliberation by the panel members. The Validation Study Result Sheet and the Recommendations in the Classification were validated using the data obtained from the ten pharmacies during the reliability testing.

**DEVELOPMENT OF THE EXTERNAL VALIDATION TOOLS**

Two external validation tools were developed under the following headings:

- Consumer Services
- Health Professionals

These validation tools were developed and then their measurement properties were established using standard psychometric techniques.
**Psychometric Evaluation**

Face and content validity were assessed by the same group of expert panel members involved in the review of the internal validation tools. Reliability testing was undertaken using the test-retest method. The *Consumer Services Tool* was administered twice at different times at a fifteen days interval under similar circumstances, to thirty randomly selected consumers of community pharmacy services. The same procedure was adopted with the *Health Professionals Tool* where twelve non-pharmacist health professionals were selected randomly and asked to participate. The correlation coefficient obtained for total scores obtained by each rater for both tools was above the minimum adopted level representing good reliability for each tool.

**DATA PROCESSING AND ANALYSES**

Data was analysed using Microsoft Excel version 5.0 and factor analysis was carried out using Biomedical Data Package version 7.0.
SECTION III

CARRYING OUT AN INTERNAL VALIDATION STUDY

Please read through the whole pack before starting data collection. Initially, use the tools in a small pilot study to get used to their practicality aspects. Then decide on a starting date and start using the tools.

For each internal validation tool there is a definition sheet which explains the corresponding validation tool. The validation tools *The Setting of the Community Pharmacy* and *Equipment and Professional Services available in a Community Pharmacy* are used once for each community pharmacy being studied. The validation tools *Dispensing a Prescription, Communicating with the Patient, and Responding to Symptoms* are each carried out ten times within the same community pharmacy. Since the prescription or individual case could influence the outcome of the process, the procedure is scored ten times to eliminate bias. In fact the *Tool ID number* given for these tools runs from 1 to 10.

Another precaution which may be taken to eliminate bias is that an observing pharmacist marks the Validation Tools. The pharmacist who is at the pharmacy does not score his own conduct.

Analysis of Data

1. The results from the validation study are entered in Excel files set up for each validation tool.
2. These files were set up using Microsoft Excel version 5.0. The fields are set up to enter total marks for each section.

For each tool:
3. The total mark obtained for each section is entered in the respective column.
4. The total score is obtained using the Autosum (∑) function in Excel.

5. The total score is written down on the hard copy of the respective tool.

Once total scores for the internal validation tools have been worked out:

6. Enter the total scores in the Validation Study Result Sheet and work out the Validation Grade by adding the total scores obtained from validation tools 1 and 5 and the averages of the total scores obtained from the validation tools 2,3,4.

7. From the Classification of Validation Grades (Section IV) obtain the Category and write it down in the Remarks section of the Validation Study Result Sheet.
### RESULT SHEET
Internal Validation Study

<table>
<thead>
<tr>
<th>Name of the Pharmacy</th>
<th>Locality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Tel No</td>
</tr>
<tr>
<td>Name of the Managing Pharmacist</td>
<td></td>
</tr>
</tbody>
</table>

#### Total Score

<table>
<thead>
<tr>
<th>01</th>
<th>THE SETTING OF THE COMMUNITY PHARMACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>02</td>
<td>DISPENSING A PRESCRIPTION</td>
</tr>
<tr>
<td>03</td>
<td>RESPONDING TO SYMPTOMS</td>
</tr>
<tr>
<td>04</td>
<td>COMMUNICATING WITH THE PATIENT</td>
</tr>
<tr>
<td>05</td>
<td>EQUIPMENT &amp; PROFESSIONAL SERVICES AVAILABLE IN A COMMUNITY PHARMACY</td>
</tr>
</tbody>
</table>

#### Tools ID No.

<table>
<thead>
<tr>
<th>Tool ID No.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Average Total Score</th>
</tr>
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<tbody>
<tr>
<td>Score</td>
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<th>Tool ID No.</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
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<th>Tool ID No.</th>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Average Total Score</th>
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</table>

<table>
<thead>
<tr>
<th>Tool ID No.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<th>Average Total Score</th>
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</tbody>
</table>

Total Score
VALIDATION GRADE

Remarks

CARRYING OUT AN EXTERNAL VALIDATION STUDY

The external validation study is used in combination with the internal validation study. It is carried out among consumers who come to the community pharmacies taking part in the study and health professionals who have clinics in the same locality.

Consumer Services Tool

1. This tool is directed towards consumers who come to the pharmacy to benefit from the professional services provided by the community pharmacist (getting pharmaceutical services, buying non-pharmaceutical products).

2. Ten consumers who enter the pharmacy are interviewed and ten sets of the tool are filled in.

3. Assign numbers consecutively to the consumers from 1 to 10 and write this down as Consumer number.

4. Enter the scores in an Excel file

5. Work out the total grade by the Autosum function ( \( \sum \) ) and write it down on the tools.

6. For each pharmacy write the ten total grades obtained in the External Validation Result Sheet and work out the Average Total Score.

Health Professionals Tool
1. This tool is directed towards health professionals who have clinics in the community pharmacy. If in the pharmacy there are no such clinics then this part of the external validation study may be extended to other health professionals who have clinics in the same locality.

2. Health professionals are approached and those who accept to participate are given this tool to fill in.

3. Each health professional willing to participate is assigned a number which is pre-filled in the tool as *Health Professional Number*.

4. Enter the scores in an Excel file.

5. Work out the total grade by the Autosum function (\( \sum \)) and write it down on the tool.

6. Write the total grades obtained in the *External Validation Result Sheet* and work out the total average grade using the formula provided.

To compare results obtained from the Internal and External Validation Study fill in the *External and Internal Validation Study Results Correlation*. The Validation Grade is worked out as a percentage so that this mark can be compared with the two marks obtained from the External Validation study.
# RESULT SHEET
External Validation Study

<table>
<thead>
<tr>
<th>Name of the Pharmacy</th>
<th>Locality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Tel No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of the Managing Pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

## Consumer Services Tool

<table>
<thead>
<tr>
<th>Consumer No.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Average Total Score</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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</tbody>
</table>

**Remarks**

________________________________________

________________________________________

________________________________________

## Health Professionals Tool

<table>
<thead>
<tr>
<th>Health Professional No.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Total</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

\[
\text{Total} \times 100 = \text{Average Total Score}
\]

\[
\text{no. of health professional} \times 50
\]
Remarks

Average Total Score
### The External and Internal Validation Study Results Correlation

<table>
<thead>
<tr>
<th>Name of the Pharmacy</th>
<th>Locality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>Tel No</td>
</tr>
<tr>
<td>Name of the Managing Pharmacist</td>
<td></td>
</tr>
</tbody>
</table>

1. Work out the Percentage Validation Grade for the Internal Validation Study

   \[
   \text{Validation Grade} \times \frac{100}{600} = \% \text{ Validation Grade}
   \]

   \% Validation Grade

2. Correlate the average total scores obtained from the External Validation Study with the \% Validation Grade obtained from the Internal Validation Study:
SECTION IV

CLASSIFICATION OF VALIDATION GRADES

Validation Grades

Yellow Category
Unacceptable Validation Grade, meaning that the community pharmacy is not offering the standard required services.

