Achieving Responsible Use of Medicines - Real Patients, Real Policy, What Really Works?

Symposium for Senior Pharmaceutical Policy Makers
Thursday 29 and Friday 30 August, 2013
Royal College of Physicians of Ireland, Dublin, Ireland

INTRODUCTION TO THE SYMPOSIUM
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Acknowledgements

We are delighted to have the support of the following organisations and individuals for this Symposium:

Organisations
- Council of Europe - European Directorate for the Quality of Medicines & HealthCare (EDQM)
- International Pharmaceutical Federation (FIP)
- IMS Institute for Healthcare Informatics (IMS)
- Pan American Health Organization (PAHO)
- The Pharmaceutical Society of Ireland (The Pharmacy Regulator) (PSI)
- World Health Organization (WHO)

Individual Champions
- Dr Kees de Jongheere, Director, Essential Medicines and Health Products, WHO
- RADM Scott Giberson, U.S. Assistant Surgeon General and Chief Pharmacy Officer for the United States of America Public Health Service
- Dr James Fitzgerald, Unit Chief, Medicines and Health Technologies, PAHO/WHO
- Dr Keith Ridge, Chief Pharmaceutical Officer, England
- Professor Bill Scott, Chief Pharmaceutical Officer, Scotland
- Dr Mark Timoney, Acting Chief Pharmaceutical Officer, Northern Ireland
- Professor Roger Walker, Chief Pharmaceutical Officer, Wales
- Dr Sabine Walser, Administrative Officer, EDQM

Project Manager and Advisory Committee
- Ms Leonie Clarke, Pharmaceutical Consultant, has acted as Project Manager for the Symposium
- Symposium Advisory Committee
  - Mr Luc Besancon, General Secretary/Chief Executive Officer, FIP
  - Dr Stephen Byrne, Senior Lecturer in Clinical Pharmacy & Course Director, MSc in Clinical Pharmacy, School of Pharmacy, University College Cork, Ireland
  - Ms Sinead McCool, Pharmacist & Continuing Education Consultant, Ireland
  - Dr Norman Morrow, retired Chief Pharmaceutical Officer, Northern Ireland
  - Ms Joanne O’Brien, Primary Care Pharmacist, Health Service Executive, Ireland
  - Ms Kate O’Flaherty, Head of Communications & Public Affairs / Acting Head of Pharmacy Practice Development, PSI & incoming Director of Health & Wellbeing Programme, Department of Health, Ireland
1. Welcome to the Symposium on Achieving Responsible Use of Medicines

This Symposium has been organised by the Irish Department (Ministry) of Health as a follow-up to the Health Ministers’ Summit which took place in Amsterdam in October 2012 on ‘The Benefits of Responsible Use of Medicines’. It also coincides with the FIP World Congress 2013 that is taking place in Dublin on 31 August – 5 September.

The main theme of the Symposium, ‘Achieving Responsible Use of Medicines - Real Patients, Real Policy, What Really Works?’ is based on the key outcomes from the Health Ministers’ Summit. Three sub-themes have also been identified:

- Government policy and enhancing responsible use of medicines to improve patient outcomes;
- Patients as key players in achieving responsible use of medicines;
- Measuring responsible use of medicines, sharing experience on how to measure responsible use of medicines and its value in health policy making.

The aim of the Symposium is to facilitate and promote collaboration by senior pharmaceutical policy makers from countries around the world to enhance the responsible use of medicines within healthcare systems and by healthcare professionals and patients. The Symposium will also focus on the value of measuring responsible use of medicines.

The Irish Department of Health has worked with WHO, EDQM, PAHO and the Symposium Advisory Committee to develop the programme for the Symposium which has been designed to examine the theme of ‘Achieving Responsible Use of Medicines’ through a series of presentations, workshops and panel discussions. We are delighted to welcome many international speakers, facilitators and delegates to this Symposium to share their experiences and views on this important theme.

This paper, which has been prepared by the Department of Health, describes the background to the Symposium and sets out some of the key topics for examination over the course of the Symposium. Delegates are encouraged to reflect on this paper, together with the reports associated with the Health Ministers’ Summit, in advance of the Symposium.

