Medicines information

Strategic development

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List of abbreviations

CMI	Consumer medicine information
DH	Department of Health
HCP	Health care professionals
MI	Medicines information
NHS	National Health Service (UK)
OTC	Over the counter
PCTs	Primary care trusts
PMI	Patient medicines information
WG	Working group

Foreword

Medicines information encompasses information targeted at health care professionals as well as patients and consumers of medicines, with the primary aim of educating individuals about medicines. Medicines information for health care professionals aims to support them in their patient-care roles, while medicines information targeted at patients and consumers of medicines aims to ensure quality, safe and effective use of medicinal products.

Globally, a range of stakeholders are involved in the development and dissemination of medicines information to health care professionals and consumers. These groups range from pharmaceutical manufacturers, to health organisations, individual health care practitioners and, more recently, other consumers through the Internet, particularly social networking sites.

Medicines information is available in a range of written formats, as spoken information and through the Internet, which is becoming increasingly accessible and popular for consumers. Often the information obtained by consumers is inaccurate, overwhelming, biased, unhelpful or not well understood. Consumers want information that they can trust, understand and act on, and which supports their medicine taking and quality use of medicines.

To this end, many countries have implemented legislation and guidelines for the development and dissemination of medicines information to health care professionals, patients and consumers. In some countries, the approach has been health-systems-based, embedding a medicines information strategy as part of a national medicines policy. In others, the approach has been set in pharmaceutical policies and legislation. There are also many countries that do not have a well-defined or coordinated strategy for a number of reasons; limited resources, for example.

This report provides experience from countries where medicines information strategies exist, and describes the core elements of a medicines information strategy, including how such strategies can be developed. Furthermore, this report identifies how a medicines information strategy can be integrated into broader medicines management policies in low-resource settings. Importantly, this report defines and promotes the role of the pharmacist, within a multidisciplinary team, in the strategic development and implementation of national medicines information policies and practices. Pharmacists, thanks to their diverse roles and breadth of practice settings, are ideally positioned to develop policy on medicines information in collaboration with other health care professionals and stakeholders; and to develop and disseminate medicines information broadly, as well as specifically targeted to their patients and clients.

This reports sets a vision for the International Pharmaceutical Federation (FIP) and pharmacy organisations around the world, as well as individual pharmacists, for collaboration and action towards high quality medicines information through well-planned, structured medicines information strategies that are embedded in national medicines policies. While it is imperative that pharmacists and other health care professionals provide information in a way that is understood and can be acted on by patients and consumers, it is important that health care professionals are well supported with quality and regulated written medicines information, by the Internet, and by the health system. The health system should provide the supportive setting that promotes the provision of medicines information, and its use as a patient-centred tool paramount to informed treatment decision-making.

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Executive summary

Medicines information (MI) is essential in enabling patients to use medicines appropriately and safely. Although a wide range of MI sources and services exist, more attention should be paid to coordinating these resources in health care. The potential to learn from other countries' experiences, especially those with established MI policies and strategies, should be capitalised upon. Through working across borders, a global approach to developing MI may be reached and linked with medicines management policies.

In order to engage and promote the role of the pharmacist in the strategic development and implementation of national MI policies and practices, the FIP Working Group on Strategic Development and Use of Medicines Information was set up to collate and share information on existing national policies, strategies and initiatives to support the development and provision of MI aimed at health care professionals and the public; and to identify the core elements that should be considered in developing a national MI strategy.

This report aims to set out a vision for FIP and pharmacy organisations internationally for collaboration and action towards high quality MI. The report describes the goals and outcomes of strategic development of MI; gives examples from countries where MI strategies exist; describes the core elements of a MI strategy as well as the process of strategic development of MI; and discusses strategic development of MI within medicines management policies in low-resource settings.

The working group used various methods to compile this report: (i) An Internet member survey of all FIP sections members in 2013; (ii) Collation of information about existing MI development strategies or policies identified primarily using online websites; (iii) A three-hour workshop session during the 2014 World Congress of Pharmacy and Pharmaceutical Sciences entitled "Experiences in developing and implementing national medicines information strategies"; (iv) An evaluation of existing FIP policy statements related to MI; and a review of the research literature from peer-reviewed journals as well as selected documents describing strategic development of MI.

Main findings:

- MI is an important part of health care, and key to the safe and effective use of medicines.
- Few countries have national MI strategies. Strategic development of MI is often included as part of national drug policies or action plans. Furthermore, MI is often seen as part of pharmacovigilance work.
- There is widely available guidance on how to compile written MI, although not extensively used.
- National medicines policies that can incorporate a MI strategy are needed.
- Pharmacists' expertise is needed to guide development and implementation of MI strategies within national medicines and health policies.
- Possibilities for strategic development of MI in low-resource settings differ from other parts of the world.

Observations for the strategic work

An inter-professional approach and widespread cooperation between stakeholders is essential in the strategic development of MI. Broad networking will positively affect the implementation of the strategy. The development of the MI strategy should be based on the current MI situation in the country / area, (i.e. identify existing good practices, as well as gaps). Research into the strategy process, analysing the evidence and informed decision-making play an important role in MI strategy development.

A vision for the strategy, alongside relevant aims and actions should be clearly defined: what is meant to be achieved; how; and according to what specific timetable. Desired outcomes should be explicit and interim markers of success used. Assessment of the strategy should be an integral part of the strategy process. Implementation of the MI strategy should be supported with resources. It should also be recognised that implementation will take time.

Recommendations

To pharmacy organisations:

- Initiate strategic development of MI nationally.
- Demonstrate the importance of MI to increase rational medicine use, medication safety and increased adherence.
- Be actively involved where strategic development of MI is started.

To pharmacists:

- Recognise the role of MI in relation to rational medicine use, medication safety and increased adherence.
- Use reliable MI sources appropriately.
- Demonstrate your MI expertise to other health care professionals and participate in inter-professional collaborative initiatives.

To educational organisations of health care professionals:

- Include inter-professional courses in the curriculum.
- Include skills on how to use MI databases and clinical decision-making tools in daily practice in the curriculum.
- Include the effective use of reliable MI sources in the curriculum.
- Promote the development of exemplary medication counselling skills.

To governments:

- Compile national medicines policies that include strategic development of MI.
- Compile national MI strategies to illustrate challenges and needs more explicitly.
- Provide resources and support to allow such work to be undertaken (including promoting and acknowledging the importance of medicines information).
- Oversee the implementation of accepted MI strategies and guidelines.
- Develop the criteria for certifying or accrediting MI centres and MI resources in collaboration with professional and educational bodies; and implement them.

1 Operational definitions

Medicines information (MI) is a broad term encompassing information targeted at health care professionals (HCPs) and patients, and available and provided in written, electronic or verbal forms.[1] It includes:

- Statutory or regulatory information, and product specific information on medicines (e.g. summary of product characteristics [SPCs] and patient information leaflet [PILs] in the EU)
- Written MI materials targeted at patients and HCPs
- MI tools, databases and information systems used in day-to-day practice by HCPs (e.g. medication review tools and drug interaction programmes)
- MI provided by drug/medicines information centres
- Oral patient education and counselling

Strategy refers to the tools and means of facilitating the implementation of a vision. A MI strategy is understood as a guideline or policy that provides recommendations on how MI could be developed, provided and organised nationally or regionally for HCPs and patients. In such a strategy, all the forms of MI described above should be taken into account. All stakeholders engaged in development and use of MI can then adopt this strategy in their own practices.

Patient counselling refers to the communication about medicines between pharmacists or other HCPs and patients.[2,3,4]

Medicines information centre (MIC) and **drug information centre (DIC)** refer to MI services where people can call or otherwise contact HCPs and inquire about medicines.[5]

2 Introduction

The current trend in health care emphasises patient-centred care through increased consideration of patient perspectives and greater patient involvement in their own health care and disease management. Medicines information (MI) is essential in order to empower patients in their medicine use, and to ensure rational and safe use of medicines and adherence to long-term therapies.[6] MI is also integral to many other aspects of pharmacy practice activities, including, for example, legislation and guidelines to be followed, or the databases and information systems that health care professionals (HCPs) use in day-to-day practice. In the future, the role of MI will increase further as pharmacotherapies become increasingly individualised. Thus, pharmacists should take an active role in developing and delivering MI practices. However, effective multidisciplinary, inter-professional collaboration is also needed to ensure that MI services have a positive impact on patients' medicines taking behaviour.

Although a wide variety of MI sources and services exist, more attention should be paid to coordinating these resources in health care. For example, the European Commission High Level Pharmaceutical Forum highlighted in 2008, among other things, the need to consider national strategies in order to meet consumer needs for MI, and furthermore, that provision of MI should be a shared responsibility of all stakeholders in health care.[7] Thus, there is a recognised need for strategic development and implementation of MI for consumers. The potential to learn from other countries' experiences should be capitalised on, especially from countries that have established policies and strategies. By assisting one another, a global approach to developing MI may be reached and linked with medicines management policies.

In order to engage and promote the role of the pharmacist in the strategic development and implementation of national MI policies and practices, the FIP Working Group on Strategic Development and Use of Medicines Information was set up, with the following specific objectives:

- To collate and share information on existing national policies, strategies and initiatives to support the development and provision of MI aimed at HCPs and the public;
- To identify the core elements that should be considered in developing a national MI strategy;
- To encourage pharmacists to take a leading role in the development of policies and strategies to strengthen MI provision; and
- To promote the role of pharmacists in the day-to-day development and provision of MI.

The expected outcome of the work was to establish guidance that FIP member organisations and individual members can use to work with governments, national non-government organisations (NGOs), international NGOs (INGOs) and other relevant stakeholders to develop and implement national or regional policies and strategies for MI in their own countries or regions. As part of the process, existing FIP policy statements related to MI were evaluated.

The aim of this report is to set a vision for FIP and pharmacy organisations internationally for collaboration towards high quality MI. The report describes the goals and outcomes of strategic development of MI; gives examples from countries where MI strategies exists; describes the core elements of a MI strategy as well as the process of strategic development of MI; and discusses strategic development of MI within medicines management policies in low-resource settings.

3 Methods

The Working Group on Strategic Development and Use of Medicines Information has used various methods when compiling this report:

- An Internet member survey of all FIP sections' members in 2013 (Appendix 2).
- Collation of information about existing MI development strategies or policies, identified primarily using online websites (from USA, Australia, Europe, India-SEA-region, Rwanda) between March and June 2014 (Appendix 3).
- A three-hour session during the 2014 FIP World Congress of Pharmacy and Pharmaceutical Sciences entitled: "Experiences in developing and implementing national medicines information strategies" (Session C3). Presenters discussed global as well as regional MI policies and strategies, covering stand-alone policies and those embedded in broader medicines management policies (Appendix 4).
- An evaluation of existing FIP policy statements related to MI (Appendix 5). The content and text of the FIP Statement of Policy on Medicines Information for Patients[8] has been used when writing this reference paper and reproduced where relevant and appropriate in its different parts. The original FIP statement is presented as Appendix 6.
- Research literature from peer-reviewed journals as well as selected documents describing strategic development of MI were reviewed and included in this reference paper (see References).

4 Goals and outcomes of strategic development of medicines information

Effective patient medicines information (MI) can be defined as information which improves patients' knowledge and understanding of treatment, self-management of illness, and that improves health outcomes. In the following sections, we discuss the role of MI related to rational use of medicines; medication safety and pharmacovigilance; rational prescribing/dispensing of medicines; and health literacy (Table 1).

Table 1. Goals and possible outcomes of MI

Goal	Possible outcome
Rational use of medicines	• Safe and effective use of medicines • Increased patient satisfaction • Increased adherence • Allow patients to make informed decisions and take a more active role in their treatments
Medication safety and pharmacovigilance	• Safe and effective use of medicines • Adverse drug events and medication errors prevented • Produce information on medicines safety profiles for HCPs and patients
Rational prescribing and dispensing	• MI facilitate, encourage and support rational prescribing • MI integrated into the relevant data systems • Communicate adequate and appropriate MI to patients
Health literacy	• MI is available to patients to access, understand and evaluate within the context of management of their medical conditions • Key principles of good writing and design are applied to written MI • Written MI is tailored to specific patient populations • Better health outcomes

4.1 Rational use of medicines

The classical definition of rational use of medicines by WHO is that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.[9] Following this definition, the FIP has defined the *responsible use of medicines* in the following way: it means that a medicine is only used when necessary and that the choice of medicine is appropriate based on what is proven by scientific and/or clinical evidence to be most effective and least likely to cause harm. This choice also considers patient preferences and makes the best use of limited health care resources. There is timely access to and the availability of quality medicine that is properly administered and monitored for effectiveness and safety. A multidisciplinary collaborative approach is used that includes patients and their families or caregivers.[10]

Information that is better suited to the needs of the patient has the potential to increase/improve patient satisfaction and can contribute to increased adherence to medicines. For example, Australia's National Medicines Policy describes that information development, implementation and provision is paramount to facilitating quality use of medicines.[11]

Providing unbiased and effective MI to patients and HCPs must be a priority for pharmacists. People who use medicines need both spoken and written MI. As medication experts, pharmacists are a key information resource for patients and HCPs. The key challenge for the pharmacist is getting such information to patients in ways that meets their needs, as well as the needs and abilities of HCPs and health systems.

The purpose of patient MI

The primary purpose of patient MI is to assist patients and HCPs in achieving the safe and effective use of medicines. This includes providing information that allows patients to make informed decisions as to the appropriate selection and use of medicines.

Patients value information about the range of treatments available, their relative effectiveness, inherent risks, if any, and their impact on lifestyle. Furthermore, patients need information for ongoing decisions about the management of medicines. Although not all patients wish to receive written information, those who do want such information ask for sufficient details to meet their needs. Patients value information that is adjusted to their individual needs and that balances benefits and harms. Most patients also want to know about the potential for adverse drug reactions.

Sources of patient MI

It is important to have a variety of effective sources of MI that patients can access. It is also important to have qualified HCPs who can assist patients in understanding this information.