Pink Category
The pink category falls below the minimum standard validation grade. Pink Recommendations are indicated to upgrade the services provided by the community pharmacist to reach the standard professional level.

Green Category
Good standard pharmacy services are provided with minor deficiencies. Green Recommendations are indicated.

Blue Category
Excellent pharmacy services are provided.

<table>
<thead>
<tr>
<th>VALIDATION GRADES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation Grade</td>
</tr>
<tr>
<td>450 - 600</td>
</tr>
<tr>
<td>350 - 449</td>
</tr>
<tr>
<td>200 - 349</td>
</tr>
<tr>
<td>&lt;200</td>
</tr>
</tbody>
</table>
**Pink Recommendations**

A. Improvement in:

i. the setting of the pharmacy to reflect a professional image

ii. the display of health promotion materials and activities to disseminate information to promote healthy lifestyles

iii. the communication with the patient during dispensing to ensure correct and safe use of medicines

iv. responding to symptoms and over-the-counter prescribing. An attempt should be made to detect symptoms suggestive of serious disease and information should be provided to ensure correct use of medicines

B. Participation in continuing education programmes, review of pharmacy journals and the use of information technology to keep abreast with the latest developments in pharmacy.

**Green Recommendations**

Improvement in:

i. documentation of patient care (e.g. maintaining patient medication records, written result sheet for diagnostic tests)

ii. written policy and procedures manual which is a compilation of written statements that present information regarding administrative and professional decisions

iii. maintaining a formulary system.

**INDIVIDUAL RECOMMENDATIONS FOR EACH VALIDATION TOOL**

**The setting of the community pharmacy**

< 120: The setting of the pharmacy may have to be upgraded to reflect a better professional image. Management of the pharmacy may be changed to incorporate established scientific systems such as formularies, policies and procedures and patient medication records.
Dispensing a prescription

< 60: The pharmacist, is in a unique position to educate patients about their disease and its drug treatment. When listening to the pharmacist the patient is not as anxious and tense as when he is speaking to the prescriber. So the pharmacist may take this opportunity to discuss with the patient the use of the prescribed medication and encourage the patient to ask questions if in doubt.

Even when the patient asks for a repeat medication, the pharmacist should consider discussing with the patient 'medication taking habits' to ensure that the patient is taking the prescribed medicines correctly. The pharmacist should also monitor the illness being treated in relation to drug related problems.

Responding to symptoms

< 60: When the patient presents a symptom, diagnosis of the condition should be attempted by interviewing the patient. This should be followed by advice on the health condition and the provision of sufficient information and instruction about the use of recommended over-the-counter products.

When the patient asks for an over-the-counter preparation questions to check that the medication is used for the correct condition are indicated. Advice to confirm the proper use of the medication enhances the effectiveness of the pharmacist's intervention.

Communicating with the patient

<60: During counselling body language influences the degree of interaction between the pharmacist and the patient. The pharmacist should try to adopt an attending role during discussions held with the patient and encourage a two-way process.
Equipment and professional services available in a community pharmacy

<60: Standards of equipment available in the pharmacy and of services provided by the pharmacist should be checked from time to time.
SECTION V

DEFINITION SHEETS OF THE VALIDATION TOOLS

01 The setting of the community pharmacy
02 Dispensing a prescription
03 Responding to symptoms
04 Communicating with the patient
05 Equipment and professional service available in community pharmacy

Gender: the use of him or he stands in all cases for him or her and he or she
DEFINITION SHEET- VALIDATION TOOL
THE SETTING OF THE COMMUNITY PHARMACY

For the purpose of this tool the following definitions apply:

- **the pharmacy premises**: all the area covered by the premises i.e. dispensary, waiting area, clinics, perfumery, stores
- **dispensary**: the area within the premises where the pharmacist exercises his profession
- **area for dispensing**: area within the dispensary where medicines are prepared for dispensing, including the preparation of labels

**General Information**

The **Tool ID Number** is a unique number assigned to the tool. For this tool, the Tool ID Number given is the pharmacy registration number. The **Monitor** is the person who performs the scoring exercise. The **date** and **time** are background data necessary for the processing of the tool.

**Details of the Pharmacy**

Baseline data on the pharmacy are needed. The approximate number of years that the pharmacy has been established might influence the validation process. Clinics are rooms made available for health professionals (e.g. general practitioners, podologists). If there is a physical separation between the dispensing counter and the area where toiletries and other merchandise are sold then this should be indicated as YES where **Separate toiletries area** is denoted. Also if there is a physical separation between the display of medicines and the display of other merchandise then this should be indicated as YES in the appropriate section.

**REPORT SHEET**

*For any section where no scores are assigned the monitor has to fill the REPORT SHEET for the section in question and the reasons for not assigning any scores must be documented.*
Section 1 to 20 covering the entire setting of a community pharmacy are described below:

1. The first section assesses the compliance to legal requirements.
   This section refers to Pharmacy licences and permits required by law at the time when the tool is used.

2. This section identifies the number of pharmacists working at the community pharmacy on a regular basis.
   As the number of pharmacists working in the pharmacy increases, there is more probability that there will be less uniformity in patient care unless the pharmacy has an established ‘standard operating procedure’ in place.
   To get the results pertaining to this section, information has to be obtained from the managing pharmacist or his representative.

3. Since the pharmacy should reflect a professional image, this section assesses the appearance of the pharmacy.
   If the pharmacy is well lighted and airy then option (i) holds. If the pharmacy is kept clean then option (ii) holds. If the pharmacy is kept in an orderly and tidy condition option (iii) applies.

4. The pharmacy should be easily accessible.
   If there is no merchandise and display stands near the doors, then option (i) applies. If the doors leading on to the pharmacy can be widely opened to allow entrance by pushchairs score (ii) applies.

5. The environment within the pharmacy is assessed in this section.
   Distribution of health promotion leaflets either personally by the pharmacist or else through a free selection is assigned option (ii). If health promotion
material is displayed in the pharmacy (entrance door or on the counter), then option (ii) is assigned.

*Health promotion material:* written information on the prevention and treatment of health problems or ailments. Material which features only a specific product information is not considered as material for health promotion.

*Ordinary Confectionery:* sweets which are not sugar-free.