We sincerely hope that everyone who takes part in this Symposium will value the opportunity to discuss the theme of responsible use of medicines with colleagues from other countries.

We look forward to meeting you in Dublin.
On behalf of the Department of Health

Dr Ambrose McLoughlin
Secretary General

Marita Kinsella
Chief Pharmacist
2. About the Theme: Achieving Responsible Use of Medicines

This Symposium aims to build on discussions about the responsible use of medicines at the 2012 Health Ministers’ Summit. That Summit brought together Health Ministers and other senior policy makers from a range of countries around the world to discuss the theme of ‘The Benefits of Responsible Use of Medicines – Setting policies for better and cost-effective healthcare.’

Health Ministers’ Summit

The Dutch Ministry of Health commissioned two reports to form the basis for the discussion at the Summit:

- WHO: ‘The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences’¹ ['WHO report']
- IMS Institute for Healthcare Informatics: ‘Advancing the Responsible Use of Medicines – Applying Levers for Change’² ['IMS Institute report']

In addition, EDQM prepared a report on its work regarding the quality philosophy and working method of pharmaceutical care entitled ‘Pharmaceutical Care - Policies and Practices for a Safer, More Responsible and Cost-Effective Health System’³ ['EDQM Report'].

Focus of the Health Ministers’ Summit

The Summit focused on how to capture lost value of medicines due to suboptimal use based on the idea that value of medicines could be gained if medicines were:

- matched to the right patient at the right time, e.g. optimising antibiotics use, preventing medication errors, making greater use of generics and managing polypharmacy;
- taken appropriately by the patient through increased adherence, especially in chronic care, and a reduction in medicines abuse;
- used within the right capabilities, i.e. by supporting system-based capabilities such as enhancing information and health informatics and ensuring robust national medicines policies.

Outcomes from the Health Ministers’ Summit

The Health Ministers’ Summit endorsed the following principles relating to the responsible use of medicines:

- Coordinate and incentivise better alignment between healthcare professionals to foster continuity of care and better management of medicines;
- Ensure patient needs determine policies to manage key usage issues, such as non-adherence which is the single largest cause of suboptimal use of medicines;
- Show commitment to successful initiatives in innovation and learning;
- Support evidence-driven policy making by investing in healthcare data to plan and evaluate effective intervention policies.

Separately, the Summit called for global action against antimicrobial resistance and highlighted the need for better management of antimicrobials in every country.

Theme of the Symposium - Achieving Responsible Use of Medicines

The main theme of the Symposium, ‘Achieving Responsible Use of Medicines – Real Patients, Real Policy, What Really Works?’ is based on the key outcomes from the Health Ministers’ Summit.

As the programme for this Symposium has been designed to facilitate the continued examination of the concept of responsible use of medicines, the following subthemes will also be explored:

- Government policy and enhancing responsible use of medicines to improve patient outcomes;
- Patients as key players in achieving responsible use of medicines;
- Measuring responsible use of medicines, sharing experience on how to measure responsible use of medicines and its value in health policy making.

How is ‘Responsible Use of Medicines’ defined?

For the purposes of this Symposium, the interpretation of the term ‘responsible use of medicines’ as set out in the WHO and IMS Institute reports has been adopted.

Both reports describe the term ‘responsible use of medicines’ as ‘the activities, capabilities, and existing resources of health system stakeholders are aligned to ensure patients receive the right medicines at the right time, use them appropriately, and benefit from them’.

This description complements the WHO definition of ‘rational’ use of medicines, i.e.
Medicine use is rational (appropriate, proper, correct) when patients receive the appropriate medicines, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost both to them and the community. Irrational (inappropriate, improper, incorrect) use of medicines is when one or more of these conditions are not met.4

These definitions focus not just on the right medicine for the right patient at the right time but also identify the need for a collaborative approach by patients, healthcare professionals and policy makers to achieve responsible use of medicines through evidence-based decision making and appropriate monitoring.

Why is the ‘Responsible Use of Medicines’ important?