The various sources of patient MI can be categorised as:

- Spoken and delivered by HCPs
- Medicine leaflets / package leaflets supplied with individual medicines
- Written for patients and HCPs
- Electronic and delivered via the Internet and other electronic tools

Best practice in information design

For written and electronic medicines information to be effective, they also need to be user-friendly. Improving the effectiveness of written medicines information can be addressed by applying key principles of good information design and writing. It is important to emphasise that good design and layout are as important as content that is easy to understand. Suboptimal health literacy is a widespread issue within an international context, where health literacy ("the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions"[12]) varies both within and between countries. These differences should be considered when developing medicines information tools. Attention should be given to methods of communication other than the usual written or spoken communication, where appropriate. For example, alternative languages and special formats (large font size, pictograms, audio versions, Braille) as well as mixed approaches (e.g. written and audio-visual) should be made available and used to meet the needs of specific patient populations.

On closer examination, it can be seen that medicines information has the potential to be used as a tool to improve health literacy. If developed and tested appropriately, it can help to inform patients of all different health literacy levels about their medicines.

Expanding regulatory function

Increasingly, authorities are creating guidelines and information about medicines. For example, the European Union requires comprehensive patient leaflets in all medicine packs, which are written according to strict guidelines. These now have to be tested to ensure they are usable by patients. There are similar guidelines in the Western Pacific Region. Also, the United States Food and Drug Administration has a more interventionist role in ensuring high quality of information, and providing more information itself to the public (largely via its website). Importantly, the usability of medicines information should be evaluated with patients to ensure that they are fit for purpose.

Need for further research

Generally, it is observed that there is a lack of research in the area of patient MI.[13,14] There is a need to determine the content, layout, delivery method and timing of written medicines information that best meet individual patient's needs. Also, there is a need to continue investigating how to effectively incorporate targeted and tailored information, in particular how to effectively convey benefit and harm information to patients via leaflets.

4.2 Medication safety and pharmacovigilance

MI has a central role in preventing adverse drug events. As patients become active partners in the management of their condition, they should have access to or be provided with reliable medication safety information. Communicating medication safety information is complex as it involves many stakeholders with various degrees of risk perceptions, needs, knowledge, and abilities.[15] For example, good risk communication must take into account the literacy level and concerns of medicine users. Pharmacists are an important source of MI for patients[16,17,18,19] and are instrumental in ensuring that patients receive appropriate safety information about their medicines. Pharmacists also play a vital role in correcting identified medication errors and improving safety systems in clinical practice.[20,21] Expanding the role for pharmacy, such as including the presence of a pharmacist in outpatient and inpatient services and increasing patient education through a pharmacist, will improve medication safety in hospital settings.[22]

Another example of a medication safety perspective is driving under the influence of psychoactive medicines. The European Commission launched the DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) project. Within this project, among other activities, guidelines for health care professionals on prescribing and dispensing medicines taking into account their impact on driving performance were generated.[23]

Pharmacovigilance involves monitoring the safety of medicines and taking appropriate action to minimise harms, such as by communicating drug safety information. Having access to reputable and up-to-date medication safety information resources will allow pharmacists to provide reliable information to patients and clinicians. In the USA, various resources are available online or via mobile technology.[24] These include the Food and Drug Administration Paediatric Labelling Information Database, a Paediatric Safety Reporting page, the Institute for Safe Medication Practices (ISMP) Risk Safety Manual, and the ISMP Consumer Safety website.

In the European Union, the European Medicines Agency guideline on good pharmacovigilance practices emphasises the importance of communicating safety information to patients and HCPs in order to promote the rational, safe and effective use of medicines, prevent harm from adverse reactions and contribute to the protection of patients and public health.[25] A new pharmacovigilance legislation (Directive 2010/84/EU and Regulation (EU) No 1235/2010),[26] which came into effect in 2012, strengthened the follow-up of the safety profile of medicines. For example, all new medicines require a public risk-management plan (RMP). Furthermore, the marketing authorisation holders need to provide an evaluation of the benefit-risk balance of their medicine, called Periodic Safety Update Report (PSUR). Medicine users are now able to report suspected adverse drug reactions in all EU Member States. A black triangle in the package leaflet is used in all EU Member States to identify medicines under additional monitoring. Reports of suspected adverse drug reactions are especially wanted of medicines under additional monitoring. In the USA, Risk Evaluation and Mitigation Strategies (REMS) are required by law when there is uncertainty about whether benefits of a drug outweigh its risks. REMS may include medication guides, patients package inserts, communication plans and Elements To Assure Safe Use (ETASU).[27] All these different pharmacovigilance activities in the European Union and the USA produce considerable information on medicines' safety profiles that can be used by HCPs and patients.

The 2000 FIP Statement of Policy on Good Pharmacy Practice and Education emphasises the importance of providing pharmacy students with the essential foundation for pharmacy practice in a multi-professional health care delivery environment. This statement recommends that students be trained about risk and safety management along with pharmacoepidemiology.[28] The FIP Statement of Policy on Pharmacovigilance also recommends that curricula address the pharmacist's importance in pharmacovigilance.[29] An opinion paper from the American College of Clinical Pharmacy Drug Information Practice and Research Network highlights the role of MI in pharmacy curricula, notably to prevent medication errors.[30] In recent years, US pharmacy schools curricula have placed a greater emphasis on medication safety.[31].

There are numerous commercial sources of drug safety information available to HCPs.[32] Although widely available in high-income countries, these sources of information might not be easily accessible to clinicians in low- and middle-income countries. Additional factors that can affect the dissemination of medication safety information to policy makers, regulators, and HCPs in these countries include lack of pharmacovigilance competence, lack of manpower, lack of stakeholders' communication, poor regulations, and a poor medication safety reporting culture.[33] Many of these countries also need technical support, equipment, training, and funding.[33]

4.3 Rational prescribing / dispensing of medicines

Rational prescribing is a multi-step, iterative approach to prescribing that requires effective patient-provider communication.[34] As the identification and review of available treatment options alongside treatment choice are core steps in the process of rational prescribing, MI becomes an important tool to achieve this goal.[34]

A variety of MI can be used to facilitate, encourage, and support rational prescribing practices across different health care contexts internationally.[35] For instance, educational intervention strategies are an example of a targeted approach that can be employed to optimise rational prescribing of medicines. It involves the utilisation of information, which would undoubtedly encompass MI.[36] The role of MI, as part of initial education undertaken in the completion of tertiary qualifications and further specialisation to qualify as prescribers of medicines, is apparent. MI is also important in continuing professional development to ensure that rational prescribing/dispensing practices reflect and consider best practice guidelines that are currently implemented. Prescribers require a range of high quality, accurate, readily accessible and easy-to-use MI which is integrated into the relevant data system(s) in use to inform rational prescribing, particularly in the practice of evidence-based medicine. Following on from this, integration of the use and provision of MI by HCPs in service provision can directly improve and help to ensure quality use of medicines by patients.

Dispensing of a medicine refers to the events and tasks performed from the point of prescription presentation to the provision of the medicines/therapeutic goods to the patient.[36,37] Therefore, MI is utilised by the dispenser, such as a pharmacist, to determine the safety and appropriateness of the prescribed medicines for the patient. It is also used to communicate adequate and appropriate information to the patient at the point of provision to best support safe and appropriate medicines use. Pharmacists rely on MI of this nature to ensure that the dispensing of medicines is safe and appropriate for patients/end users. Undoubtedly, the use of MI is integral to the practice of the profession.

The pharmacists' role in dispensing non-prescription medicines is also vital. FIP's Statement of Policy on Self-care including Self-Medication — The Professional Role of the Pharmacist (1996, Jerusalem) detailed the professional role of the pharmacist on advice-giving on the treatment of symptoms and referral to physicians.[38]

4.4 Health literacy

Multiple definitions of health literacy exist, where one example refers to health literacy as "the ability to access, understand, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the life-course".[39] Medicines play a role in health maintenance and promotion and thus, in accordance with the aforementioned definition of health literacy, MI must be available for patients to access, understand and evaluate within the context of the management of their medical conditions.

Suboptimal health literacy is a widespread issue within an international context. As part of the Adult Literacy and Life Skills Survey conducted in 2006, 59% of adult Australians had poor health literacy skills.[40] When comparing the Australian results to those obtained from Canada for adults aged 16–65 years, the findings were comparable where less than half were determined to have sufficient health literacy skills or higher.[40] On closer examination, health literacy impacts health and is associated with economic burden for the health care system.[41] Poor health literacy has been found to be an independent predictor of all-cause mortality in the elderly who reside in the community.[42] Poor health literacy has been associated with a larger number of hospitalisations, reduced ability of individuals to understand labelling, and impacts observed medicines-taking behaviour, amongst other suboptimal outcomes.[43] It has been linked to worse physical health and also mental health, where those with poor health literacy had a higher chance of reporting difficulties impacting their activities.[44] Hence, the burden which can be associated with suboptimal health literacy highlights the need to address this issue at a population level.

When examining the relationship between heath literacy and MI, understanding of written MI is linked to sufficient patient health literacy.[45] From a strategic development perspective for MI, improving the effectiveness of written MI can be addressed by applying key principles of good writing and design. With variations in health literacy levels amongst different patient populations, tailoring of the information to specific patient populations and health literacy levels is important in order to maximise the usability, utilisation, and impact of MI on patient related outcomes, as evidenced by the inclusion of tailored information as a core component within two different conceptual models of health literacy.[46]

There are a number of specific patient populations for which attention should be given to further methods of communication that augment usual written or spoken communication of information, where appropriate. For example, alternate languages and special formats (large font size, pictograms, audio versions, Braille) should be used to meet the needs of specific patient populations such as (but not limited to): children, the elderly, hearing impaired, visually impaired, ethnic minorities, or pregnant/breastfeeding women as some exemplar subpopulations. Moreover, for a number of these patient subpopulations, specifically, the role of information has been emphasised by its mention in FIP policy statements pertaining to maternal, newborn and child health, or the management of chronic disease.[47]

Initiatives such as the AHRQ Health Literacy Universal Precautions Toolkit in the USA[48] and Health Literacy Project in Australia[49] complement and advocate for health literacy initiatives. On closer examination, it can be seen that MI has the potential to be used as a tool to improve health literacy and if developed and tested appropriately, can help to inform patients of all different health literacy levels about their medicines. This then plays a role in the initiation and maintenance of a feedback loop for identification of population-level health literacy deficiencies, optimisation of existing health literacy levels, and MI to then lead to improved health literacy levels post implementation of optimised MI.

4.5 Role of the pharmacist

The 2008 FIP Statement of Policy on Medicines Information for Patients underlines the pivotal role of pharmacists in the provision of reliable and valid written and spoken MI to patients.[50] As patients increasingly access information from the Internet, pharmacists can act as a guide to, and interpreter of, this type of information as well. Spoken information remains the priority for patients, but should be closely linked to written information. Both spoken and written information should be tailored to reflect the health literacy of the patient and/or care giver. Pharmacists should ensure that written information is not used as a substitute for discussion. They should also encourage patients to use written MI and welcome any questions this may raise.

National initiatives can encourage patients to engage with pharmacists and ask questions about their medicines. Pharmacists should also ensure that they collaborate with fellow HCPs, to make sure that patients receive appropriate, consistent, and correct messages. It is the pharmacists' responsibility to ensure that the information they provide is objective, understandable, non-promotional, accurate and appropriate. Further, the pharmacists can use written material with the medicines as a reminder document to support the spoken information that is given to the patient. Pharmacists should encourage patients to seek objective and accurate information. Furthermore, they should guide patients to reliable MI websites, and utilise tools to assess the reliability of online MI. An example of such a tool is DARTS-checklist (Date, Author, References, Type and Sponsor).[51] Pharmacists may also consider developing and providing medicines information services making use of new information technology, such as email, chat and mobile telephone applications to support patient education and self-management.

4.6 Value and outcomes of medicines information

The strategic development of medicines information is likely to benefit many parties and lead to many short-, medium-, and long-term outcomes.

Short-term outcomes include:

- Increased communication between patients, pharmacists, and other health care professionals.
- Better informed patients before, during, and after medicines use, regarding their medicine(s), associated risks, benefits, and actions required to be taken.

- Increased collaboration among all parties involved in developing high quality medicines information.
- Attention drawn to medicines information activities and their importance.

Medium-term outcomes include:

- Improved patient experience and satisfaction, for patients and/or caregivers who are actively involved in managing their health.
- Improved patient motivation to take a more active role in their treatment, if the information received meets their needs.
- Better access to reliable, quality information needed by the public, patients, and caregivers.
- Improved patient communication with health care professionals, and increased patient ability to manage their own health.
- Promotion of safe self-medication
- Improved pharmacovigilance efforts and promotion of safe and appropriate use of medicines along the continuum of health care provision and treatment.
- For the health care system as a whole: increased public confidence, improved cost effectiveness via the development of quality, consistent information nationally; and strengthened partnerships between statutory and independent sector information and service providers.

Long-term outcomes include:

- Improved patient adherence and health status, aided by the receipt of relevant and tailored medicines information which has been developed according to high quality standards.
- Improved health literacy of patients, reduced inappropriate medicines use, improved patient health outcomes, and lower health care costs. These are particularly important for an ageing population where increasing numbers of chronic conditions and incidence of multiple comorbidities are seen.

We will observe sustained international collaboration between different regulatory bodies, and mutual learnings between countries who have implemented strategies supporting the development of MI and those who are seeking to improve their MI strategic development frameworks. Globally, there also will be a dynamic development of MI (with adequate mechanisms in place to facilitate the adaptation of MI where necessary to best suit its purpose) and provision of consistently high quality MI.

5 Examples from countries where medicine information strategies exist

This section gives examples of how three countries have developed MI. The USA is an example of a country with a long tradition of developing MI. The second example is UK, where a strategy called "Better information, better choices, better health" outlined a three-year strategic action plan, which set out 25 activities to improve access to information, signposting and quality of information.[52] Finally, the example from Finland shows how a MI network was established to implement the first national MI strategy.[53]

5.1 USA

National Council on Patient Information and Education (NCPIE) was founded in 1982 with a mission to stimulate and improve communication of information on the appropriate use of medicines to consumers and HCPs. NCPIE brought together public and private stakeholders.

In 1992, a law took effect that required pharmacists to offer to counsel most patients, at least those on new prescriptions. In 1996 "HIPPA" law, which governs patient privacy of health information, affected consumer behaviour as it stated that patients' rights must be conveyed at all doctors' visits, and at dispensing of prescriptions, usually via electronic signature pad. This affected counselling performance as pharmacists started to insert the patient medicines information (PMI) leaflets in the prescription bag with minimal oral counselling.