6. In this section the professional image projected is assessed.
   
   The appearance of the pharmacist is assessed. If the pharmacist is wearing a lab coat then option (i) holds. If there exists a dress code where certain types of clothing (eg sports wear) are not used for the pharmacy option (ii) applies. If there is no music played in the pharmacy or if the sound is kept low so as not to interfere with communication then option (iii) holds.

7. In this section the toilet facilities are assessed.
   
   The facilities, which should also be available to the public, are assessed.

8. The appearance from the outside is assessed in this section.
   
   The presence of a sign denoting the existence of the pharmacy is scored in option (i). If the main door leading to the pharmacy is not obscured with stickers option (ii) holds. The third option scores the shop window. If the shop window is organised with health promotion advertisements and other items particular to a pharmacy then option (iii) holds.

9. The size of the dispensary is assessed in this section.
   
   If during observation session it is evident that for the amount of dispensing taking place there is enough area and space, then option (i) holds. Also if
there are no physical barriers to effective communication between the pharmacist and the patient score (ii) applies.

10. The setting of the area for dispensing is assessed in this section.

If the dispensing area is set in a separate area from the dispensary (totally separated) option (i) holds. If the dispensing area is set in a secluded area within the dispensary i.e. behind the dispensing counter but in a secluded area, then option (ii) applies. If the area for dispensing is located on the dispensing counter, option (iii) holds. If the work surface of the area for dispensing is always kept free and tidy option (iv) applies. If on the other hand the work surface has to be cleared before use or daily then option (v) holds.

11. In this section facilities available in the dispensary, excluding toilet facilities accessible to the public, are assessed.

The availability of a source of drinking water is scored in option (i). The facility of a wash hand basin with cold water with or without hot water is assessed in options (ii) and (iii) respectively. Facilities for waste disposal (waste bin) in the dispensary are assessed in option (iv).

12. In this section the presence of a formulary is assessed.

A formulary is a list of products that are readily available in the pharmacy. Option (i) scores the availability of a formulary for pharmaceutical items. If the formulary is regularly updated and changes brought to the attention of other pharmacists and other health professionals, then score (ii) applies. The frequency of updating per year is at the discretion of the managing pharmacist.
13. The criteria followed for inclusion of a pharmaceutical product in the stock list is assessed in this section.

This section is irrespective of whether a formulary exists or not. If products are included following the requests by clients, then score (i) applies. If products are included after identifying products requested on prescriptions or after discussions with the prescribers, then option (ii) holds.

14. This section assesses the procedure generally followed when a request for a prescription medicine which is not kept in stock is made.

If the patient is told to come again and the medicine is ordered, then option (i) holds. If the requested product is taken note of and the product is not ordered, option (ii) holds. If the product is not ordered and no further action is taken, option (iii) applies.

15. Procedures carried out to ensure that medicines are of good quality are assessed in this section.

Methods undertaken to ensure that medicines are not beyond the expiry date are scored. If the pharmacist adopts an organised procedure (through documentation) together with or without a random check then score (i) applies. If the pharmacist follows a random check whereby products are checked from time to time then score (ii) applies.

16. This section assesses the system used by the pharmacist for storing and displaying medicinal products.

If medicines which require a prescription or are pharmacy-only products are stored out of reach of the public, option (i) holds. If the medicines are stored to protect them from sunlight and heat option (ii) holds. If antiseptics and other products for external use are stored separately (in a separate shelf or cupboard or section) from oral and injectable medications option (iii)
applies. The availability of a refrigerator for storage of medicines is scored in option (iv).

17. Policies and procedures which are established to minimize hand over problems between the staff are assessed in this section.

If policies and procedures are written, then score (i) holds. If the policies and procedures are not documented and are passed from one pharmacist to another verbally, then score (ii) applies. Policies and procedures may be established but not used in practice. If the policies and procedures are put to practice then option (iii) applies. If there is a list of medicines which are only dispensed upon receipt of a prescription, then score (iv) applies.

18. Personal medication records (PMR) kept at the pharmacy are assessed.

The PMRs can be kept manually or on computer. This section assesses the content and utility of PMRs.

19. The degree of confidentiality of patient information is assessed in this section.

Information includes that retained through memory or held in records. If the information is only available to pharmacists, then score (i) applies. If on the other hand, the information is available or (in the case of information retained through memory) passed on to other personnel working in the pharmacy score (ii) applies.

20. The actual use of PMRs is assessed in this section.

If prior to dispensing a medication, the pharmacist goes and checks the PMR, then option (i) holds. If the pharmacist checks the PMR prior to suggesting a medication over-the-counter and prior to giving any advice on medications, option (ii) holds. If before dispensing the pharmacist documents the medication in PMR then option (iii) holds.
DEFINITION SHEET- VALIDATION TOOL
DISPENSING A PRESCRIPTION

The tool is performed 10 times in the same pharmacy

For the purpose of this tool the following definition applies:

patient--the person for whom the medication is prescribed or his representative

General Information and Details of Pharmacist

The Tool ID Number is a unique number assigned to the tool. Assign numbers consecutively to tools performed in the same pharmacy. For each pharmacy start from 1. The monitor is the person who performs the scoring exercise. The date, time, name of pharmacy and locality of pharmacy are background data necessary for the processing of the tool. Details of the pharmacist present when the tool is performed is essential since the validation process for each community pharmacy has to be performed with the same pharmacist.

The Prescription

Consider every prescription one transaction. For each prescription use one tool and assess the whole process. In this section list down all medications prescribed together with the corresponding instructions. However, if the patient states that one of the prescribed medications is not needed (either because prescriber has told patient to start using it at a later stage or because patient already has the medication) then it is not listed down.

REPORT SHEET

For any section where no scores are assigned the monitor has to fill the REPORT SHEET for the section in question and the reasons for not assigning any scores must be documented.

Section 1 to 10 covering the procedure of dispensing a prescription are described below:
1. The *first* section examines at what stage the pharmacist gets involved during the dispensing process.

   Deduct no scores if during the dispensing process an assistant gets the medication(s) for the pharmacist and/or handles the cash register. If this is the case, score from option (i) or (ii).

2. In the *second* section the tool aims to confirm the patient’s details available to the pharmacist.

   If the pharmacist asks for whom the prescribed medication is, and upon receiving the answer, the pharmacist shows that the patient is familiar to him, option (i) holds. Select options from (ii) if on the other hand the pharmacist indicates that the patient is not a regular customer. After the transaction the monitor may ask the pharmacist whether the pharmacist knows the patient. This may help the monitor for the scoring process.

3. This section analyses whether the pharmacist probes the patient to check the knowledge of the patient about the prescribed medication.

   Sometimes it is the pharmacist who referred the patient to the prescriber. Give a full score (both i and ii) if during dispensing the pharmacist shows that this was the case.