Medicines are the ubiquitous technology in healthcare systems in the sense that they are the most frequently and widely used intervention. Although pharmaceutical expenditure typically constitutes a significant proportion of healthcare budgets, second only to staffing costs, medicines remain one of the most cost-effective interventions available to manage patients. Advances in pharmaceutical research mean that there are now treatment options available for diseases and conditions that were previously inevitably fatal or significantly reduced patients' quality of life.

However, there are challenges associated with the use of medicines including:

- The growing cost of pharmaceutical innovation when government resources are under pressure;
- The fact that many medicines do not have the optimal effect because the wrong medicine is used or because it is not taken correctly;
- Limiting the adherence risk around the use of medicines;
- The lack of infrastructure to support the effective delivery and use of medicines in many parts of the world.

These factors potentially combine to result in patients not accessing the medicines they need when they need them or getting suboptimal outcomes from the medicines that they do take. Together this represents an inefficient use of limited healthcare resources, both in terms of the medicines themselves as well as the professionals involved in the supply and administration of the medicines to patients.

In addition, there is pressure on many countries to reduce spending on health while achieving greater efficiencies and improving patient outcomes. The IMS Institute

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report estimates that 8% of total health expenditure, or about $500 billion (US dollars) per annum could be saved through optimising the use of medicines. The report suggests that implementing a strategy of responsible use of medicines should be a top health priority to improve health outcomes as well as the potential budgetary impact. In order to achieve this goal policy makers must consider and measure the impact on the quality and safety of patient care of potential cost-saving measures.

**WHO and IMS Institute reports on responsible use of medicines**

The WHO and the IMS Institute reports both include several examples of good practice and successful initiatives from different countries in achieving responsible use of medicines. The WHO report sets out policy lessons from case studies from low- and middle-income countries. It makes a number of recommendations which are intended to guide national policy makers to create a policy framework for responsible use of medicines. The IMS Institute report provides an insight into the drivers of inefficiencies in medicines use and the levers that can make a difference in responsible use of medicines. It also quantifies the avoidable costs of suboptimal use of medicines and provides a series of recommendations to enhance responsible use of medicines based on the evidence from case studies in low-, middle- and high-income countries.

The WHO and IMS Institute reports both emphasise that:

- medicine prescribers, pharmacists and other dispensers, and patients are key stakeholders in the process of responsible use of medicines.
- A functioning delivery system is a prerequisite to the implementation of the recommendations regarding the responsible use of medicines.
- certain capabilities need to be in place in a healthcare system, ranging from a reliable and resilient supply system to robust quality controls and appropriate healthcare financing.

**EDQM report on pharmaceutical care**

The EDQM report approaches responsible use of medicines from an alternative angle. It makes the case for the value of pharmaceutical care and how it can improve the efficient and safe use of medicines, leading to the best possible medication outcome for the patient which is the ultimate goal of responsible use of medicines. Pharmaceutical care involves the process through which a pharmacist co-operates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. The report concludes that implementing pharmaceutical care as a necessary quality-enhancing element in healthcare requires innovative approaches to improve patient participation, inter-professional collaboration in terms of therapeutic planning and monitoring, and a better focus on improving medicine use through monitoring of outcome-related indicators of pharmaceutical care.
In order to measure the impact of pharmaceutical care, under the auspices of the EDQM, experts from authorities and academia are currently co-operating on a pilot project to develop, test and validate a basic set of pharmaceutical care quality indicators across different countries in Europe (in and beyond EU member states), disciplines, medical traditions and healthcare systems with harmonised working approaches. The European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (steering body) within the EDQM is co-ordinating this work. The preliminary findings of this project will be presented at the Symposium.

**Exploring the theme of ‘Achieving Responsible Use of Medicines’ at the Symposium**

The work documented in the WHO, IMS Institute and EDQM reports which were prepared in advance of the 2012 Health Ministers’ Summit has provided a very valuable basis for this Symposium. The Irish Department of Health therefore wishes to acknowledge these three organisations for their permission to reference the reports in this paper and at the Symposium.