An Action Plan for Provision of Useful Prescription Medicine Information was published in 1996.[54] It defined the goals for PMI as "consumers armed with greater knowledge about the medicines they take will be empowered to make better-informed decisions". Furthermore, it recognised that the broader distribution of PMI will ultimately result in improved health outcomes and fewer medication-related problems. The criteria for useful PMI were defined as scientifically accurate, unbiased in content and tone, specific, comprehensive, presented in an understandable format, timely, up-to-date and useful.

The US policy developments have led to a wide distribution of MI: FDA required that on certain medicines or therapy classes that pose a serious and significant public health concern, a medication guide must be distributed at the pharmacy. These medication guides are paper handouts that address issues that are specific to certain medicines and medicines classes, and contain information that can help patients avoid serious adverse events, or patient adherence to directions for the use of the medicine that are essential for its effectiveness.[55] By 2014, there are nearly 400 Guides. Furthermore, FDA requires Patient Package Inserts with certain medicines. PMIs are also developed privately and distributed in pharmacies with prescriptions. In 2010, FDA notified that patients may receive different types of information, developed by different sources that may be duplicative, incomplete, or difficult to read and understand. Thus, the current system is not adequate to ensure that patients receive essential MI needed to use a drug safely. FDA recommended that a single document with standardised content and format based on approved prescribing indication(s) should be adopted. The National Library of Medicine's DailyMed was seen as an opportunity to serve as the repository for PMI in the future.

The FDA's Division of Drug Information (DDI) in the Center for Drug Evaluation and Research (CDER) offers unique opportunities for health care professionals and students to learn more about the FDA and drug regulation. The division offers a series of educational webinars focused on supporting the FDA's mission of promoting and protecting public health through interaction and education to strengthen current and future partnerships and relationships between clinicians and researchers.[56]

The provision of medicines information (drug information) is among the fundamental professional responsibilities of all pharmacists worldwide. Recent practice trends have placed pharmacists in increasingly complex patient-care roles and have necessitated a higher level of competence by all pharmacists in meeting the needs of our patients especially in low resource settings. The goal of providing carefully evaluated, evidence-based recommendations to support medicine use and practices, is to enhance the quality of patient care in a variety of practice settings including hospital managed care, outpatient care centres, managed care environments, medical communication centres as well as academic-based drug information centres. Medicines information can be patient specific, academic or a population-based decision-making process.

The American Society of Health-System Pharmacists (ASHP) developed, and approved on April 10 2014, Guidelines on the Pharmacist's Role in Providing Drug Information.[57] The primary focus of these guidelines is to describe contemporary medication information activities, including the application of a systematic approach, appropriate documentation methodology and the use of high-quality Drug Information Resources to provide excellent oral and written communication of medical information to patients, caregivers and other health care providers.[57]

5.2 United Kingdom

In 2003, a vision "Building on the best — Choice, responsiveness and equity in the NHS" was published in the UK. It acknowledged information as an essential prerequisite to making informed choices about health and health care. A public health consultation, "Choosing Health?", confirmed the need to improve information. Building on the commitments set out, the Department of Health (DH) published the health information strategy "Better information, better choices, better health" in 2004.[52] It outlined a three-year action plan for local and national levels, aiming to put information at the centre of health care in the UK. The strategy was compiled by four task groups with members from the DH, National Health Service (NHS), patient and voluntary organisations and key players from pharmaceutical and health care industries. The work was led by the DH.

Better Information, Better Choices, Better Health set out 25 activities which aimed to improve access to information, signposting and quality of information, open the relationship between HCPs and patients, organisational roles and responsibilities and communication and support (Table 2).[52] Significant recourses were available for the implementation of this strategy (£40 million a year for NHS Choices).

Table 2. Summary of activities set out in the *Better Information, Better Choices, Better Health*[58]

Activity	Lead	Work with	Timescale	Progress from 2004–2010
Translation and interpretation service	NHS Direct	Bowne Global Solutions (a translation agency)	Starting 2005	Available to all via NHS (National Health Service) Direct phone service. NHS Direct is an organisation, which was set up to provide easy access to health information.
Community-based Navigators – to improve community access to information.	DH (Dept of Health)	PCTs (Primary Care Trusts)	Starting 2005	The number of opportunities to train as an expert patient has increased, work is continuing to improve this further.
NHS Direct Interactive – Televised information	NHS Direct Online	DH	Dec 2004	Was available on Sky (subscription digital TV) until 31 March 2009. Still available on Freeview (Free digital television service in the UK).
NHS Direct Self-help Guide	NHS Direct	Thomson Directories	Dec 2004	Was distributed nationally with Thomson Local Telephone Directory in 2004, and is still available online.
National procurement of information resources	NHS Direct and NHSIA (NHS Information Authority)	DH and NPfIT (National programme for IT)	Complete by March 2005	No evidence of progress.
Information to Support Choice of Hospital	DH	NHSIA, PCTs	Dec 2004	"Choose and book" available since 2004. (Online service to choose a hospital for treatment.)
HealthSpace – an online health organiser.	NHS Direct online	NPfIT	Dec 2004 complete by 2007	Available since December 2003. A summary of care records is available online but not complete clinical care records, which was the aim.

Activity	Lead	Work with	Timescale	Progress from 2004–2010
Information Accreditation Scheme	DH and NHS Direct online	PCTs, Regulatory bodies, VCS organisations	During 2005	The Information Standard launched November 2009, after piloting. Current status: www.england.nhs.uk/2013/09/30/info-stand/
Health Search Engine	NHSIA	DH and NPfIT	January 2005	NHSIA (NHS Information Authority) had initial responsibility for this and was disbanded in 2005. There is currently no health specific search engine, responsibility was passed to NHS Connecting for Health and plans for a health search engine also feature in NHS Direct Strategy.
Widen access in the community	PCTS	Local strategic partners	Starting 2005	This is a very broad and quite vague action point. Efforts have been made to increase expert patients in the community. Local databases were an aim set out by "Our health, our care, our say" in 2006, there is currently no evidence of these.
Develop and pilot power questions	DH	Professional bodies, local NHS organisations	Starting 2005	"Questions to ask" Published in October 2007. Ask about medicines campaign 2003-2008. Seen to have achieved a number of objectives, resources still available online.
Information prescriptions — to signpost patients to appropriate information about their condition	DH	Professional bodies, local NHS	Starting 2005	Are available for a number of conditions on NHS Choices website. Information prescriptions are not yet personalised so this task has not been fully completed. Evidence exists for the benefits of information prescriptions in practice and also suggests provision through community pharmacies.
Copying letters to patients	SHAs (strategic health authorities) and PCTs	DH	Dec 2004	Initiative is now used in practice and is seen as useful by both HCPs and Patients
Mainstream communication training for HCPs	DH	Professional and regulatory bodies, NHSU, local NHS	Starting 2005	Courses are available, but may not be seen as "mainstream" yet. Guidance is available for undergraduate and preregistration pharmacy programmes.
Code of Practice on Communication	DH	Professional bodies, local NHS	Starting 2005	No evidence found.
Commissioning and prioritisation framework to determine what information budgetary spending should be dedicated to, and procurement methods for the strategy.	DH	PCTs and VCS (voluntary and community sector) organisations	Starting 2005	The engagement cycle was published in April 2009. This is a way of using patient and public engagement to aid world class commissioning, a process which must be undertaken by PCTs.

Activity	Lead	Work with	Timescale	Progress from 2004–2010
Matching information provision with local needs	PCTs	Local NHS organisations	Starting 2005	Evidence of efforts to map local area health demographics, no complete publication available.
Patient information bank — an online database of quality assured information and leaflets for HCPs to give to patients.	NHS Direct online and DH	Local Partners	Available early 2005	Attempts at building a patient information bank failed.
Increase frequency and access to healthy living and local service information	PCTs	Local partners	Started before the strategy	Aims to produce local databases of support groups and information. No evidence of complete databases available to the public.
Make information available through local partners.	PCTs	DH	April 2005	Under the pharmacy contract community pharmacies must play a role in public health and signposting. They must support up to six local or national campaigns a year and provide signposting to reliable information sources
Local Use of "Get the Right Treatment" Campaign	PCTs	DH	Dec 2004	"Get the right treatment" was a national advertising campaign launched in 2000. There is no evidence for localised use after the initial phase.
Share best practice in good information provision	PCTs	PCTs	Dec 2004	No evidence of a system for information sharing. It may be taking place on a less official basis.
Segment population and identify best practice for communicating with each group for PCTs	DH	PCTs	April 2005	Work was carried out by the DH into mapping population health demographics. No published evidence of this.
Make health editorial content available for use locally	DH	PCTs	April 2005	No evidence found.
Review and strengthen marketing support provided to the NHS.	DH		April 2005	No evidence found.

The main issues leading to successful implementation of the strategy were buy-in from stakeholders, political will aiming to empower patients, and significant available resources.[58] Stakeholder involvement during the planning phase while generating and developing ideas was seen as very useful, but also in the implementation stage. Especially, the networks of different organisations led to greater visibility and acknowledgement of the projects. In fact, many projects included in the strategy were already underway and

the strategy brought them together, leading to better visibility of different projects nationally. The Department of Health coordinated the work and had a strong authority and mandate to do so.

The planned three-year time scale was possibly too short to get all activities planned in the strategy completed. Actions with success were those which were underway when the strategy was written. However, this strategic work was still seen as important in bringing the already existing projects together and aiding their success.

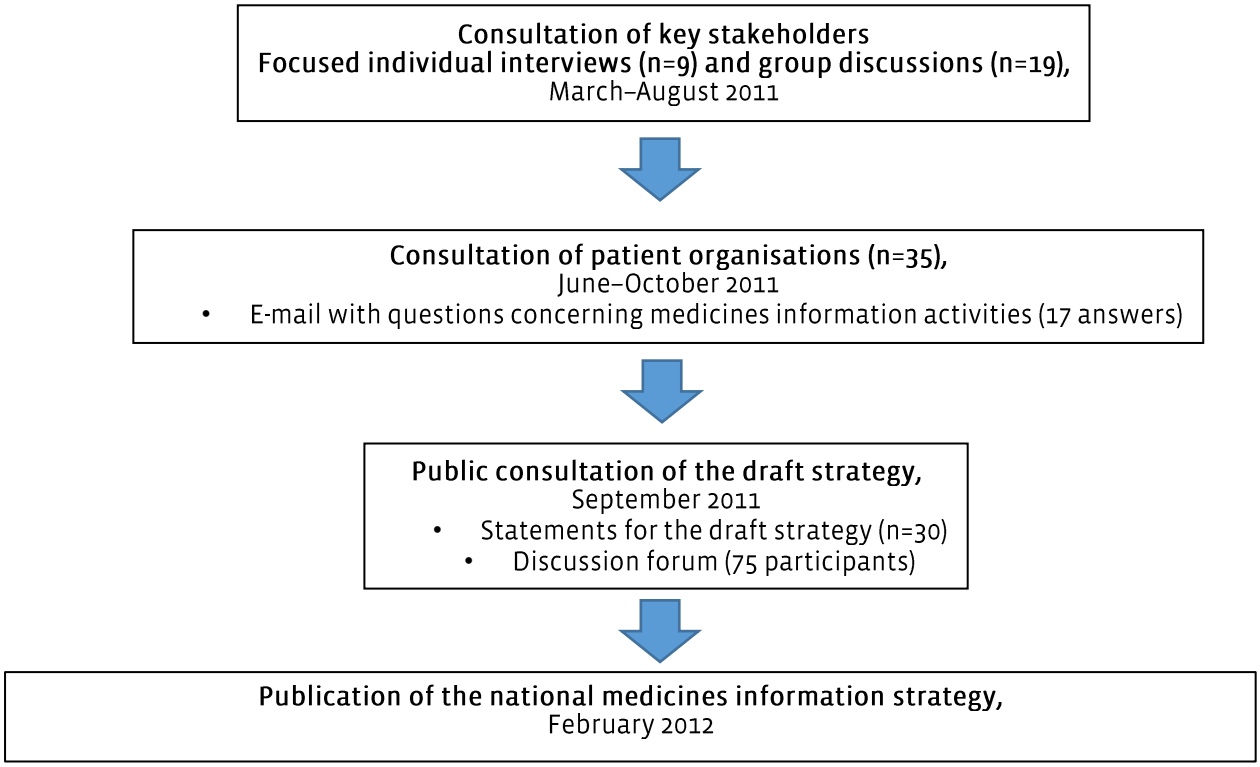
After the three year strategic period, the DH published "*The power of information: Putting all of us in control for the health and care information we need*" in 2012.[59] This new strategy focuses on developing the quality and use of electronic care records and information flow between different organisations and professionals. Thus, the focus of the work has changed.

5.3 Finland

As mentioned in the introduction of this report, the European Commission hosted a Pharmaceutical Forum during 2002–2005. In its final recommendations,[7] it suggested that MI should be developed in a strategic way within the member states. Furthermore, sharing good practices between the member states was encouraged. Following these recommendations, MI was recognised as one of the key components to increase rational medicines use among the population in the national medicines policy published in Finland in 2011.[60] The medicines policy was composed under the lead of the Ministry of Social Affairs and Health, in cooperation with pharmaceutical sector stakeholders and patient organisations. After the launch of the policy, the Ministry appointed Finnish Medicines Agency (Fimea) to compile a national medicines information strategy and coordinate its implementation. Thus, Fimea had a strong national mandate for this task and it was appreciated by the stakeholders as a neutral party to lead this work.

The Medicines Information Strategy was compiled in close cooperation with stakeholders. Fimea interviewed different interest groups, from pharmaceutical industry to patient organisations and professional organisations from different HCPs including pharmacy, medicine and nursing. Furthermore, discussion forums were organised and consultations conducted based on the draft of the strategy (Figure 1). A detailed description and evaluation of the process has been published.[61] Thus, the Medicines Information Strategy describes a national view of the current status of MI practices as well as the challenges which need to be addressed.[53] This was an evidence-informed policymaking process based on scientific stakeholder interviews.

Figure 1. Process of compiling the medicines information strategy for Finland (Hämeen-Anttila et al. 2013)



The focus of the Finnish MI Strategy is wide, including six strategic objectives (Table 3).[53] Under each of the objectives there are more specific goals and proposals for actions. Altogether there are 37 proposals for action in the whole document.