4. The decision taken by the pharmacist to continue the dispensing process is scored in section 4.

   If a problem is identified, continue scoring on this tool once it is solved by choosing option (i). If the pharmacist decides to proceed but the medication is not available at the pharmacy, scoring depends on the action the pharmacist takes in such a situation. The scores from (ii) to (vi) scan through the levels of assistance offered by the pharmacist:
Score vi--the pharmacist does not take any action and informs the patient that the request cannot be met with;
Score v--the pharmacist tries to get the medication and discusses with the patient a convenient arrangement for collection at a later time;
Score iv--the pharmacist informs the patient to go to another pharmacy;
Score iii--the pharmacist refers the patient to another pharmacy that has the medication (may be after phoning the other pharmacies in the locality);
Score ii -- the pharmacist contacts the prescriber.

5. The pharmacist selects the product and this section assesses the degree of rechecking performed by the pharmacist.
   A final glance by the pharmacist at the prescription to compare the product against the prescription is scored as (i). Assign score (ii) if the pharmacist looks at the product to check its expiry date.

6. The type of information provided by the pharmacist is scored in this section.
   A common practice is for the pharmacist to write the dose on the packet. This is assigned as score (iii). It is not a label because for the purpose of this tool the minimum information for a label includes the name of the medication and instructions on how to take the medication.

7. In this section the pharmacist is assessed for commitment shown to confirm that the information conveyed is understood by the patient.

8. This section is aimed to assess the type of interaction between the pharmacist and the patient.

9. This section is aimed to assess the type of relationship which is built up between the pharmacist and the patient.
10. This section assesses the contribution of the pharmacist towards the therapeutic management of the patient.

   Score i-- the pharmacist discusses with the patient how he can combine medication dosing with work, sleep or other medication.

   Score ii-- the pharmacist gives advice on health condition.

   Score iii-- the pharmacist advises on common drug interactions and reassures patient on the use of medications that may be taken safely with the medication prescribed.
DEFINITION SHEET - VALIDATION TOOL
RESPONDING TO SYMPTOMS

The tool is performed 10 times in the same pharmacy. It is not required that the ten symptoms presented are the same.

For the purpose of this tool the following definitions apply:

patient-- the person who is suffering from the symptom or is using the over-the-counter preparations or his representative

symptom(s)-- symptoms related to one condition such as sore throat and running nose are considered as one symptom and one tool should be used

This tool is sub-divided into response to seventeen common symptoms presented at the pharmacy. The first five sections assess general response to symptoms. In sections 6 to 22 the response to the individual symptom is assessed. Only one of the sections 6 to 22 may be filled. After filling the three parts of one of the sections 6 to 22 go to section 23.

General Information and Details of Pharmacist
The Tool ID Number is a unique number assigned to the tool. Assign numbers consecutively to the tools performed in the same pharmacy. For each pharmacy start from 1. The monitor is the person who performs the scoring exercise. The date, time, name of pharmacy and locality of pharmacy are background data necessary for the processing of the tool. Details of the pharmacist present when the tool is performed is essential since the validation process for each community pharmacy has to be performed with the same pharmacist.

Presentation of Symptom
This tool should be used when a patient presents a request for an over-the-counter medicine or presents a symptom. Consider non-related requests for over-the-counter preparations and non-related symptoms presented by the same patient as a different transaction, use a different
Responding to Symptoms tool. In this section list all the symptoms presented and all medications dispensed in relation to the symptom.

**REPORT SHEET**

*For any section where no scores are assigned the monitor has to fill the REPORT SHEET where the section in question and the reasons for not assigning any scores must be documented.*

Sections 1 to 10 covering the procedure of responding to symptoms are described below:

1. The *first* section scores the pharmacist for the commitment made to identify the patient.

   If the pharmacist asks for whom the medication is or is aware who the patient is (for example because of a repeated request), then score (i) applies. If the pharmacist knows the patient and so is aware of the patient’s age, medications taken and allergies, score (ii) applies.

2. In the *second* section the tool aims to assess the information gathered by the pharmacist to establish a profile of the symptoms of the patient.

   If the pharmacist asks the patient to describe the symptom(s), score (i) applies. If the pharmacist asks the patient when did the symptom(s) start and how long has the patient been experiencing the symptom(s), score (ii) holds. If the pharmacist asks the patient whether he is experiencing any other symptoms, score (iii) holds. If the pharmacist asks whether there is anything which makes the symptom(s) worse or makes the patient feel better, score (iv) holds.

   *If during the conversation the patient starts describing the profile of the symptom(s) and all information is presented to the pharmacist without the need for the pharmacist to ask the question(s) then the scores should still be assigned.*
3. This section assesses the procedure carried out by the pharmacist to establish a treatment history of the patient.

   If the pharmacist asks the patient whether he has already used a medication to treat the symptom(s), score (i) holds. If the pharmacist asks the patient whether a medical doctor was consulted for the symptom(s), score (ii) holds. If the pharmacist asks the patient whether the symptom(s) occurred previously and if this was the case, what medication was prescribed or used, score (iii) holds. If the pharmacist checks with the patient what medications are being taken, score (iv) applies.

4. This section assesses the intervention of the pharmacist to check whether there are any risk factors.

   If the pharmacist asks the patient whether he suffers from chronic conditions such as hypertension, diabetes, asthma, cardiovascular disease, score (i) applies. If the pharmacist asks the patient whether he suffers from any allergies (food, medicine) score (ii) holds.

5. In this section the detection of symptoms suggestive of serious disease and the subsequent course of action is assessed.

   If any of the symptoms listed and defined as suggesting the presence of a serious disease are present, scoring is continued at section 25. If no such symptoms are detected then scoring should be continued in sections 6 to 22 depending on the symptom(s) presented (follow the subsections).
### Definition of Symptom Suggestive of Serious Disease

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle swelling</td>
<td>Swelling at ankle excluding swelling after a long distance flight</td>
</tr>
<tr>
<td>Anorexia</td>
<td>When it is a long standing symptom and patient is not following a diet</td>
</tr>
<tr>
<td>Blood loss from any orifice</td>
<td>Excluding minor bleeds and loss due to minor cuts and bruises</td>
</tr>
<tr>
<td>Difficulty in swallowing</td>
<td>Patient presents inflammation of throat</td>
</tr>
<tr>
<td>History of severe injury</td>
<td>Patient is experiencing a symptom related to a past occurrence of severe injury</td>
</tr>
<tr>
<td>Increasing breathlessness</td>
<td>Patient complains of continuous, unusual breathlessness</td>
</tr>
<tr>
<td>Loss of weight</td>
<td>Unexplained i.e. when the patient is not dieting and symptom is long standing</td>
</tr>
<tr>
<td>Menstrual abnormality</td>
<td>Recurrent abnormality: missed periods, frequent periods, heavy flow</td>
</tr>
<tr>
<td>Persistent or recurrent pyrexia</td>
<td>Infection occurring without indication of bacterial infection</td>
</tr>
<tr>
<td>Pain in chest, abdomen, head or ears</td>
<td>Excluding headache</td>
</tr>
<tr>
<td>Spontaneous bruising</td>
<td>Over large areas</td>
</tr>
</tbody>
</table>
Swelling or lumps of any size any location throughout the body

Tenderness over the blood vessels pain over blood vessels

Urinary symptoms incontinence, excluding cystitis

Yellow or green discharge from bacterial or fungal infection penis or vagina

Yellow or green sputum bacterial infection

6-22. In this section questions put forward by the pharmacist specific to the symptom(s) presented by the patient are assessed.