In preparation for the Symposium, delegates are encouraged to reflect on the three reports:

- WHO: ‘The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences’
- IMS Institute for Healthcare Informatics: ‘Advancing the Responsible Use of Medicines – Applying Levers for Change’
- Council of Europe, European Directorate for the Quality of Medicines and Healthcare (EDQM): ‘Pharmaceutical Care - Policies and Practices for a Safer, More Responsible and Cost-Effective Health System’

For the convenience of delegates, a summary of the recommendations from each of the reports has been included in the Appendix to this paper.

The Symposium has been designed to examine the theme of ‘Achieving Responsible Use of Medicines’ through a series of presentations, workshops and panel discussions. Speakers from around the world have been invited to the Symposium to make presentations on the theme of responsible use of medicines from the perspective of policy makers and patients. Each of the presentations is intended to address various elements of the theme such as adherence, pharmaceutical care, access to medicines, medication safety, and supply chain issues. There will also be a

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strong focus on the value of evaluating and measuring the impact of new approaches to achieving responsible use of medicines.

Delegates will also have the opportunity to ask questions and share their experiences formally at the plenary sessions and workshops as well as informally over the course of the Symposium.
3. Overview of the Symposium Programme

This section is intended to provide an overview of the different elements of the Symposium. To see the full programme, please visit the Symposium webpage at http://www.dohc.ie/issues/symposium/.

Networking Event - Thursday 29 August 2013

All delegates are invited to the Networking Event on the evening of Thursday 29 August which will give delegates the opportunity to renew connections and meet new colleagues from other countries with similar roles and areas of interest in an informal setting.

Symposium - Friday 30 August 2013

The Symposium on Friday 30 August will comprise a number of elements:

Presentations from invited speakers

Invited speakers from around the world will set the scene through a series of presentations on topics such as the role of patients in responsible use of medicines, evaluating services provided by community pharmacists and what still needs to be done in ensuring patient access to medicines.

Flash Presentations

In addition, there will be a series of short updates on projects/initiatives from around the world that aim to enhance responsible use of medicines to provide a forum for those who wish to share progress on key projects with other participants.

Panel Discussion

A panel discussion session will allow speakers and delegates to exchange views on the topics covered in the Presentation session.

Workshops

The afternoon session will be mainly devoted to a series of small group workshops which aim to:

1. Give delegates the opportunity to share ideas and experiences with colleagues with common interests;
2. Examine initiatives and policies related to the workshop theme that delegates have been involved in;
3. By collectively analysing the issue, to identify possible innovative new approaches and policies;
4. Identify if there are opportunities for participants to collaborate on relevant projects or policy initiatives.

For each topic, the participants at the workshop will identify the problem(s) that need(s) to be addressed, look at solutions and identify key learnings. The output of each workshop will be shared with all participants at the final plenary session.

**Informal Networking**

Delegates will have the opportunity to continue informal discussions with colleagues over lunch and coffee breaks.
4. Next Steps

**FIP 2013**

The outcomes of the Symposium will be presented at the FIP Pharmacy World Congress in Dublin on Tuesday 2 September.

**Symposium Report**

A written report of the Symposium will be prepared and made available to all delegates in the Autumn of 2013.
WHO report on responsible use of medicines

The WHO report, through a series of eleven case studies from developing countries around the world, provides sound practical examples of national-level policies to promote the responsible use of medicines. The report’s recommendations aim to guide national policy making at two levels. Seven high level strategic recommendations are designed to create the policy framework for responsible use of medicines and each one is accompanied by more concrete, point-of-implementation tactical recommendations linked to the relevant case studies. A summary of these recommendations is set out below:

- **Strategic recommendation 1:**
  Develop and mandate a List of Essential Medicines at the national level to inform reimbursement decisions and ensure access to essential medicines.
  - **Tactical recommendation 1.1:** A list of essential medicines should be identified at the national level to regulate access to medicines in public healthcare facilities and to ensure a broader, more efficient use of these medicines.
  - **Tactical recommendation 1.2:** Partial to full reimbursement should be granted at the national level to medicines included in the essential medicines list in order to increase access and promote their use in the healthcare system.