Table 3. Strategic goals and objectives in medicines information (MI) in Finland in 2012–2020[53]

To establish a multi-disciplinary MI network in Finland • Establishing a national MI network. • Incorporating research and follow-up in MI activities. • Participating in international initiatives.
To ensure that health care professionals use reliable information sources and services • Increasing awareness of reliable information sources. • Improving the accessibility and usability of MI. • Utilising experts and existing specialist services.
To ensure a high level of medicines expertise and multidisciplinarity in health care • Improving medicines expertise and developing training in medication counselling. • In basic and continuing education emphasising a patient-centred attitude, a multidisciplinary approach and support for patient self-management.
To base medication counselling on national guidelines and local agreements • Harmonising the provision of medication counselling in health care • Using MI to support the provision of pharmacotherapies in various settings. • Ensuring medication counselling in patient self-care.
To ensure the medicines users use reliable information sources and services • Ensuring the availability of reliable MI. • Promoting the readability and usability of package leaflets. • Producing MI in minority languages and for other special groups. • Increasing the use of information and communications technology to disseminate MI.
To achieve a high level of health literacy among the general public. • Promoting health literacy among children and adults.

In order to implement the MI strategy in Finland, a Medicines Information Network was built. The network has five working groups (WGs): coordination group; research WG; education WG; WG for developing MI for HCPs; and another one for developing MI for patients. The 37 proposals for action were distributed to these WGs to be prioritised and implemented through development projects. Examples of prioritised proposals for action and development projects started are shown in Table 4. The activities of the MI network are based on research and existing best practices.

There are altogether some 60 organisations involved in the different WGs of the network, and around 100 individual persons. Fimea is coordinating the work. There are no resources allocated to the network from the Ministry or Fimea, besides the work of the coordinator.

Table 4. Examples of development projects started in the MI network

Development project
• Current care guidelines for self-medication formulated during 2014–2016. • A multi-disciplinary forum for teachers of pharmacotherapy was held in November 2014 in order to increase inter-professional cooperation. Another forum will be held in November 2016. • A summary of reliable MI which can be found on the Internet in Finnish has been published for patients. • A summary of MI services available for HCPs has been published. • Cooperation between clinical pharmacologists and clinical pharmacists will be promoted by different projects. • School medicines education has been promoted by a project where pharmacy students went to schools around Finland to give medicines education lessons. • A research strategy for the MI network has been published. The aim of the research strategy is to identify and describe the main research areas within MI research, to be used by researchers to build up cooperation within this field. • Research projects have been started in order to base work on the current situation and needs of MI: Internet survey to evaluate different patient groups' MI needs and sources used (n=2,489). • Survey to members of the Finnish Union of Practical Nurses to evaluate their MI needs and sources used (n=750).

The first period of the network (2012–2014) has ended and a new three-year period has commenced. During January–June 2015, all members of the WGs were interviewed and the strengths and weaknesses of this kind of cooperation were evaluated in order to follow the evidence-informed decision making process. Based on the preliminary results, some strengths and weaknesses have been identified (Table 5, p25). Organisations also identified that in addition to cooperation within the Network, the MI Strategy has influenced the work of their own organisation as well.

Table 5. Strengths and weaknesses of the cooperation within the National MI Network in Finland based on interviews of the working group members (n=80) (unpublished).

Strengths	Weaknesses
Increased cooperation to develop quality MI.	Lack of resources.
Cooperation between bodies representing HCPs and patients have increased.	Demands time from other work.
The recognition of the relevance of MI for medication safety and rational medicine use has increased	Same people are involved in many working groups.
Cooperation not only specifically related to MI, but more widely to medication safety has increased.	Equity of workload among network members.
Patient perspective has become clearer.	Too many working groups.
Tools to help medication counselling have been developed (see Table 3).	Communication challenges between working groups.
Education relating to MI has been organised.	Organising of the network and planning its actions took the whole first strategy period. There was no time for concrete actions.
MI network has provided a new channel to receive information and to influence practices in the field.	Limited joint actions between working groups.
Network provides an important communication forum for stakeholders.	Bureaucracy and paperwork required in the MI network.
Network has brought stakeholders together.	Part of the working group members are not committed to strategy work.
Potential possibility to influence political decision making.	
Accessibility of information improved among working group members.	
Information on good practices, ideas and motivation to develop practices in own field.	
Working group members have had a possibility to get to know each other and their work, which makes them easier to contact if needed in daily practices.	

6 Core elements of a medicine information strategy

It is evident from the experiences of the countries with active strategic planning of MI that there is value in the collaboration that occurs as part of developing and implementing a MI strategy. Acknowledging and raising awareness of the current high quality MI available are among the most important elements that such a strategy should include. Furthermore, empowering medicine users to navigate to reliable information within the huge amount of MI they encounter is extremely important (e.g., Power questions in the UK, or school medicine education to increase health literacy in Finland).

The strategic goals should be based on careful analysis of the current MI practices in the individual country or area. The analysis should include evaluation of the good practices available (to be retained and publicised) as well as challenges and shortcomings (to be overcome and solutions found). This kind of analysis should be done in collaboration with stakeholders in the field. In accordance with the FIP Statement of Policy "Collaborative Pharmacy Practice",[62] collaboration with other HCPs and patients should be promoted also in the strategic work aimed at improving MI practices.

A majority of the respondents from the survey targeted to FIP members viewed high quality MI aimed at patients, medicine users and HCPs as core elements to be considered when developing a national MI strategy (Appendix 2). Other aspects to be considered were developing patient-centred educational programmes for the professionals providing medicines information, and the role of drug information centres and collaboration between centres.

7 The process of strategic development of medicines information

7.1 Initiation phase

Based on the analysis done by the WG (Appendices 2–4) and the experiences of the countries which have established a MI strategy, strategic development of MI should be an integral part of medicine policies and should be recognised as an important tool to increase medication safety, rational medicine use and adherence to long term therapies.

The initiation of developing a MI strategy can come from any pharmaceutical sector key stakeholder. However, national / governmental health authorities, including the ministry of health as well as national authorities regulating the pharmaceutical sector should strongly support or lead the work (Appendix 2).

7.2 Developing the medicine information strategy

All professionals, including nurses, pharmacists and physicians, need MI for their work. For example, a nurse needs skills and tools to recognise which symptoms of the patient may be related to medicine use — in order to refer such a patient, e.g., to a physician.[63] Nurses also need MI in order to identify medicines, e.g., specific tablets. Pharmacists and physicians need more advanced information on actions, interactions and side-effects of medicines. Thus, the needs of each profession should be considered when drafting the MI strategy and implementing it. Furthermore, the needs of patients should also be included in order to educate and empower patients rather than seeing them as passive recipients of MI.

It is important to identify existing good practices and tools, as well as assessing the gaps in a MI strategy. Methods which could be used to determine the needs of a range of stakeholders include, for example, interviews, consultations, surveys, requests for comments on draft documents etc. Table 6 shows different organisations and stakeholders which may be asked to get involved, depending on the component of the MI strategy and the interests and expertise of the stakeholders (Appendix 2).

Table 6. Examples of different organisations and stakeholders which may be involved in drafting the MI strategy

- Public administration: governmental agencies, medicines agencies
- Scientific societies representing different professions
- Pharmaceutical industry organisations
- Hospital pharmacies, dispensaries, community pharmacies
- Universities, polytechnics, vocational institutions and complementary education units representing different professions
- Hospitals
- Companies offering pharmaceutical services
- Companies producing MI
- Patient associations and organisations
- Student associations and organisations

7.3 Implementation phase

The key for successful implementation of the MI strategy is to initiate multidisciplinary inter-professional interest and widespread cooperation between stakeholders, including organisations representing patients. Additionally, there needs to be a coordinator for the work. It is recommended that the coordinator should come from a “neutral” background and have authority and mandate for the overall strategy.

Resources are needed for implementation. However, the stakeholders may be interested in putting their own resources to the work as long as the strategy is compiled in cooperation and the goals set are seen as important by the different stakeholders. The support of the ministry of health is very important not only from the resources point of view, but also supporting such work and seeing it as important.

It has been seen in countries where strategic development of MI has proceeded that projects which have an owner and which have already been planned or started earlier are those that succeed most often. Therefore, it is highly important to engage stakeholders already at the beginning, find out their current work towards high quality MI, and use it in the strategic work.

The strategic development of MI should be open, transparent and actively promoted. The work should be organised, e.g., through working groups which meet regularly. It is important to have people who are interested in developing MI and who are capable to be members of the various WGs of the overall MI strategy. Each WG should have their own action plans regarding how they promote the MI Strategy and put it into action. These action plans should explain the development projects that the WG aims to start, the responsible organisations for such development projects, the timetable and resources used as well as how the success of the project will be followed-up.

Networking is a good way to increase awareness. National level organisations which are involved in the strategic development of MI will use their own channels and distribute information of the work of such a network and its achievements. Again, the support from the ministry of health is paramount in receiving attention to such work. Open IT platforms should be used to further publicise the work of the network. Relevant national networks (e.g., network of patient safety experts in health care, etc.) should be identified and the strategic development of MI endorsed.

The power of media to raise awareness should not be underestimated, but instead utilised if possible. One way to increase media attention is to conduct research on different perspectives of rational medicine use and publish the research results. Also stories from real patients often gain media attention. Such stories could include, for example, descriptions of what kind of information a cancer patient needs at the time of diagnosis when she or he is in a crisis (not much oral information can be digested, written information should also be provided); how the MI needs develop when accepting the situation (more detailed information should be available to show all the treatment options, side-effects and how one can possibly help to overcome them). An illustrative story could also be used showing how a patient may face conflicting information about his or her medicines from different sources and how (s)he decides what to believe.

7.4 Evaluation phase

It is important that during the initiation and development phases as concrete plans of action as possible are made. They should include aims of the development projects, responsible organisations and persons, timetable, resources and indicators for follow-up. Indicators provide evidence for decision makers that certain aims have or have not been achieved. They enable assessment of intended outputs, outcomes, goals, and objectives.

Evaluation phase should be planned upfront to be completed in parallel to the development and implementation phases. The evaluation phase should also be considered to include a feedback cycle phase which provides ongoing feedback to either compilation or implementation phase or both.

During the evaluation phase, both process as well as impact (short-term outcomes) and outcomes (long-term outcomes) should be evaluated. Process indicators measure ways in which MI and MI services are developed and provided (i.e., error rates). On the other hand, outcome indicators measure the broader results achieved through the provision of MI and MI services. These indicators can exist at various levels: population, agency, and program levels, and can include, for example, information on patient satisfaction of MI, utilisation of different MI services, or level of health literacy.

8 Strategic development of medicines information within medicines management policies in low-resource settings

Countries with low resources settings lack adequate MI due to limited availability of current literature as well as have poor documentation and dissemination of the available information. Generally references are not available and sometimes biased information is disseminated, so dissemination of MI is often hampered by a faulty process.[64] When countries develop economically and more resources become available, it becomes easier for health care systems to adapt MI in different facets of health management. In any way, dissemination of MI to HCPs is a complex process. MI is an important issue due to lack of facilities, equipment and human resources, leading to structural, HCP related, accessibility, educational, legal regulation/monitoring and financial challenges (Table 7). The priority is to increase accessibility of MI targeted to HCPs and develop their skills for providing counselling to patients. The role of the HCPs is then to provide reliable MI to their patients.

At present, any system that has provided MI and used it meaningfully to achieve rational use of medicines, have been systems where the medicine is paid for by a "single payer", and there is a strong interest in ensuring that medicines are used well, not only for health aspects but also financially.[65]

The concepts of MI need to be integrated into the existing medicine management practices to offer widespread access to health information, address the basic health needs of societies and the advantages of interactivity, information tailoring and anonymity. Each reliable source of MI is valuable; it is important to learn which source is best for the specific information being sought.

MI can be embedded at various stages of medicines management, for example:

- Manufacturing
- Regulation
- Distribution and supply chain
- Maintaining health and other records
- Rational use of medicines
- Feasibility to access (easily, conveniently and practically accessible MI source)
- Continuing education and professional training
- Awareness among HCPs and patients
- Development of a local or national multidisciplinary network

Table 7.Challenges of medicines management policies in low-resource settings

Challenges	Description
Structural challenges[66,67,68]	Inefficient health care system Difficulty with access to medicine Lack of high technology software Poor electronic drug distribution management systems
HCP challenges[53,69,70,71]	Irrational use of medicines* Inappropriate maintenance of prescribing details and queries asked by patients† Lack of training to retrieve information and conduct quality analysis Unable to upgrade practicing related skills on continuous basis Prescribing and quality of care Lack of basic professional training Pre-services education challenge[69]‡
Accessibility of MI[69,72]	Inequitable technology for accessibility
Educational challenges[53,69,73]	Inadequate health literacy Lack of awareness of correct and safe use of medicines Inefficient continuing in-service / on-the-job training for medical education
Legal regulation and monitoring challenges[73,74]	Limited monitoring of off label usage Uncontrolled advertisement, promotion and sale Poor monitoring of methods of quantification of annual needs and management of emergency medicines Immoderate regulation, supervision, monitoring and enforcement in documentation and maintenance records of MI.[73]
Financial challenges[73,75]	Unaffordable medicines and medical information due to financial issues

*__Irrational use of medicines__: inappropriate, ineffective, and economically inefficient use of medicines by HCP.
†__Inappropriate maintenance of prescribing details and queries asked by patients__: The record of enquiry, enquirer and type of enquiry should be maintained by HCP for archiving patients' medical history and for clinical purposes.
‡__Pre-services education challenge__: Pre-services education is the training initiative programme conducted to train and educate the members of HCP, so as to disseminate unbiased and appropriate MI as a part of induction training.

8.1 Manufacturing

The medicine and health care authorities should develop mandatory guidelines for packaging, labelling and package inserts from the manufacturing process onwards, as is the case, for example, in the US and European Union. The information provided must be authentic, individualised, accurate, relevant and unbiased. A number of tools like DARTS checklist,[51] Flesch reading ease (FRE) score and Baker Able leaflet design (BALD) criterion[76] have been developed to help in assessing the reliability and design of MI.