If the information is already available to the pharmacist because the patient has given the information earlier on during the conversation with the pharmacist, then the scores should still be assigned.

6a-22a. This section assesses the pharmacist’s assessment of accompanying symptoms presented.

If any accompanying symptoms are detected, then these should be marked in the list provided in this section. If the accompanying symptom(s) are not included in the list it should be written down in the last row under the sub heading Other. If any of the listed accompanying symptoms is detected since these warrant referral, scoring should be continued at section 27. If no accompanying symptoms requiring referral are present then score (i) is assigned and scoring is continued at section 6b-22b.

6b-22b. In this section the management recommended by the pharmacist is assessed.
23. In this section the information provided to the patient by the pharmacist on how to manage the condition is assessed.

If no medication is recommended but the pharmacist explains home nursing and recommends supportive measures, score (i) holds. If a medication is supplied then scoring should be carried out choosing from scores (ii) - (iv) depending on the extent of information provided. If home nursing as well as a medication is supplied, then scoring should be carried out from (ii) to (iv).

24. This section assesses how the pharmacist ends the session.

If the pharmacist gives some information about the patient's ailment, score (i) holds. If the pharmacist gives information and reassures the patient about symptoms so that the patient feels in control of the situation, score (ii) holds. If the pharmacist tells the patient to come again or seek medical advice if symptoms persist, score (iii) holds.

25. This section assesses documentation carried out by the pharmacist.

If the pharmacist offers diagnostic tests such as BP monitoring, weight, blood analyses, score (i) holds. A list of diagnostic tests recommended according to the symptom(s) is presented below. If the pharmacist provides written information for the patient to pass on to the General Practitioner, score (ii) holds.

*Recommended Diagnostic Tests*

- Ankle swelling: blood pressure monitoring, heart rate, blood glucose analysis, weight
- Anorexia: weight, blood glucose
- Blood loss from any orifice: blood pressure monitoring, heart rate
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Additional Tests/Examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty in swallowing</td>
<td>body temperature</td>
</tr>
<tr>
<td>History of severe injury</td>
<td>examination of the area</td>
</tr>
<tr>
<td>Increasing breathlessness</td>
<td>heart rate, blood pressure monitoring</td>
</tr>
<tr>
<td>Loss of weight</td>
<td>weight, height</td>
</tr>
<tr>
<td>Menstrual abnormality</td>
<td>record of events of previous menstrual periods</td>
</tr>
<tr>
<td>Persistent or recurrent pyrexia</td>
<td>body temperature</td>
</tr>
<tr>
<td>Pain in chest</td>
<td>heart rate, blood pressure monitoring</td>
</tr>
<tr>
<td>Pain in abdomen</td>
<td>body temperature, test strip urinalysis</td>
</tr>
<tr>
<td>Pain in head</td>
<td>body temperature</td>
</tr>
<tr>
<td>Pain in ears</td>
<td>examination of outer ear, body temperature</td>
</tr>
<tr>
<td>Spontaneous bruising</td>
<td>examination of the area, blood glucose analysis</td>
</tr>
<tr>
<td>Swelling or lumps of any size</td>
<td>examination of lumps</td>
</tr>
<tr>
<td>Tenderness over blood vessels</td>
<td>examination of the area</td>
</tr>
<tr>
<td>Urinary symptoms</td>
<td>test strip urinalysis, body temperature</td>
</tr>
<tr>
<td>Yellow or green discharge from penis or vagina</td>
<td>description of discharge</td>
</tr>
<tr>
<td>Yellow or green sputum</td>
<td>description of sputum, body temperature</td>
</tr>
</tbody>
</table>
26. This section assesses recommendation of referral.

If the pharmacist informs the patient about the need to seek medical advice immediately, score (i) holds. If the pharmacist indicates seriousness of symptom and suggests to the patient to seek medical advice if symptoms persist for more than 24 hours, score (ii) holds. If the pharmacist recommends a medication until the patient seeks medical advice, score (iii) holds.

27. This section assesses the procedure undertaken by the pharmacist before referring.

If the pharmacist asks the patient or he is already aware that the patient has a family doctor, score (i) holds. If the pharmacist gives advice to the patient on the procedure to be followed and which actions should be avoided until medical advice is sought, score (ii) holds.

28. This section assesses the method of referral.

If the pharmacist refers the patient to his family doctor, score (i) holds. If the pharmacist offers to phone and make an appointment for the patient who does not have a family doctor, score (ii) holds. If the pharmacist gives the telephone number, clinic times of a general practitioner or of another health professional to a patient who does not have a family doctor, score (iii) holds.

29. This section assesses the general advice provided by the pharmacist.

If the pharmacist offers additional information (verbal advice, written literature) about the symptom(s), score (i) holds. If the pharmacist does not alarm the patient to avoid creating a panic state but indicates the emergency of the situation score (ii) holds.
DEFINITION SHEET- VALIDATION TOOL

COMMUNICATING WITH THE PATIENT

The tool is performed 10 times in each pharmacy

For the purpose of this tool the following definition applies:

    patient -- person who asks for advice from the pharmacist or his representative

General Information and Details of Pharmacist

The Tool ID Number is a unique number assigned to the tool. Assign numbers consecutively to the tools performed in the same pharmacy. For each pharmacy start from 1. The monitor is the person who performs the scoring exercise. The date, time, name of pharmacy and locality of pharmacy are background data necessary for the processing of the tool. Details on the pharmacist present when the tool is performed is essential since the validation process for each community pharmacy has to be performed with the same pharmacist.

Advice Given

This tool is used when the pharmacist gives advice to the patient in any circumstance i.e.

• when pharmacist gives advice to complement a prescribed medicine
• when advice is given upon dispensing an over-the-counter medication
• when patient presents the pharmacist with a symptom
• when patient asks for advice on a medication or on a nonpharmaceutical product

In this section indicate under which circumstance was advice by the pharmacist given and give a brief description under Comments section.

REPORT SHEET

For any section where no scores are assigned the monitor has to fill the REPORT SHEET where the section in question and the reasons for not assigning any scores must be documented.

Sections 1 to 10 covering aspects of communication with the patient are described below:
1. The *first* section looks at the encounter stage when the patient and the pharmacist meet.