- **Strategic recommendation 2:**
  Invest to ensure national medicines procurement and supply systems are efficient and reliable to support the responsible use of medicines.
  - **Tactical recommendation 2.1:** Establish centralised, tender based procurement of essential medicines. Funds for medicines provided by international aid organisations should preferably be used through the same system, and comply with national priorities.
  - **Tactical recommendation 2.2:** Establish routine quality testing procedures to verify that medicines procured through the national tendering system are of assured quality. Results of quality tests should inform the selection of medicine suppliers.
  - **Tactical recommendation 2.3:** Establish a routine performance feedback system to ensure that suppliers who cannot deliver medicines of assured quality in time are informed, and excluded from future tenders.

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- **Strategic recommendation 3:**
  
  Promote a shift in focus to early screening and accurate diagnosis to guide / inform medicines prescription and avoid overuse, underuse and misuse of medicines.

  - **Tactical recommendation 3.1:** Promote focus on accurate diagnosis, with the aid of diagnostics where possible, in order to guide the appropriate prescription of medicines.
  
  - **Tactical recommendation 3.2:** Mandate early screening in at-risk segments of the population to ensure patients are diagnosed in time to maximise the benefits of treatment.

- **Strategic recommendation 4:**
  
  Facilitate the implementation of evidence-based treatment guidelines; where they exist, remove regulatory or administrative barriers and directly target all key stakeholders: prescribers, dispensers and patients.

  - **Tactical recommendation 4.1:** Sensitise and promote the engagement of prescribers, dispensers and patients through multi-stakeholder workshops, determining educational requirements for healthcare professionals, and public information campaigns.
  
  - **Tactical recommendation 4.2:** Reassess regulatory requirements on the dispensing of selected medicines to ensure their wider availability and accessibility. Regulations should permit over-the-counter availability of medicines of appropriate risk–benefit.
  
  - **Tactical recommendation 4.3:** Reduce redundant paperwork and the administrative burden of prescribing / dispensing particular essential medicines to ensure appropriate patient access.

- **Strategic recommendation 5:**
  
  Promote initiatives that put patients at the centre of treatment in order to maximise adherence to therapy.

  - **Tactical recommendation 5.1:** Promote the creation of, and provide technical support to community-based initiatives aimed at improving patient engagement and adherence to treatment.
  
  - **Tactical recommendation 5.2:** Facilitate healthcare professionals in providing closer therapy support to patients, to motivate their health-seeking behaviour.

- **Strategic recommendation 6:**
  
  Monitor medicine use, from purchase to health outcome, to evaluate the real-world efficacy of treatment and guide evidence-based policy making.
- **Tactical recommendation 6.1**: Institute a system of centralised monitoring of the purchase of medicines to inform budgeting and ensure optimal funding allocation to essential medicines.
- **Tactical recommendation 6.2**: Collect data on medicine use at the national level to identify and evaluate prescribing trends and expenditure.
- **Tactical recommendation 6.3**: Design a system to measure patient use of medicines, preferably at the point of dispensing, to assess patient adherence to therapy.
- **Tactical recommendation 6.4**: Design a system to collect and aggregate information on patient health outcomes to measure real-world efficacy and safety of medicine use.

- **Strategic recommendation 7:**
  Ensure sustained, top-down commitment of national authorities and promote active, bottom-up engagement of prescribers, patients and dispensers to the principles and policies fostering the responsible use of medicines.

- **Tactical recommendation 7.1**: National authorities should provide sustained, top-down policy and financial commitment to initiatives fostering a responsible use of medicines.
- **Tactical recommendation 7.2**: Build consensus on medicine use among national and local stakeholders by stimulating the active engagement of prescribers, dispensers and patients.

On the role of governments in the pursuit of responsible use of medicines, the WHO report states that it is not necessary for Ministries of Health to own every step of the process and argues that good regulation of the market along with public-private partnerships and private contributions also have a role to play.
IMS Institute report on responsible use of medicines

The IMS Institute report includes over 50 recommendations that address six specific levers of suboptimal use of medicines:

- Patient non-adherence
- Untimely medicine use
- Antibiotic misuse and overuse
- Medication errors
- Suboptimal generic use
- Mismanaged polypharmacy

These recommendations are distilled into five ‘top’ recommendations based on low implementation costs, best potential for improving health outcomes and rapid time to impact. These five recommendations along with the key success factors identified for each one are summarised below:

1. **Support greater role of pharmacists to own medicines management for patients**
   - Engage multiple stakeholders, especially pharmacists’ contribution;
   - Remunerate for additional services;
   - Collect, track, and analyse data;
   - Easy access to patients (e.g. phone or face-to-face);
   - Improve communication skills.