8.2 Regulation

An overall supervision of MI must be developed and monitored by the medicine and health care regulatory authorities. To provide authentic MI, the regulatory authority should maintain a repository of easily accessible national level databases (example: National Formulary of India,[77] Health resources and services

administration (HRSA), Centres for Medicare and Medicaid services (CMS) and Agency for health care research and quality (AHRQ)[77,78] The services should meet the requirements on the basis of the end user with customised versions, for example, specialised information on therapeutics and pharmacology for HCPs, and chemical and physical properties for researchers. The multidisciplinary regulatory body should govern quality, accessibility and adherence to Standard Treatment Guidelines (STG), National Formularies (NF) and Essential Medicine Lists (EML), and coordinate the rational use of medicines. Monitoring the use of these reliable information sources and services by the HCPs is another important task for the regulatory body. Off label appropriate use should be closely monitored.[69]

In low resource regions, where health care may be in the private sector, there may be no regulatory control to enforce the usage of MI.[71,79] Therefore, it is suggested that concepts of EML and STGs be part of the curriculum. These could be included as a mandatory part of the prescribing habit.

Promotion of pharmaceuticals should be based on the use of good information practices consistent with the principles embodied in the WHO Ethical Criteria for Medicinal Drug Promotion.[65] Even the use of electronic communications for uncontrolled advertising, promotion, and sale of medical products via the Internet should be regulated.[80].

8.3 Distribution and supply chain

When supplying medicinal products from pharmacies and subsidiary pharmacies, every effort must be made (through the advice and guidance of pharmaceutical personnel) to ensure that the users of the medicinal products are aware of the correct and safe use of the product. An electronic drug distribution management system should be available. There should be a process to review the method of quantification for annual needs and how emergency medicines are being managed.

The pharmacy personnel, if properly trained with MI, can ensure rational use of medicines, like in Kenya where shopkeepers (not pharmacists) are trained on the adequate dose of anti-malarial medicines - sales included 83% adequate dose in three months and 90% in seven months from a mere 32% before training.[81] Before the training, advice was only given in 2% of sales of antimalarials. This increased to 94% and 98% in the two subsequent observation rounds post-intervention.

8.4 Maintaining health and other records

Medical records play a vital role for MI. The medical records should include the details of the enquiry, enquirer and type of enquiry. The majority of health care in low resource settings is in the private sector, where there is minimal supervision, monitoring and poor means of enforcement. In many cases, MI is provided in an informal way, without documenting any records and information.[64] Because high technology information software is not available in low resource settings, efforts such as Health Internetwork Access to Research Initiative[82] have made some health information easily available to the least developed countries.

However, these are the countries that have the most problems with the technology required to access the information. The bare minimum infrastructure needed for such a facility could be one computer, some DI resources and a telephone line, as was done in Bhutan.[64] In Bhutan, a database was created using only the above mentioned infrastructure to maintain prescribing details and answer queries. Pharmacists were trained for retrieving information, conducting quality assurance analysis and upgrading of skills on a continuous basis.

8.5 Rational use of medicines

Whether in a developed or developing region, the rational use of medicines should be a rule of thumb for health care sectors. More than 50% of all medicines worldwide are prescribed, dispensed, or sold inappropriately and 50% of patients fail to take them correctly.[69] In low resource regions, medicines are still unaffordable, unavailable, unsafe and improperly used.[73] Providing MI in low resource regions is an issue but ensuring that HCPs use that information is the main challenge. From a citizen and patient perspective, MI can be considered to be a right, and it should be an essential component of the rational use of medicines.

Appropriate prescription practice involving appraisal of prescriptions, using standard methods and indicators, can usefully identify general prescribing problems and quality of care. The WHO/INRUD (International Network for the Rational Use of Drugs) indicators can be used to identify general prescribing

and quality of care problems at primary care facilities.[83] The WHO/IMCI (Integrated Management of Childhood Illness) indicators can be used to assess the quality of treatment in children. WHO/INRUD and WHO/IMCI methodologies have been used much more in developing and transitional countries. The Monitoring, training and planning (MTP) approach to improve quality use of medicines in hospitals has been used by the Centre for Clinical Pharmacology and Drug Policy Studies at Gadjah Mada University, Yogyakarta, for developing medicine information.[65]

The state sponsored health care systems can provide MI on a limited list of medicines (or EML) which are part of the state health care system and some level of monitoring is a must. Otherwise, prescribers will use the medicines as they see fit and the full effect of providing information will be lost.[69,73]

Systems for monitoring medicines use have arisen out of financial necessity in some instances rather than for health reasons.[65,84] For example, the health care system in Turkey has a comprehensive payment system for medicines run by the Social and Welfare Department. This is to ensure that the medicines budget is controlled as well as used appropriately. The Health Department makes use of this medicines use information to improve prescribing practices. The data generated by the payment system can be used to improve prescribing and also to investigate if there are major deviations from the information provided.

8.6 Feasibility of access

Improving the accessibility and use of MI is another major challenge. It is widely recognised that primary care practices with limited resources should have access to primary (journals); secondary (indexing and abstracting) and tertiary (general reference books) sources of information. In low resource regions, lack of internal professional management or information technology expertise, little or no access to external expertise and lack of financial resources, results in poor economics and weak health care infrastructures. Non-affordability, lack of education on health, weak public distribution systems for medicines and shortage of trained health care personnel, all adversely affect ability to access medicines in developing countries.[85]

In order to overcome issues regarding access to MI, HCPs can be provided a basic MI service with e/mobile resources (e.g. Martindale, National formulary of India NFI, British National Formulary, eTG (e-Therapeutic Guidelines) or Micromedex with a time-limited access paid for by the governments. Another resource could be the hard copy of the national formulary of the country (as in the case of India, where primary health care facilities under the government-run National Health Mission were provided with hard copies of NFI 2011). A complementary time-limited subscription for web sites is also possible. Other existing resources that can be used by HCPs are e-drug discussion groups (for example, e-drug — Essential Drugs in English: http://list.healthnet.org/mailman/listinfo/e-drug). These resources should be sufficient for initiating a modest MI service. In addition, it is important for HCPs to become more active, to gain information from a variety of sources including medication guides, the internet and social media. Patients should also have easy access to various sources of MI.

MI resources should be developed and continuously updated by evaluating the primary literature. The most reliable evidence comes from reports on randomised controlled trials. Proper evaluation of these trials requires considerable experience, and systematic reviews of combined trials (meta-analyses) may be necessary. This information can be made available through country based National Information Center for Drugs and Pharmaceuticals (NICDAP). Regional Drug and Therapeutics Center (RDTC) are responsible for a range of issues relating to medicines use and medicines safety. These include monitoring and advising on prescribing of medicines.

8.7 Continuing education and professional training

In low resource regions, there is lack of basic professional training which can lead to dissemination of biased and inappropriate MI.[71] Continuous training is required, combined with monitoring, feedback and reinforcement. With the help of proper training programmes, there should be pre-services education of HCPs. Pre-services education (induction training) is the training initiative programme conducted to train and educate the members of HCP, so as to disseminate unbiased and appropriate MI. Examples include: Medical Education Partnership Initiative (MEPI), Nursing Education Partnership Initiative (NEPI), Human Resources for Health Program (HRH) and Global Health Service Partnership (GHSP).[71] Training programmes should assist medicine users in utilising the reliable information sources and services. Several universities obligate pharmacotherapy and patient counselling courses. These courses provide pharmacotherapeutic knowledge; skills required in communicating with patients about their diseases and treatments; and develop students' understanding of reflectivity so that they can learn to assess their communication skills and counselling

performance. Also, FIP has published a freely available resource that can be used when developing patient counselling courses for pharmacists, called "Counselling concordance, communication — Innovative education for pharmacists" (2012).[2] These educational programmes will promote the use of authentic and reliable information and communications technology to disseminate MI and promote the readability and usability of package leaflets.

Continuing in-service medical education (CME) is a requirement for licensure of health professionals in many industrialised countries. In many developing countries, opportunities for CMEs are limited. In these countries, no incentives are offered for CME since it is not required for continued licensure. CMEs are likely to be more effective if they are problem-based, targeted, involve professional societies, universities and the ministry of health, and are face-to-face.[69,86]

The training programmes can include the interaction of HCPs and consumers on medicines training of pharmacists and medicine sellers, improving prescribing in the private sectors and educational programmes for the general public.

8.8 Awareness among health care professionals and patients

The biggest barrier to initiating MI services is the lack of awareness of its necessity. In such cases, examples can be given of MI contributing to better health outcomes. On occasion, HCPs are also unable to utilise accurate and relevant MI. HCPs, patients and the general public should be aware of their role in the health sector. The strategy is to increase awareness of reliable information sources to HCPs and patients.

Awareness can be promoted by Internet, television and computers, by providing offline CDs, various educational and training programmes, medical education programmes, face-to-face communication, and free mobile apps and graphics. Media-based approaches (posters, audio tapes, radio and TV programmes), play a crucial role in building the awareness. Street theatre performed both at urban and rural centres is one more example of such an approach which has been used to promote awareness of the rational use of medicines, e.g., in Germany and Delhi.[65] However, it should be noted that in a few countries direct–to-consumer (DTC) advertising of prescription medicines on radio, television, or magazines is used to share MI with the general public. This is a highly controversial subject and FIP does not support DTC advertising of prescription medicines (Appendix 6).[50]

In low-resource settings, there is a critical need of both service and political leadership for developing health systems; and an adaptation of a MI system that delivers the basic health needs of societies systems to the specific needs of country and local settings.

9 Conclusions

General points

- MI is an important part of health care, and key for safe and effective use of medicines.
- Few countries have national MI strategies. Strategic development of MI is often included as part of national drug policies or action plans. Furthermore, MI is often seen as part of pharmacovigilance work.
- There is guidance widely available concerning how to compile written MI, although not extensively used.
- National medicines policies are needed. Pharmacists' expertise is needed to guide this work where it is seen as a great opportunity for pharmacists to be highly active in this area.
- Possibilities for strategic development of MI in low-resource settings differ from other parts of the world.

Observations for the strategic work

- An inter-professional approach and widespread cooperation between stakeholders is needed in the strategic development of MI. Wide networking will positively affect the implementation of the strategy.
- The development of the MI strategy should be based on the current MI situation in the country / area, i.e. identifying existing good practices and, on the other hand, deficiencies. Research into the strategy process and evidence informed decision making play an important role.
- A vision for the strategy, alongside relevant aims and actions should be clearly defined: what is meant to be achieved, how and according to what specific timetable. Desired outcomes should be explicit and interim markers of success used.
- Assessment of the strategy should be an integral part of the strategy process.
- Implementation of the MI strategy should be supported with resources. It should also be recognised that the implementation will take time.

Recommendations

To FIP:

- Adopt a FIP policy statement in order to highlight the importance of strategic development of MI

To pharmacy organisations:

- Initiate strategic development of MI nationally
- Demonstrate the importance of MI to increase rational medicine use, medication safety and increased adherence
- Be actively involved if strategic development of MI is undertaken

To pharmacists:

- Recognise the role of medicines information in relation to rational medicine use, medication safety and increased adherence.
- Use reliable medicines information sources appropriately.
- Demonstrate medicines information expertise to other health care professionals and participate in inter-professional collaborative initiatives.

To educational organisations of HCPs:

- Include inter-professional courses in the curriculum.
- Include skills on how to use medicines information databases and clinical decision-making tools in daily practice in the curriculum.
- Include the effective use of reliable medicines information sources in the curriculum.
- Promote the development of exemplary medication counselling skills.

To governments:

- Compile national medicines policies which include strategic development of medicines information.
- Compile national medicines information strategies to illustrate challenges and needs more explicitly.
- Provide resources and support to allow such work to be undertaken (including promoting and acknowledging the importance of medicines information).
- Oversee the implementation of accepted medicines information strategies and guidelines.
- Develop the criteria for certifying or accrediting medicines information centres and medicines information resources in collaboration with professional and educational bodies; and implement it.

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Appendices

APPENDIX 1. Terms of reference: FIP Working Group on Strategic Development and Use of Medicines Information

(October 2014)

Introduction

The current trend in health care emphasises the patient perspective and patient involvement, specifically, patient-centred care. Medicines information is essential in order to empower patients in their medicine use and in ensuring rational and safe use of medicines and adherence to long-term therapies. [1] Pharmacists should take an active role in developing medicines information practices. However, multi-disciplinary collaboration is also needed.

Medicines information (MI) is integral to many aspects of pharmacy practice activities. In the future, the role of medicines information will increase further as pharmacotherapies become increasingly individualised. In this Working Group (WG), medicines information is understood as a broad concept including information targeted at health care professionals and patients, and available and provided in written, electronic or verbal forms. [2] It includes, for example:

- Development of medicines information materials,
- MI databases and information systems used in day-to-day practice by health care professionals,
- Work conducted by Drug Information Centres,
- Patient counselling,
- Effective use of medicines information materials by patients.

Strategy refers to the tools and means of facilitating the implementation of a vision. In this WG, a MI strategy is understood as a guideline which gives suggestions on how MI could be developed nationally or regionally for health care professionals as well as patients. In such a strategy, all forms of MI described above can be taken into account. All stakeholders engaged in the development and use of MI can then adopt this strategy in their own practices.

Although a wide variety of MI sources and services exist, more attention should be paid to coordinate these resources in health care. For example, the European Commission High Level Pharmaceutical Forum highlighted in 2008, among other things, the need to consider national strategies in order to meet consumer needs for MI, and furthermore, that provision of MI should be a shared responsibility of all stakeholders in health care.[3] Thus, there is a recognised need for strategic development and implementation of MI for consumers. The potential to learn from other countries' experiences should be capitalised on, especially from countries that have established policies and strategies. By assisting one another, a global approach to developing MI may be reached and linked with medicines management policies.

Objectives

The aim of this WG is to engage and promote the role of the pharmacist in the strategic development and implementation of national MI policies and practices.

The specific objectives of the project are to:

- Collate and share information on existing national policies, strategies and initiatives to support the development and provision of MI aimed at health care professionals and/or the public;
- Identify the core elements that should be considered in developing a national MI strategy;

- Encourage pharmacists to take a lead role in the development of policies and strategies to strengthen MI provision; and
- Promote the role of pharmacists in the day-to-day development and provision of MI.

Expected outcomes

The expected outcome of this project is to establish guidance that FIP Member Organisations and individual Members can use to work with governments, Non-Government Organisations (NGOs), International NGOs (INGOs) and other relevant stakeholders to develop and implement national or regional policies and strategies for MI in their own countries or regions.