   When the pharmacist either gives immediate attention to the patient as soon as he walks to the dispensing counter if there are no other patients or the pharmacist gives immediate attention to the patient who is next at the dispensing counter, score (i) holds. If the pharmacist greets the patient by welcoming him to the pharmacy, score (ii) holds. Perhaps the pharmacist knows the patient and addresses him by name or surname and in that case score (iii) holds. If the pharmacist is known to the patient and if not, the pharmacist introduces himself to the patient, score (iv) applies.

2. Body language presented by the pharmacist to show skills of reception and encouraging two-way communication are assessed in this section.

   If the pharmacist faces the patient by keeping shoulders square to patient, score (i) holds. When the pharmacist keeps a good eye contact with the patient which is varied and consistent but not stare at a distant object, score (ii) holds. When the pharmacist tries to reduce the distance between himself and the patient by leaning towards the patient or moving towards the patient by going down from behind the dispensing counter score (iii) applies. When the pharmacist acts as an open communicator by keeping hands open in relation to torso and not crossed or at the side with palms of hands facing front, option (iv) holds. If the pharmacist maintains an interested facial expression and makes encouraging gestures such as nods, smiles, hand gestures, score (v) applies. If the pharmacist shows that he can understand the feelings of the patient from the body language used by the patient, then score (vi) applies.

3. The *third* section assesses the pharmacist’s attending role.
If the pharmacist allows the patient to talk about things that are of concern to him, score (i) applies. If the pharmacist is a good listener and interrupts the patient only to clarify points mentioned by the patient, score (ii) applies. If the pharmacist uses a pleasant and convincing tone by which he shows that the patient’s experience is understood, score (iii) is assigned.

4. Section *four* assesses the establishment of trust and rapport in improving the pharmacist-patient relationship

When the pharmacist tries to understand the concerns, actions, perceptions, emotions and motivations of the patient, score (i) applies. If the pharmacist respects the dignity and privacy of the patient by speaking confidentially and acting professionally, score (ii) is assigned. When the pharmacist succeeds to establish a relationship built on trust and friendship, then score (iii) applies.

5. The probing carried out by the pharmacist to access relevant information from the patient is assessed in this section.

When the pharmacist poses open ended questions which allow open expression from the patient and only few close ended questions, score (i) applies. If the pharmacist poses close ended questions, which can be answered with either a “*Yes*” or “*No*” response or with few words, and few open ended questions then score (ii) applies. If the pharmacist poses close ended questions only score (iii) holds. If the pharmacist adopts an excessive questioning technique (which results in a passive reaction from the patient), then score (iv) holds.

6. The commitment by the pharmacist to focus on the needs of the patient are assessed in this section.

If the pharmacist asks the patient to repeat the major issues of the counselling session, score (i) applies. If the pharmacist provides concrete
information which is specific information in clear terms score (ii) applies. If the pharmacist does not indulge in telling stories and past experiences, score (iii) applies.

7. In this section assertive behaviour expressed by the pharmacist is assessed.
If when speaking the pharmacist speaks slowly and repeats key information to ensure that he is understood, then score (i) applies. If the pharmacist assumes a preaching, didactic style where he presents himself as an expert, score (ii) holds.

8. Verbal information given by the pharmacist is assessed in this section.
If the pharmacist explains the information given and offers valid reasons, for each issue mentioned, score (i) holds. If the pharmacist projects the image of having a sound background about medications and health-related issues, score (ii) applies.

9. The ability of the pharmacist to detect what is important to the patient is assessed here.
The ability of the pharmacist to adjust to the patient’s background (age, personality, educational level) is scored in step (i). When the pharmacist anticipates that the patient perceives issues discussed, differently from the pharmacist, score (ii) is assessed. When the pharmacist is able to detect the level of knowledge of the patient about medications or a health condition, score (iii) applies. When the pharmacist is able to perceive the expectations of the patient from medications, score (iv) applies.

10. The process of conclusion of the counselling interaction is assessed in this last section.
When the pharmacist asks for any questions on the part of the patient, score (i) holds. If the pharmacist offers any further advice to the patient whenever needed and encourages the patient to contact him if further information is needed, then score (ii) applies. If the pharmacist does not rush the patient through the counselling session score (iii) applies. Score (iv) applies when the pharmacist concludes the process by greeting the patient. If the pharmacist does not end the interview abruptly score (v) applies.
DEFINITION SHEET-VALIDATION TOOL
EQUIPMENT AND PROFESSIONAL SERVICES
AVAILABLE IN A COMMUNITY PHARMACY

For the purpose of this tool the following definitions apply:

- **pharmacist**--the managing pharmacist or the pharmacist on duty
- **controlled drugs**--narcotic and psychotropic drugs which are listed under the relevant legislation depending on the country or state where the study is being run.

*General Information*

The **Tool ID Number** is a unique number assigned to the tool. For this tool, the Tool ID Number given is the pharmacy registration number. The **monitor** is the person who performs the scoring exercise. The **date and time** are background data necessary for the processing of the tool.

*Details of the Pharmacy*

Data on the pharmacy are needed. Since this tool is directed towards the managing pharmacist, the name of the managing pharmacist and the pharmacy board registration number are essential.

**REPORT SHEET**

*For any section where no scores are assigned the monitor has to fill the REPORT SHEET for the section in question and the reasons for not assigning any scores must be documented.*

Section 1 to 10 covering equipment and professional services available in a community pharmacy are described below:
1. The first section assesses the participation of the managing pharmacist in continuing education programmes and the contribution made by the managing pharmacist towards pharmacy practice research and development.

To obtain the data pertaining to this section, information has to be obtained from the managing pharmacist. If the pharmacist regularly attends continuing education lectures organised by professional bodies or sponsored by the pharmaceutical industry, score (i) holds. If the pharmacist periodically reads through professional pharmacy journals such as *The Pharmaceutical Journal, Middle East Pharmacy*, score (ii) holds. If the pharmacist uses information technology such as the internet to access informative professional pharmacy-related web sites, score (iii) holds. If the pharmacist currently has or is willing to have pharmacy students attending for practice sessions in the community pharmacy, score (iv) holds. If the pharmacist collaborates with project supervisors in the collection of data for studies being carried out within the ambit of pharmacy practice research, score (v) applies.

2. In this section references and information sources available in the pharmacy are assessed.

If a recent edition of an indexed drug reference such as the *British National Formulary, The Pharmaceutical Index* is available, score (i) holds. The availability of a current edition of a drug compendium such as *Martindale: The Extra Pharmacopoeia, Physician's Desk Reference* is assessed in score (ii). The availability of a reference book in pharmacology and therapeutics such as *Goodman and Gilman's The Pharmacological Basis of Therapeutics* is scored in step (iii). If an updated copy of laws and regulations relevant to pharmacy is available, score (iv) applies.