2. **Invest in medical audits targeting elderly patients who are more likely to be taking multiple medicines**
   - Collect data on elderly patients’ medication regimens;
   - Mandate regular audits;
   - Remunerate for the service.

3. **Implement mandatory reporting of antibiotic use by provider**
   - Collect data on antibiotic prescribing and dispensing;
   - Summarise and report the data publicly;
   - Institutionalise antibiotic use reporting;
   - Invest in human resources to enforce / manage / analyse reporting.

4. **Encourage positive attitude and culture towards error reporting**
   - Establish policies that encourage disclosure of errors;
   - Engage all healthcare workers;
   - Provide a system for error reporting;

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- Educate health professionals on how to report errors and how to reduce errors.

5. **Support targeted disease management programmes for prevalent non-communicable diseases, such as diabetes, in patients at highest risk**
   - Set up a data tracking system;
   - Engage multiple stakeholders;
   - Invest in remuneration and infrastructure;
   - Educate on communication skills and IT use.

The IMS Institute’s recommendations and underpinning analyses are based on insights from policy interventions and case studies with proven quantified impact from a health outcome and/or cost containment perspective. The intention is that these evidence-based examples from different countries will inspire health policy leaders to tackle these challenges in a targeted way.

The report makes the point that the feasibility of these recommendations varies country by country and depends on the relevant Health Minister’s corresponding spheres of influence to drive change and that a combination of the following factors is necessary for successful implementation: policies to trigger improvement in medicines use; stakeholder collaboration; education of health professionals and patients; availability of health informatics for informed decision-making; and the alignment of incentives to optimise clinical and/or dispensing practices.
EDQM report on pharmaceutical care\textsuperscript{10}

Pharmaceutical care is a quality philosophy and working method for professionals within the medication process. The EDQM report cites the definition of pharmaceutical care established by Charles D. Hepler and Linda M. Strand\textsuperscript{11}, i.e.

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life.

As stated previously, pharmaceutical care involves the process through which a pharmacist co-operates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This, in turn, involves three major functions:

1. identifying potential and actual drug-related problems;
2. resolving actual drug-related problems; and
3. preventing drug-related problems.

The EDQM report invites Governments and policy makers to:

- Acknowledge that optimal health and development should be built on the core pillars of participation, promotion, protection, prevention and provision and that an appropriate healthcare approach must be patient-focused and ensure patient participation in the healthcare decisions affecting them, fostering their medication-related health literacy;
- Commit to take specific action against health damage, diminished quality of life, workforce reductions, and wasted healthcare resources that arise from the inappropriate use of medicines and drug-related problems;
- Acknowledge available evidence that the pharmaceutical care philosophy and working methods can help achieve the benefits of responsible medicine use for individual patients and healthcare systems at national and regional levels by addressing issues of inappropriate medicine use in a comprehensive manner and, thereby, improving patient outcomes;
- Promote and implement the pharmaceutical care philosophy and working methods in their national healthcare systems;
- Introduce in all countries of the world, generally applicable quality indicators for pharmaceutical care to provide themselves with valid information for policy making and to set professional standards and best practices in the field;


\textsuperscript{11} Hepler CD & Strand LM. Opportunities and Responsibilities in Pharmaceutical Care. Am J Pharm Educ; 1989(53): 75-135
• In this context, support the wide application of generally applicable quality indicators for pharmaceutical care, as detailed in the EDQM report, and provide for a mid-term strategy to follow up on the results and measures taken in response to the data generated;
• Support programmes and activities for international collaboration to further develop pharmaceutical care standards, guidelines and training for the implementation and monitoring of pharmaceutical care using, inter alia, generally-applicable and specific quality indicators;
• Avail themselves of the professional expertise of public health institutions, relevant professional associations (notably of pharmacists, medical doctors, nurses and other relevant professions) and patient organisations.