As this guidance would be an "umbrella" for developing MI, the process would also include evaluating the existing FIP Policy Statements related to MI. The reference paper to be drafted should address the following:

- Define key terms related to strategic development of MI
- Describe the goals and outcomes of strategic development of MI
    - Describe how MI is integral to pharmaceutical care and how it is an important tool to help improve: medication safety, rational use of medicines, pharmacovigilance, rational prescribing/dispensing of medicines, and health literacy.
    - Value of MI and extent of the expected impact which may be achieved by the strategic development of MI
    - Short-term, medium-term, long-term outcomes
- Provide examples from countries where MI strategies exists
    - Detail the process of how the strategy has been compiled, which stakeholders have been involved, and the identified trigger in starting the process
    - How the MI strategies have been implemented
    - The flaws and deficiencies in existing policies
    - Potential solutions to flaws and deficiencies
- Describe the process of strategic development of MI
    - Where to start, with suggestions of possible leaders on national / regional levels, concrete actions on how to proceed
    - Possible roles of individual pharmacists as well as pharmacy organisations
    - Ways to involve patients and the media
    - Ways to build an awareness strategy for all stakeholders
    - Ways to follow-up
    - Describe how strategic development of MI may be embedded in broader medicines management policies in countries where the infrastructure does not support development of stand-alone MI policies

Working group progress and time schedule achievements to date

The WG has been active since October 2012. The following tasks have been completed to date:

- Needs analysis through:
    - an Internet member survey of all FIP sections members in 2013 (report available)
    - collation of information about existing MI development strategies or policies, identified primarily using online websites (from USA, Australia, Europe, India-SEA-region, Rwanda) in March–June 2014 (summaries available)
- A three-hour session organised and held during the Bangkok FIP Congress (2.9.2014) entitled: Experiences in developing and implementing national medicines information strategies (Session C3). Presenters discussed global as well as regional MI policies and strategies, covering stand-alone policies and those embedded in broader medicines management policies. (slides available)
- WG meetings held at FIP congresses in Dublin 2013 and Bangkok 2014 (minutes of the meetings available)

Summary of findings (as at September 2014)

Based on the above mentioned activities, the following findings have been shown:

- Few countries have national MI strategies. Strategic development of MI is often included as a part of national drug policies or action plans. Furthermore, MI is often seen as part of pharmacovigilance work.
- There are extensive legal regulations on marketing authorisations and guidance concerning how to compile written MI and labelling for authorised medicines.
- National medicines policies are needed. Pharmacists' expertise is needed to guide this work where it is seen as a great opportunity for pharmacists to be highly active in this area.
- Possibilities for strategic development of MI in developed countries differ from other parts of the world.
- A multidisciplinary approach and widespread cooperation between stakeholders is needed in the strategic development of MI.

Organisation

The current organisation of the WG is described below.

Coordinator: Katri Hämeen-Anttila (Finland; email: katri.hameen-anttila@fimea.fi)

Working group members:

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Vivien Tong (Australia)
Pradeep Mishra (India)
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Stephen Mullenix (USA)
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Stefan Wild (Switzerland)
Rafia S. Rasu (USA)
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Hager Ben Mosbah (IPSF)
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Expert support:

Associate Professor Parisa Aslani (University of Sydney, Australia)
Professor Theo Raynor (University of Leeds, UK)
Professor Marja Airaksinen (University of Helsinki, Finland)

General support: FIP Health and Medicines Information Section executive committee members

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APPENDIX 2. National strategic plans for the development and use of medicines information. Internet survey for members of FIP sections.

Background

The current trend in health care emphasises patient perspective and involvement, specifically patient-centred care. Medicines information is essential in order to empower patients in their medicine use and in ensuring rational and safe use of medicines and adherence to long-term therapies. Pharmacists should take an active role in developing medicines information practices. However, multi-disciplinary collaboration is also needed.

Medicines information is related to many aspects of pharmacy practice activities. In the future, the role of medicines information will increase further, as pharmacotherapies will increasingly be individualised. In this project, medicines information is understood as a wide concept including information targeted to health care professionals and patients, and in written, electronic or verbal forms. It includes, for example,

- Development of medicines information materials,
- Use of medicines information databases and information systems in day-to-day practice by professionals,
- Work of drug information centres,
- Patient counselling,
- Development of medicines information materials targeted to patients etc.

Strategy refers to the tools and means of facilitating the implementation of the vision. In this project, a medicines information strategy is understood as a guideline which gives suggestions on how medicines information could be developed nationally for health care professionals as well as patients. In such a strategy, all forms of medicines information described above can be taken into account. It is assumed that all stakeholders engaged in medicines information would follow the strategy in their own practices. Thus, in this project, strategy does not refer to a legislative strategy.

Although a wide variety of medicines information sources and services exist, more attention should be paid to coordinate these resources in health care. For example, the European Commission High Level Pharmaceutical Forum highlighted in 2008, among other things, the need to consider national strategies in order to meet consumer needs for medicines information, and furthermore, that provision of medicines information should be a shared responsibility of all stakeholders in health care. Thus, there is a recognised need for strategic development and implementation of medicines information for consumers. In fact, some EU countries have either developed or are currently developing national strategies for medicines information. The potential for learning from other countries' experiences should be utilised; however, it is not known which countries have national medicines information strategies and policies.

The aim of this project is to engage and promote the role of the pharmacist in the strategic development and implementation of national medicines information policies and practices.

Expected final outcomes and impact

The final outcome of this project is to establish guidance or a practical tool that FIP Member Organisations can use to work with governments to develop and implement their own national policies and strategies for medicines information. We aim that this guidance will be in a form of FIP Policy Statement on strategic development of medicines information. To assist in achieving these aims an Internet survey was conducted. The specific objectives of this survey were to:

- Collate and share information on existing national policies, strategies and initiatives to support the development and provision of medicines information aimed at health professionals and/or the public.
- Identify the core elements that should be considered in developing a national medicines information strategy

- Identify key stakeholders who should be involved in strategic development of medicines information

Methods

Data collection and analysis

An Internet survey was conducted in May to June in 2013 using Webropol survey tool. The survey was piloted and the questionnaire was revised according to pilot answers (n=25). The pilot survey was sent to FIP Working Group and PIS ExCo members, who distributed it through their own networks.

The survey was sent to all FIP sections' members through sections' secretaries and chairs. Respondents were first asked about existing national medicines information strategies and to describe the strategies. The second part of the survey was to identify core elements which should be considered if developing such a strategy. Of the identified core elements, respondents were asked to identify more specific areas which should be covered. Thirdly, respondents were asked to identify stakeholders and their role if a medicines information strategy were to be developed, and the ways how pharmacists could be involved in developing it.

The data of the survey was analysed with Microsoft Excel using descriptive statistics. Due to the low number of responses for the main survey (n=19), the results of the pilot study are merged with the results of the main survey in this report.

Results

Background information on respondents

Details of background variables of the respondents are in table 1. The median age of the entire group was 35 years and of the 44 respondents 25 were female. Hospital Pharmacy was the largest FIP section among the respondents.

TABLE 1. Demographic information (n=44)

Variable	n
Age	
<20	0
20–29	15
30–39	13
40–49	10
50–59	5
<60	1
Gender	
Female	25
Male	19
FIP section	
Hospital pharmacy	13
Pharmacy information	10
Academic pharmacy	7
Community pharmacy	5
Social and administrative pharmacy	5
Military and emergency pharmacy	4
Industrial pharmacy	2
Clinical biology	1

Variable	n
Continent (countries)	
Europe (*Belgium, Denmark, Finland, Germany, Hungary, Norway, Republic of Macedonia, Serbia, Spain, Turkey, Ukraine*)	14
Americas (*Brazil, Canada, Chile, Costa Rica, Ecuador, El Salvador, Peru, United States of America*)	13
Africa (*Egypt, Nigeria, Republic of Rwanda, Republic of the Sudan, South Africa*)	9
Asia (China, Nepal, Philippines)	4
Australia	1
Other (Yemen, unknown)	3
First pharmacy or professional degree *	
< 5 years ago	11
5–10 years ago	8
11–15 years ago	10
16–20 years ago	4
< 20 years ago	10
Unknown	1
Field of pharmacy	
Academia	10
Hospital pharmacy	9
Military / emergency pharmacy	5
Professional association	3
Community pharmacy	2
Pharmaceutical manufacturing	2
Research and development	2
Government	3
Other	8‡

*Other than pharmacy degree: Pharmacy technician; assistant or professor (PhD)
‡Other fields of practice: student, retired, public health pharmacy, medical device industry, health care publishing and information industry, federal pharmacy's board, drug information, development of quality assurance system for compounding preparations

Existing national policies, strategies and initiatives

Of the respondents, 41 % (n=18) reported having an existing strategy for medicines information (Table 2). Most of them include both patient and health care professionals' perspectives.

TABLE 2. Existing national medicines information strategies (n=44)

Type of strategy	% (n)
Strategy which includes both patient and health care professionals *	30 (13)
Strategy which includes only health care professionals *	9 (4)
Strategy which includes only patient *	2 (1)
No strategy	32 (14)
Don't know	27 (12)

* See table 3

The respondents who indicated having a medicines information strategy (n=18) described their strategy as follows (Table 3): 27 % have drug information centre activities for the public and 27 % for health care professionals, 13 % have a national medicines policy, and one respondent in the pilot survey described a national strategy for medicines information.

TABLE 3. Respondents' descriptions of their existing medicines information strategies (n=15)*

Content	% (n)
Drug information centre activities for the public	27 (4)
Drug information centre activities for health care professionals	27 (4)
National medicines policy	13 (2)
Other	40 (6)†

* More than could be described
† Others were: Electronic medicine monitoring system, Good Pharmacy Practice, medicine information (strategic), pharmaceutical counselling, rational drug use and regulatory agency

Developing medicines information strategy

In the second part of the survey, the respondents were asked to identify core elements which should be included if a national medicines information strategy were developed. All of the core elements which were presented in the survey were regarded as important to be included (73%–93%) (Table 4). High-quality medicines information targeted at patients and medicine users was the most important element to be included (93%).

Elements which the respondents viewed as not so important to be included were: 1) Education and continuing professional education (11 %) and 2) Development of medicines information aimed at special patient populations (11 %). Reasons for their opinion were not requested.

TABLE 4. Core elements in the development of a national medicines information strategy (n=44)

Should the element be included in the medicines information strategy?			
Core element	**Yes % (n)**	**No % (n)**	**Don't know % (n)**
High-quality medicines information aimed at patients and medicine users *(see Table 5)*	93 (41)	5 (2)	2 (1)
High-quality medicines information aimed at health care professionals *(see Table 6)*	86 (38)	0	14 (6)
Development of educational programs at university level for health care professional degrees and continuing professional education for health care professionals *(see Table 7)*	84 (37)	11 (5)	5 (2)
Development of the role of drug information centres *(see Table 8)*	84 (37)	9 (4)	7 (3)
Availability of patients' medication records to health care providers for patient care *(see Table 9)*	84 (37)	9 (4)	7 (3)
Development of medicines information aimed at special patient populations *(see Table 10)*	84 (37)	11 (5)	5 (2)
Medicines information services by the health care professionals *(see Table 11)*	73 (32)	7 (3)	20 (9)
Other *(see Table 12)*	41 (18)		

Contents of the core elements in a national medicines information strategy

Information for patients

Of the respondents, 83 % regarded that "availability of adequate and reliable information resources aimed at patients and medicine users" is an area which should be covered if a national medicines information strategy were developed (Table 5).

TABLE 5. Development of high-quality medicines information aimed at patients and medicine users (n=40)

Areas of medicines information*	% (n)
Availability of adequate and reliable information resources aimed at patients and medicine users	83 (33)
Use of information and communications technology to disseminate medicines information to patients and medicine users	70 (28)
Assessment of the usefulness and impact of medicines information	40 (16)
Other	10 (4)†

* More than one could be chosen
† Other areas were: develop methods of assessing the level of understanding of patients and medicine users, standards for what information should be provided and formatting standards, same as that given by professions (individual), promote health activity , changing bad habits, psychological advice and any preventive strategy that decrease the need of medicines

Information for health care professionals

"Strategies to increase awareness of availability of reliable and up-to-date information sources among health care professionals" was viewed by 89 % of the respondents as an area which should be covered if a national medicines information strategy were developed. (Table 6). "Access to reliable information resources for health care professionals" was also viewed as an important area by 79 %.

TABLE 6. Areas that could be developed in terms of high-quality medicines information aimed at health care professionals (n=38)

Area of medicines information *	% (n)
Strategies to increase awareness of availability of reliable and up-to-date information sources among health care professionals	89 (34)
Accessibility of reliable information sources for health care professionals	79 (30)
Availability of adequate and reliable information resources for health care professionals and health care practice sites, including pharmacies	34 (13)
Other	13 (5)†

* More than one could be chosen
† Other areas were: alerts and recalls of medicines; clinical practice guidelines systematic reviews comparative effectiveness; health care professionals should be curious about information on their own; risks associated with commercial sources of medicines information/promotion; use the knowledge you possess already in a more appropriate manner

Development of educational programmes

"Knowledge of pharmacotherapies" (86 %) and "Patient-centred medicines information" (84 %) were seen as important areas which should be taken into account when developing educational programs for pharmacists – and as such they should be recognised in a national medicines information strategy (Table 7). Critical information evaluation skills (78 %) and patient counselling skills (78 %) were also regarded as areas to be included.

TABLE 7. Development of educational programmes (n=37)

Area of development*	% (n)
Knowledge of pharmacotherapies	86 (32)
Patient-centred medicines information	84 (31)
Skills to evaluate information critically	78 (29)
Patient counselling skills	78 (29)
Multidisciplinary collaboration	68 (25)
Information retrieval skills	62 (23)
Use of pictograms in patient counselling	54 (20)
Use of online medicines and health information resources	30 (11)
Skills to interpret cost analysis of medicines	27 (10)
Information skills for public health promotion	24 (9)
Other	16 (6)†

* More than one could be chosen
† Other areas were: good practices of storage, human behaviour and communication skills, knowledge of drug-related software packages, skills to simplify the medically complex situations to simple ones that aid understanding, systematic review and comparative effectiveness, trustworthy personality

Role of the drug information centres

"Increasing collaboration between drug information centres" was viewed as an area which should be covered if a national medicines information strategy were developed (62 %) (Table 8). Of the respondents, 57 % regarded "promoting the work of the centres" also as an area which should be developed.