3. This section looks into the dispensing equipment available in the pharmacy.

If the dispensing equipment is stored in a clean place such as a cabinet and is kept in good condition and free from dust, score (i) holds. If the tablet and capsule counting...
aids are cleaned after use and kept clean to avoid cross contamination, score (ii) applies. If the dispensing balance is accurate and is checked periodically to be accurate, score (iii) applies.

4. In this section the refrigerator available in the pharmacy is assessed.

If the refrigerator is kept in a cool place in the pharmacy away from direct sunlight, score (i) applies. If the refrigerator is cleaned and defrosted regularly, score (ii) applies. Score (iii) applies when the refrigerator is fitted with a thermometer and if the temperature of the refrigerator is kept between \(20^\circ C\) and \(80^\circ C\) then score (iv) holds. When in the refrigerator either only pharmaceutical items are stored or if this is not the case, pharmaceutical items are stored separately from other items, then score (v) applies.

5. In this section the storage of control drugs is assessed.

If the controlled drugs are kept in a locked cabinet then score (i) holds. If the key is kept by the pharmacist on duty, then score (ii) holds. If a stock control exercise is carried out periodically to check the stock of controlled drugs then score (iii) applies. If the required registers and documentation for controlled drugs is kept up to date then score (iv) holds.

6. This section assesses the containers used for dispensing other than original packs.

If the containers are clean and free from contamination, score (i) applies. If the containers protect medicines from environmental factors such as light, moisture, score (ii) applies. If special containers are used for dispensing such as child resistant, score (iii) holds. If the containers are easy to open by elderly patients and patients suffering from disability such as arthritis, score (iv) applies. If the pharmacy uses different types of containers depending on the medicine dispensed, then the rating should be carried out based on the fact whether the containers are suitable for the specific medicines dispensed.
7. The labels attached to medicines dispensed are assessed in this section.
   If the label is clear, legible and suitable for elderly patients and those with eye sight problems, score (i) is assigned. The preparation of the label using a mechanical printer (typewriter or computerised system) is assessed in score (ii). If the label is prepared so as to be understandable by the patient (e.g. language), score (iii) applies.

8. The weighing scales available in the pharmacy are assessed in this section.
   A routine check carried out to ascertain that the weighing scales are properly calibrated is scored in step (i). If the weighing scales give the reading in the metric system, score (ii) applies. If weighing scales are available for infant weighing in an appropriate area, score (iii) applies. If in the pharmacy there is a reference chart of the average weight, score (iv) holds.

9. The diagnostic equipment used in the pharmacy is assessed in this section.
   The availability of blood pressure measuring equipment is scored in step (i). If the equipment is checked periodically, score (ii) applies. In step (iii) the availability of diagnostic test strips (urinalysis, blood testing) is assessed. In step (iv) the storage of the diagnostic test strips and their routine checking is assessed.

10. In this section documentation of diagnostic tests carried out in the pharmacy is assessed.
    Documentation sheet refers to documentation of the diagnostic test which is kept at the pharmacy for records and/or is given to the patient. Scores (i) to (iv) assess the data compiled within such a documentation sheet.
SECTION VI

THE EXTERNAL VALIDATION TOOLS

Consumer Services
Health Professionals
1. Both tools are intended to be self-administered by consumers of community pharmacy services and non-pharmacist health professionals respectively.

2. To minimize bias the *Consumer Services Tool* should be answered by ten consumers for each community pharmacy where the validation study is undertaken.

3. Non-pharmacist health professionals who have clinics in the area of the community pharmacy where the validation study is undertaken should be asked to participate in the external validation study through the administration of the *Health Professionals Tool*. 
SECTION VII

MARKETING THE VALIDATION TOOLS

Having worked through this handbook and being convinced of the necessity of the validation tools for the development of the pharmacy process, whatever the buzz word that is used at the time - pharmaceutical care, clinical pharmacy, extended role, drug expert or healthcare adviser - it is of paramount importance to communicate this view to the real active personnel. To do this, as the experience in Switzerland amply and successfully shows, there is need of good presentation.

Pharmacy, of necessity, is a subject in which one must be able to talk. This requires practice in itself. The more practice one gets the better one will become and the more confident one will be able to present the case. This handbook is meant to inspire confidence in those wishing to introduce the validation process in their practice. 'Confidence' displayed by the pharmacist in applying the tools is an important aspect of the validation process and the value of a lucid presentation of the tools is enormous. The validation process serves as a mirror of the activity performed. Open the handbook, find a suitable tool, and try it on a colleague or on your preceptor where you carry out your pharmacy practice. 'Validation' needs reassurance and a sense of confidence in application. One has to be fully convinced of what one is doing and present well, avoiding breaks and expressions of doubt such as by using the word "er". Even if one is not very familiar with the subject covered in the tool the text is designed so that one should be able to make up a coherent presentation once it is well practised.

The presentation of the validation process is not the time to demonstrate that a process cannot be improved or that it is a perfect form of assessment. It is the time to invite questions and to show that one has an intelligent assembly of tools to test an example of the essential features used in a good pharmacy practice. In all presentations on introducing validation give
the salient positive findings on the tools presented and also mention the relevant negative aspects.

One is often asked to present the case for the introduction of a validation process to a meeting. This must be properly prepared including visual aids as necessary. The principal details, shown on an overhead projector are helpful as a reminder to you and in this way the audience may more easily remember the details of your presentation if they 'see' as well as 'hear' them. It is worth noting the following points before making your presentation:

- Practise your presentation from beginning to end and leave nothing to chance. Do not assume that the audience are familiar with what you are saying especially if the meeting involves health administrators. Many assume that pharmacy is easy to understand, a case sometimes met with when interacting with some physicians, who may feel that they already know it all and hence they build a protective wall. It is important to break this barrier.

- Do not speak to the screen; speak to the audience. Use your practice of speaking to clients in a pharmacy.

- Do not crack jokes, unless you are confident that they are appropriate. Validation is a new process and those who are yet to be convinced about its advantages may take an easy way out by associating the process with a joke.

- Do not make sweeping statements like 'pharmacy is the best profession'. These do not help.

- Remember that a judgement needs to be passed on your presentation and on it may depend whether validation is adopted or not. In this case it is wise to remember how one is normally advised to act in a court of law - dress up, stand up, speak up, and shut up.
• Read the whole text before you present it as this helps you to answer queries. Read also about other relevant professions. Remember that no pharmacist can work in isolation and that team work is important.

• Read the original references and other research publications on the subject as this makes you feel more confident. In particular read those papers related to the more recently exposed aspects of pharmacy such as those on the development of pharmaceutical care.

• Make your own notes. Do not laboriously repeat the standard information from this handbook. Adapt to your own country, state and institution.

• Research information to develop your own slant in the tools. Your own views may be relevant and precious. Do not hesitate to put them forward. Pharmacy Practice is still developing and your personal contribution to its development may be very factual and practical.