TABLE 8. Development of the role of drug information centres (n=37)

Ways of development*	% (n)
Increase in collaboration between centres	62 (23)
Promotion of the work of the centres	57 (21)
Funding and administrative aspects of medicines information centres	51 (19)
Evaluation of the work of drug information centres	30 (11)
Increase in international collaboration between centres	27 (10)
Other	14 (5) †

* More than one could be chosen
† Other ways were: develop methods of evaluation of work and how it can be improved, outline standard services to be offered by DICs, participation of DI centres in academic detailing, health professional education, reporting and analysing experiences with use of medicines in populations, easy access, establishment of drug information centres

Information about patients' medicine use

"Availability of information about patients' medicine use to all professionals involved in care of the patient" was viewed by 84% of the respondents as an area which should be covered if a national medicines information strategy were developed (Table 9). Another important area was "sharing information on patients' medicine use by all health care professionals with each other to improve rational medicine use" (78%).

TABLE 9. Development of the availability of patients' medication records to health care providers for patient care (n=37)

Areas of patient's medication records*	% (n)
Availability of information on patients' medicine use to all health care professionals involved in the care of the patient, with the patient's approval	84 (31)
Sharing of information on patients' medicine use by all health care professionals with each other to improve rational medicine use	78 (29)
Comprehensive recording of information on patients' medicine use by all health care professionals	76 (28)
Access to information on patient's medicines use by the patient	59 (22)
Other areas	14 (5) †

* More than one could be chosen
† Other areas were: reconciliation of medicine use in transitions of care from home to hospital to other care facilities; improve basic communication skills based on better understanding of patient perspective; all this should be with patient autonomy in focus, professionals should not get information the patient does not want to share (except maybe emergencies); ensure easy accessibility of available information; make a unit to control records

Information for special patient populations

Children and adolescents (92%) and the elderly (86%) were patient populations which respondents viewed as special populations to be encompassed if a national medicines information strategy were developed (Table 10). Of the respondents, 68% regarded the deaf and hard of hearing and 65% the blind and visually impaired as special populations which should also be included.

TABLE 10. Special patient populations which should be encompassed in a medicines information strategy (n=37)

Patient population*	% (n)
Children and adolescents	92 (34)
Elderly	86 (32)
Deaf and hard of hearing	68 (25)
Blind and visually impaired	65 (24)
Ethnic minority groups	54 (20)
Pregnant and breastfeeding women	49 (18)
Low literacy (including health literacy)	38 (14)
Other	11 (4)†

* More than one could be chosen
† Other populations were: vulnerable groups like people with mental problems etc., groups that use a lot of medicines, or medicines that are complicated in one way or another, victims of criminals (violence)

Medicines information services

"Multidisciplinary cooperation in medicines information services" was viewed by 78% of the respondents as an area which should be covered if a national medicines information strategy were developed (Table 11). When looking at medicines information services targeted to patients, "use of counselling aids to assist in patient education" (38%) and "obtaining information from the patients about their knowledge of medicines" (38%) were regarded as the most important areas to be covered.

TABLE 11. Areas of medicines information services by the health care professionals (n=32)

Areas of medicines information*	% (n)
Medicines information services for health care professionals	
Multidisciplinary cooperation in medicines information services	78 (25)
Harmonising the provision of medication counselling in health care	69 (22)
Establishment of a national medicines information network	66 (21)
Medicines information services for patients	
Use of counselling aids to assist in patient education	38(12)
Obtaining information from the patients about their knowledge about the medicines they are using	38 (12)
Use of pictograms	19 (6)
Tailoring of medicines information for individual patients	19 (6)
Other	25 (8)†

* More than one could be chosen
† Other areas were: best plan for student (more practices); better understanding of patient perspective; develop a printable bulletin, journal etc; obtain information about problems the patient may have with access to prescribed medicines; adverse effects and information on self-medication; organising workshop for specific group of patient; reliable internet sources for patients, that they are adapted to the individual patient and his/her context

Other areas to be included in a medicines information strategy

Respondents' identified the following other areas to be included in a medicines information strategy: content of information (33%), education (17%), role of IT-technology and its' use (11%) and implementation of medicines information strategy (11%) (Table 12).

TABLE 12. Other areas to be included in a medicines information strategy (n=18)

Areas of information*	% (n)
Content of information	33 (6)
Education	17 (3)
Role of IT and its use	11 (2)
Implementation of strategy	11 (2)
Other	44 (8)
Adequate information resources and tools	
Awareness of counterfeit medicines	
Flow of information	
General access to evidence based databases	
Global standard format	
Methods of obtaining knowledge	
Research	
Role of government and regulatory authority	

* More than one could be mentioned

Ways of working towards development and implementation of a medicines information strategy

Respondents' indicated as the stakeholders which should be involved when developing a national medicines information strategy: pharmacy associations (98 %), tertiary educational institutions (98 %), ministry of health (93%), pharmacy students' associations (80 %) and hospital pharmacies (80 %) (Table 13). Pharmacy as a field was seen as the most important to be represented compared to medicine or nursing

TABLE 13. Stakeholders to be involved in a development of a national medicines information strategy (n=44)

Stakeholder*, Field	% (n)
Scientific or professional associations	
Pharmacy	98 (43)
Medicine	80 (35)
Nursing	64 (28)
Pharmacy technician	25 (11)
Tertiary educational institutions (e.g. universities)	
Pharmacy	98 (43)
Medicine	77 (34)
Nursing	57 (25)
Pharmacy technician	18 (8)
Other	5 (2)†
Governmental agencies	
Ministry of health	93 (41)
National medicines agency	73 (32)
Social insurance institution	41 (18)
Pharmaceuticals pricing board	39 (17)
Other	2 (1)‡
Students' associations	
Pharmacy	80 (35)
Medicine	66 (29)
Nursing	43 (19)
Pharmacy technician	14 (6)
Other	2 (1)
Other stakeholders	
Hospital pharmacies	80 (35)
Health information experts	75 (33)
Community pharmacies	73 (32)
Patient or advocacy support organisations	55 (24)
Pharmaceutical industry	55 (24)
Information design experts	48 (21)
Private health insurers	25 (11)
Linguists	20 (9)
Social welfare organisations	18 (8)
Other	7 (3)§

* More than one could be chosen
† Other fields were veterinary and sociology
‡ One respondent indicated that it depends on the country
§ Others were: consumer forum, all health care practitioners, young generation

Of the respondents, 32 % regarded that the ministry of health should take the leading role when developing a national medicines information strategy. National medicines agency, pharmacy associations and

community pharmacies were seen as other possibilities to take the leading role of such development by 14% of the respondents (Table 14).

TABLE 14. Stakeholder which should take the leading role when developing a national medicines information strategy (n=28)

Stakeholder*, Field	% (n)
Governmental agencies	
Ministry of health	32 (9)
National medicines agency	14 (4)
Other	18 (5)†
Scientific or professional associations in the field of	
Pharmacy	14 (4)
Medicine	7 (2)
Tertiary educational institutions in the field of	
Pharmacy	4 (1)
Medicine	4 (1)
Other	4 (1)‡
Others	
Community pharmacies	14 (4)
Hospital pharmacies	4 (1)
Other	25 (7)§

* More than one could be mentioned
† Other governmental agencies were governmental agencies and (national) health authorities in general, ministry of health in collaboration with professional organisations and medicine, pharmacy and drug regulatory bodies
‡ Other tertiary institution was university in general
§ Other stakeholders were family health teams, national bodies, pharmacists, physicians, national health funding and national health research (one unknown answer)

Involving pharmacists in development of national medicines information strategies

The most common means of how pharmacists could be involved in the development of national medicines information strategies is shown on table 15. Identifying needs for educating and training of pharmacists on provision of medicines information (19 %) was the most common mean mentioned.

TABLE 15. Ways to involve pharmacists in development of national medicines information strategies (n=43)

Way of involvement*	% (n)
Identifying needs for educating and training of pharmacists on provision of medicines information	91 (39)
Identifying types of medicines information to be disseminated for different target audiences	81 (35)
Identifying needs for educating and training of other health care professionals on provision of medicines information	81 (35)
Raising awareness of the need for multi-disciplinary collaboration in medicines information	79 (34)
Assessing problems related to medicines information needed to be addressed in the strategy	77 (33)
Identifying target audiences needing medicines information	72 (31)
Other suggestions	7 (3)†

* More than one could be chosen
† Others were: assessing pharmacovigilance; participation in the preparation of the National List of Essential Medicines; raising awareness on the importance of developing national medicines information generally

Discussion

The results of this survey indicate that few countries have national medicines information strategies. On the other hand, it seems that the strategic development of medicines information is often included as a part of national drug policies or action plans e.g., for drug information centres. As medicines information is closely connected to a wider context such as patient safety or adherence, this may be well justified. However, it is important that medicines information is recognised as an essential tool to empower patients in their medicine use and ensuring rational and safe use of medicines, and as such, strategic development of medicines information is taken into account.

The majority of the respondents viewed high-quality medicines information aimed at patients, medicine users and health care professionals as core elements considered when developing a national medicines information strategy. Other aspects to be considered in a medicines information strategy were developing the educational programs of the professionals providing medicines information, and furthermore, the role of drug information centres. Knowledge of pharmacotherapies is an essential part of medicines information and it needs to be patient-centred. Because of the wide range of information available, professionals need to be more critical when evaluating information. Furthermore, developing the role of drug information centres is important, including collaboration with other centres.

Limitations

This survey was sent to individual FIP members, and thus, it represents only the view of the pharmacy field. The number of responses was very low so the results may be considered as indicative. However, there were responses from all over the world from many different countries. The real situation whether or not national medicines information strategies exist may not be covered with this survey. However, the aim of this survey was also to identify the core elements and key stakeholders that should be considered in developing a national medicines information strategy as the basis of the work for the working group. With this survey, basis for a discussion was gained.

APPENDIX 3. Existing medicines information development strategies or policies, identified primarily using online websites

Summary of documents identified relevant to the strategic development of medicines information in Australia

Name of the document (year)	Link to the document	Responsible organisation and link to the organisation website	Notes
National Medicines Policy- Australia (2000)	http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029EEAC8CA257BF0001BAF3F/$File/NMP2000.pdf	Australian Government Department of Health (www.health.gov.au)	• This document outlines Australia's National Medicines Policy, where Quality Use of Medicines (QUM) forms part of this policy • QUM deems that medicines should be utilised: judiciously, appropriately, safely and efficaciously (p.3) • Page 3 describes that information development, implementation and provision is paramount to facilitating QUM • Page 5 outlines strategies that could aid QUM
The National Strategy for Quality Use of Medicines: Plain English Edition (2002)	http://www.health.gov.au/internet/main/publishing.nsf/Content/8ECD6705203E01BFCA257BF0001F5172/$File/natstrateng.pdf		• Outlines the responsibilities of various groups such as consumers, health care professionals, government, and stakeholders with regards to facilitating QUM • 1 of the key foundations of QUM identified is providing information (which indicates the importance of the development of appropriate and viable medicine information) • Page 14 outlines the characteristics that this information should have
Best practice guidance on prescription medicine labelling (2008)	http://tga.gov.au/industry/labelling-pm-best-practice.htm#.U5orMyiJo1k	Therapeutic Goods Administration (www.tga.gov.au)	• Outlines the requirements that manufacturers/sponsors should adhere to with regards to prescription medicine label design and content • Also makes mention to how the product name (or active ingredient) should be used in Consumer Medicine Information (CMI) and the Product Information (PI) • Should be read in conjunction with the Therapeutic Goods Order 69, which is the legislative document which mandates certain labelling requirements for medicines in Australia
CTD (Common Technical Document) Module 1- Administrative information and prescribing information for Australia (2015)	https://www.tga.gov.au/sites/default/files/ctd-module-1-150701.pdf		• Module 1.3 in the document outlines requirements for medicines information such as CMI, PI and labelling for applications made to the Therapeutic Goods Administration • This document essentially seems to be aimed at medicine sponsors who develop this information

Name of the document (year)	Link to the document	Responsible organisation and link to the organisation website	Notes
Australian Regulatory Guideline for over-the-counter medicines Appendix 3: Guidelines on presentation aspects of OTC applications (2012)	https://www.tga.gov.au/sites/default/files/otc-argom-121109.pdf		• This document outlines the requirements for CMI, PI and packaging for OTC medicines • It outlines the content that is required to be included in OTC labels (see Section 3) • Sections 4 and 5 refer to PIs and CMIs respectively
Writing about medicines for people: Usability guidelines for Consumer Medicine Information (3rd edition) (2006)	http://communication.org.au/product/writing-about-medicines-for-people/	Communication Research Institute (http://communication.org.au/)	• The focus of this document is on the development and testing of CMI, the standardised Patient Information Leaflet format implemented in Australia for all prescription and Pharmacist Only medicines (Schedule 3 over-the-counter) • These guidelines provide an outline of what CMI is, how it is used by consumers, a detailed explanation of the CMI layout utilised, detailed principles for development and user testing of the document • User testing is at present considered the gold standard in medicine information leaflet performance testing within a broad context • This document is aimed at CMI developers, namely the medicine sponsors/manufacturers, as they are primarily responsible for CMI development
ASMI Code of Practice (2015)	http://www.asmi.com.au/media/13874/asmi_code_of_practice_jan_2015.pdf	Australian Self Medication Industry (www.asmi.com.au/home/default.aspx)	• Section of interest: Section 7 (CMI) (p.33) • This is relevant for Schedule 3 (Pharmacist Only) OTC medicines • Reinforces that CMI must be objective, where CMI development should be centered around consumers
ASMI Labelling Code of Practice (2004)	http://www.asmi.com.au/documents/Industry/labelling_code_of_practice.pdf		• Provides guidance on how to develop OTC labels • Outlines the purpose and expectations of OTC labels, OTC label content, benchmark standards for OTC label performance and the process of OTC label development • Testing process (user testing) similar to that outlined in the Usability Guidelines published by the Communication Research Institute for CMI development and testing
Principles about writing and testing Consumer Medicine Information (2006)	http://www.asmi.com.au/documents/Industry/CMIs/CMI_Principles%20about%20writing%20and%20testing.pdf		• Outline of what CMI is, performance benchmark standard for CMIs, and the role of CMI