This handbook is designed to help achieve the above. The advantage is that the principal author has herself gone through all the process and so one could follow the text with leisure. Keep the same simple approach and avoid a tendency to complicate matters. The selling point of these tools is in their simplicity in application and in adoption.

The following is a suggested plan of how a presentation for initiating the validation concept in community pharmacy to an audience could be planned:

1. Objective: Introduction of a Validation Process. What is Validation?
2. Present Situation: Give the essential details, other relevant information, possibility of negative reactions and information, extent to which action will interfere with normal activity and mention briefly other relevant problems.

3. Past History: Briefly mention past problems and success of pharmacy practice, list problems still active and how past problems were detected and solved. Record objectives to developing pharmacy practice research.

4. Relation to Others: The involvement of other professionals and consumers. Give a background of the social and communication facilities and record keeping data available.

**Hints for Preparing and Introducing a Validation Process at the Individual Community Pharmacy Level**

When the validator (or researcher) approaches the community pharmacist to introduce the concept of validation there are three initial objectives:

- obtain professional rapport with the pharmacist and gain his confidence.

- obtain all relevant information which allows assessment of the pharmacy and its environment.

- obtain general information regarding the pharmacy, its background, social situation of the area and its major problems.

In particular it is important to relate how these factors affect the pharmacist and his life. The assessment of the pharmacy as a whole is of utmost importance.
The following notes may serve as a guide as to how one may obtain the necessary information. During the taking of a history or making of an examination of the situation at the pharmacy there are two complementary aims:

- Obtain all possible information about the pharmacy and its environment (compose a 'database').
- Present the validation process as a possibility of providing practical tools for identifying existing problems rather than as another form of an old style inspection, which may elicit suspicion and a defensive attitude from the pharmacist.

For each possibility or role one needs to think of a different tool, and each tool has to have the possibility of being self contained. A possible way is to determine a hypothesis for the tool which one will need to support or to reject. A good history would help to make a more specific tool rather than approaching the pharmacist with just a set series of rote questions. However, until one gains experience in carrying out a validation process, one cannot know the possible significance of the information one gathers, and an obvious change of questioning must be considered in the process.

The validator is encouraged to make his own notes, his own observations and write his own tools. After one month he should be sufficiently confident and proficient thanks to his notes and experience. One would have enough knowledge and information to be able to develop a final tool. Each tool should carry a summary explaining the reasons behind the tool and the assessment it intends to make. The validator working on his own may initially find the tool to be incomplete and occasionally incorrect. Nevertheless the exercise will always help pharmacy practice to inculcate an inquiring approach to pharmaceutical care and to highlight areas in which further questioning, investigation or research is needed.
Training to become a pharmacist involved in validation exercises includes the distinct challenges of learning:

- to have a natural, sincere, receptive and when necessary supportive relationship with staff (internal validation tools) and clients (external validation tools).

- to obtain wide experience of the pharmaceutical care process, how this process affects patients and how a pharmaceutical care programme is carried out.

- the optimum means of working with clients and colleagues to facilitate the validation process with the least possible inconvenience.

- to understand the importance of a scientific background of the process including the advances in statistics and information technology which are being made and how these can be applied to improve pharmaceutical care.

**Practice Tips**

Your clinical skills and knowledge can help to develop, adapt and apply validation tools in the community. Take advantage of developments which took place in clinical pharmacy in hospitals and clinics and adapt them to the community. It is particularly helpful to meet as many pharmacists and patients as possible before devising or applying the tools.

- Pharmacy Practice is a practical subject and first hand experience is invaluable. The more pharmacists you can meet, the sooner you will become proficient and the more you will learn about devising relevant validation tools.

- Choose a medium-size text book in which you read up about each disease or process about which one is devising a particular tool.
• Attaching the tool to an individual patient rather than to an epidemiological study is a great help in devising a good practically useful tool. Remember that to practise pharmaceutical care without using text books is like a sailor without a chart, yet to study a medicine rather than the patient is like a sailor who does not go to sea”. Refer to the figure allegory on the validation tools to a boat in Chapter Ten in the book.

• Regularly pick up and read the editorials or any articles which interest you in a general pharmacy journal but it is also an often forgotten exercise which is however very useful to consult medical journals and even those of nursing and other professions. Even if at first you are not able to put information into context, they will keep you in touch with new developments that add interest. Nevertheless, it is not sensible to delve too deeply into any one subject when you are just beginning.

Hints for Action at the Scene of the Validation Process

1. One is advised to take good written notes as these would be found to be of great assistance.

2. Either highlight, underline or mark in a distinct form any key features you will wish to refer to. Another good way is to keep a separate reminder sheet.

3. Talk formally and avoid speaking too quickly or too slowly or having a tête á tête with the pharmacist.

4. Stand upright - it helps to make you appear confident. Do not pass any comments on your appearance or that of anybody else as regards stature, obesity, hearing, eyesight or appearance. Be neither derogatory nor over-pleasant. Look at the person whom you are addressing.
5. Try to avoid interruptions but if they unavoidably occur, start your point again by repeating the last relevant sentence.

6. When dealing with a particular tool, stick to the same format.

7. When interviewing a patient never argue with the patient or even appear to argue. If the patient wishes to make an additional point or clarification it is best to welcome this. If irrelevant, politely say to the patient you will come back to this in a moment, after you have completed the interview.

**Final Tips**

In introducing these validation tools a significant amount of disaster, or great deal of irritation and frustration and a lot of unpleasantness can and must be avoided in a community pharmacy setting by proper communication. Do not treat the medical doctor as the "boss" but as part of a team all of whom significantly help the patient. It is only good courtesy if on the first visit one takes time to meet the staff at the pharmacy and find out what their job is, what their difficulties are and how they view the patient and yourself.

**Points to Remember**

**TIME:** On the one hand one must respect the time that the pharmacist and patients are giving. On the other hand when you talk to anyone, try not to appear in a rush or they will lose concentration and not listen. A little time taken to talk to somebody properly will help enormously.

**LISTEN:** Active listening to someone is not easy but is essential for good communication. Many people stop talking but not all appear to be listening. Sitting down with the pharmacist and the patient during parts of the interview if possible may be advantageous both in helping you to concentrate and in transmitting to the pharmacist and patient that you are willing to listen.
**SMILE:** Grumping or irritation is the best way to destroy your project. The pharmacist or patient may just put on their brakes and stop. A smile helps everybody to relax and is essential since validation is sometimes associated with an examination and may cause the same sense of apprehension.

**REASSURANCE:** If you appear confident and relaxed this helps others to feel the same. Being calm without excessive body movements can help. Reassure the pharmacist and his team that they are (or are capable of) working effectively.

**HUMILITY:** No one, in particular the pharmacist or patient is inferior to you.
References