Name of the document (year)	Link to the document	Responsible organisation and link to the organisation website	Notes
Usability guidelines for writing CMIs (2002)	http://www.asmi.com.au/documents/Industry/CMIs/CMI%20Usability%20Guidelines%20for%20Writing.pdf	Australian Self Medication Industry (www.asmi.com.au/home/default.aspx)	• Outlines the usability guidelines and the changes that have been made when comparing the current usability guidelines to previous editions, issues to consider and the purpose of the guidelines
The Vocabulary for CMI- An explanatory note (no date, cited 2017 Jan 12)	http://www.asmi.com.au/documents/Industry/CMIs/CMI_Vocab%20Explanatory.pdf		Brief statement which guides the user on how to use the vocabulary list containing user-friendly terms, useful for when developing medicine information (see document link "The Vocabulary for CMI - An Explanatory Note" below)
The Vocabulary for CMI - An Explanatory Note (2004)	http://www.asmi.com.au/documents/Industry/CMIs/CMI_VOCAB.pdf		• Contains a list of user-friendly terms to help reduce the medical jargon burden of CMIs
How to present the evidence for consumers: preparation of consumer publications (2000)	http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cp66.pdf	National Health and Medical Research Council (www.nhmrc.gov.au)	• Detailed document outlining and elaborating on the process of developing information materials for consumers with respect to clinical practice guidelines • Page ix provides a flow chart of where this fits into the bigger picture • This a highly relevant document- it will be worthwhile and of great use to read in detail
SHPA Standards of Practice for Medicines Information Services (2013)	https://www.shpa.org.au/sites/default/files/uploaded-content/field_f_content_file/51._medinfo_ps.pdf	Society of Hospital Pharmacists Australia (www.shpa.org.au)	• This document authored by the Society of Hospital Pharmacists Australia act as guidelines for persons involved in the delivery of medicines information services • Provides various definitions for specific aspects or types of medicines information services available (please see page 1 of the document for more detail) • Outlines the processes that should be undertaken or considered when delivering medicines information services
Australian Safety and Quality Framework for Health Care: Putting the framework into action: Getting started (2011)	http://www.safetyandquality.gov.au/wp-content/uploads/2011/01/ASQFHC-Guide-Policymakers.pdf	Australian Commission on Safety and Quality in Health Care (www.safetyandquality.gov.au)	• Page 3 of interest- provides guidelines for policy makers with regards to development of information resources for patients

Development strategies for medicines information in the USA

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Legal requirements for medicines information: National and state			
National			
Labelling and advertising requirements: 21 U.S.C. 314 21. U.S.C. 352	United States Code (U.S.C.) 21 U.S.C. 314: (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=314) 21. USC.352: (www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec352.pdf)	United States Federal Government	Aim: To regulate the labelling and advertising requirements of all manufactured prescription medicines for human use
Format and content requirements for over-the-counter (OTC) drug product labelling : 21 CFR 201.66	Code of Federal Regulations (CFR) (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.66)	United States Federal Government	Aim: To regulate the labelling of all manufactures over-the-counter medicines for human use
Dietary supplements patient information requirements: 21 U.S.C. 352(x)	United States Code (U.S.C.) (http://www.fda.gov/Food/DietarySupplements/))	United States Federal Government	Aim: To regulate the labelling and claims information made to consumers about all dietary supplements
State			
California Code of Regulations: Title 16, addition of section 1202.7 (Passed January 2010)	http://www.pharmacy.ca.gov/laws_regs/labeling_requirements.pdf	State of California	Aim: To create a “standardised patient-centred” label for prescription drug containers Gives standard requirements for all drug containers dispensed to patients in the state of California

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Drug information centres in the US			
Prevalence			
Current status of pharmacist-operated drug information centers in the United States, October 2004	www.ncbi.nlm.nih.gov/pubmed/15509125	Independent study conducted by researchers: Rosenberg JM, Koumiss T, Nathan JP, Cicero LA, McGuire H	Aim: To look at the affiliations, staffing, services, resources, quality assurance, involvement in education, and funding of DIC in the USA Looked at 151 institutions thought to be DICs (drug information centres) Number of DICs has "declined steadily since 1986". Number of drug-information pharmacists "is at its lowest in 30 years". "Only half of DICs surveyed had a formal quality assurance programme". Conclusions about DIC resources: most common DIC affiliation with hospitals and medical centres; second most common with pharmacy schools Indicates that MI is generated from protocol of large medical centre or pharmacy school and conveyed by the pharmacist
Update on the status of 89 drug information centers in the United States, October 2009	www.ajhp.org/content/66/19/1718.abstract	Independent study conducted by researchers: Rosenberg JM, Koumis T, Nathan JP, Cicero LA, McGuire H [UPDATE]	Aim: Assessing changes in the previously identified DICs Decrease in number of DICs: only 75 active Conclusions: biggest changes were "increases in the number of DICs focusing on educating health-professions students, the complexity of drug information questions, and the amount of time required to answer each request"
Collaboration			
Collaboration between a drug information center and an academic detailing program, January 2014	www.ajhp.org/content/71/2/128.abstract	Independent study conducted by researchers: Wisniewski C, Robert S, Ball S	Aim: To assess the relationship between a DIC and an academic detailing program Conclusion: two-way communication between the DIC and academic program, open conversation with many professional opinions

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Drug information resources			
Systematic approach to drug information requests, December 1975	http://www.ncbi.nlm.nih.gov/pubmed/1211401	Independent paper conducted by researchers: Watanabe AS, McCart G, Shimomura S, Kayser S	Aim: Design systematic technique to answering drug information (DI) questions This research and technique serves as foundation and gold standard for all drug information request approaches
Modified systematic approach to drug information requests, 1987	Unable to find paper directly online. Cited in following presentation: http://faculty.ksu.edu.sa/jamilah/312%20PHCL/ModifApproach%20AnsQ.pdf	Independent paper to serve as a follow-up (Systematic approach to drug information requests, 1975)	Aim: To further develop and update the systematic technique illustrated by Watanabe *et al* Modified approach from Steps I – V to Steps I – VII
Contemporary drug information: an evidence-based approach, 2008	Textbook	Textbook written by Gaebelein C, Brenda L, Gleason	Aim: Outlines framework for evaluation of contemporary health care information, offers tools for evaluating such materials, and the role in clinical decision making
ASHP guidelines on the pharmacist's role in providing drug information	www.ashp.org/DocLibrary/BestPractices/DraftDocs/DraftGdlDI.aspx	Guidelines by the American Society of Health-System Pharmacists (ASHP)	Aim: To offer a framework for how pharmacists can provide DI to patients Cites the Watanabe et al. approach
Drug information- the systematic approach, April 2013	http://jpp.sagepub.com/content/26/2/78.abstract	Independent study conducted by researcher: Nathan JP	Aim: Educating the pharmacy practitioner on proper guidelines for fulfilling DI requests
List of drug information databases available to pharmacy practitioners; gold standards included	See Appendices 1 and 2.	N/A	Aim: To show gold standard databases that should be used based on DI request category Gives description of what each database provides

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Federal (FDA) guidelines on medicines Information: Guidances on labelling, advertising			
Comprehensive list of FDA's guidances	www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm	US Department of Health and Human Services (HHS)- Food and drug administration (FDA)	Aim: comprehensive compilation of FDA guidance (including advertising, labelling, and OTC products among other guidance on bioequivalence issues, biopharmaceutics, microbiology, chemistry and manufacturing controls, clinical, clinical pharmacology, concept papers, current good manufacturing practices, drug development tools, drug safety, e-submissions, generics, OTC, small entity compliance guides, user fees, etc.)
Guidance: Useful written consumer medication information, July 2006	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080602.pdf	US Department of Health and Human Services (HHS)- Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To help individuals or organisations to create "useful written consumer MI". Helps evaluate current MI and develop quality future MI Includes criteria on the nature of MI (accuracy, unbiased nature, comprehensive, up-to-date) Includes criteria on content of MI (drug name, indications, contraindications, directions, precautions, Adds) Includes criteria on written appearance of MI (10pt or larger font, bolder type, use of both upper and lower case, adequate spacing, short-moderate line length, text and colour with strong contrast) Gives an example of what a satisfactory MI leaflet for a prescription drug should look like
Guidance for industry: Brief summary: Disclosing risk information in consumer directed print advertisements, August 2015	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM069984.pdf	US Department of Health and Human Services (HHS)- Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: Provide guidance on "disclosure of risk information in prescription drug product advertisements directed toward consumers in print media" States that FDA would not object to a printed advertisement as long as it gives a brief summary OR the actual patient-approved labelling (note that patient approved labelling is different than prescriber labelling)

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Guidance for industry: Direct-to-consumer television advertisements- FDAAA DTC television ad pre-dissemination review program, March 2012	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM295554.pdf	US Department of Health and Human Services (HHS)- Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: Guidance is to inform companies how the FDA will "implement the requirement for the pre-dissemination review of direct-to-consumer television advertisements" States that the FDA may require the submission of a television advertisement 45 days before its dissemination FDA can review the advertisement. To include advertisements of certain categories (1. Initial advertisement of any Rx or new indication of Rx 2. Advertisement for a drug with REMS 3. Advertisement for a CII drug 4. First advertisement following safety-labelling update 5. Replacement advertisement for an advertisement that previously violated FDA guidance 5. Any other advertisement the FDA deems necessary to review
Guidance for industry: consumer directed broadcast advertisements, August 1999	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070065.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To help "assist" sponsors in advertising prescription drugs through for example radio, telephone, or television Advertisements must have brief summary or meet adequate provision requirement (major statement + adequate provision)
Guidance for industry: Fulfilling regulatory requirements for post marketing submissions of interactive promotional media for prescription human and animal drugs and biologics, January 2014	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To inform companies on how to fulfil regulatory requirements for "post marketing submission of interactive promotional media" for their prescription drugs. Interactive promotional media was defined as "modern tools and technologies that allow for real-time communications and interactions (e.g., blogs, micro blogs, social networking sites, online communities, and live podcasts) Inform firms to submit the entirety of the sites at the initial time of display, as well as any third party sites, which the firm may be participating with. Also informs firms to submit an updated version of the site once every month

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Guidance for industry: "Help-seeking" and other disease awareness communications by or on behalf of drug and device firms , January 2004	http://www.fda.gov/OHRMS/DOCKETS/98fr/2004d-0042-gdl0001.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To "provide guidance to industry regarding so-called "help-seeking" and other disease awareness communications" Recommendations, not required, on disease awareness communications to public
Guidance for Industry: Product name placement, size, and prominence in advertising and promotional labeling, January 2012	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM375784.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To "clarify the requirements for product name placement, size, prominence, and frequency in promotional labelling and advertising for prescription human drugs, including biological drug products, and prescription animal drugs"
Guidance for Industry: Presenting risk information in prescription drug and medical device promotion, May 2009	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To demonstrate how the FDA "evaluates prescription drug and medical device promotional pieces to determine whether they adequately present risk information"
Guidance for industry: Labelling OTC human drug products - questions and answers, December 2008	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM078792.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To assist manufacturers, packers, and distributors in standardised labelling content and format of over-the-counter products
Guidance for Industry: Labelling of nonprescription human drug products marked without an approved application as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers, September 2009	www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM180790.pdf	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To assist in labelling requirements of those drugs covered under the Dietary supplement and Nonprescription Drug Consumer Protection Act

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Guidances for Industry: Guidances for labeling of specific classes of medications.	www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065010.htm	Food and Drug Administration (FDA) – Center for Drug Evaluation and Research (CDER) – Division of Drug Information	Aim: To assist in developing labelling for different classes of medications used to treat different disease states Guidance for geriatric labelling Guidance for hypertension, combined oral contraceptives, non-contraceptive oestrogen drugs, biologics, abuse-deterrent uploads, topical acne products Patient counselling for biologics
Federal guidelines and samples of medicines information: Pharmacist to patient written communications			
How to create a pill card, December 2014	http://www.ahrq.gov/patients-consumers/diagnosis-treatment/treatments/pillcard/index.html	US Department of Health and Human Services (HHS) – Agency for Healthcare Research and Quality (AHRQ)	Aim: To help pharmacists create an easy to understand "pill card" for patients Guides pharmacist to use a table to create a written medication regimen. Guides pharmacist to use pictures to show important MI. Gives charts with pictures to help indicate time of day, pill shape, and common disease states. Guides pharmacist to write down the "Use for" (indication) of each medication and correct instructions
Is our pharmacy meeting patients' needs? Pharmacy health literacy assessment tool user's guide, October 2007	https://www.ahrq.gov/sites/default/files/publications/files/pharmlit.pdf	US Department of Health and Human Services (HHS) – Agency for Healthcare Research and Quality (AHRQ)	Aim: Assesses the quality of verbal and written pharmacy communication to the average patient. Provides an assessment tool to determine if MI in written and verbal form is easy for a patient to understand. Looks at wording, overall visual appearance, graphics, font size, organisation, etc. for the written MI. Looks at words used, presence of interpreters, etc. for the verbal MI. Provides examples of action for quality improvement.
Independent organisation guidelines on medicines information			
Guidelines for physicians for counseling patients about prescription medications in the ambulatory setting, 2004	http://www.talkaboutrx.org/documents/ama_guidelines.pdf	American Medical Association (AMA)	Aim: gives guidelines for how physicians can/ should distribute medication records and written counselling information to patients in the ambulatory setting
ASHP Guidelines on the Pharmacist's Role in Providing Drug Information, 2015	www.ashp.org/DocLibrary/BestPractices/SpecificGdlMedInfo.aspx	American Society of Health-System Pharmacist (ASHP)	Aim: to act as a guidance document to "help pharmacists in various practice settings develop a systematic approach to providing medication information"

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
ASHP guidelines on pharmacist-conduct patient education and counseling, 1996	www.ashp.org/DocLibrary/BestPractices/OrgGdlPtEduc.aspx	American Society of Health-System Pharmacist (ASHP)	Aim: to "help pharmacists provide effective patient education and counselling" Gives guidance on the environment and content
General chapter ‹17› Prescription Container Labelling in USP 36-NF31, November 2012	www.usp.org/usp-nf/key-issues/usp-nf-general-chapter-prescription-container-labeling	United States Pharmacopoiea (USP)	Aim: to provide "a universal approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacists". Guides that the labels should be organised in a "patient-centred" manner
National Council on Patient Information and Education	www.talkaboutrx.org/	National Council on Patient Information and Education (NCPIE)	Aim: to "advance the safe, appropriate use of medicines through enhanced communication" Offers sample materials and guidelines to both patients directly and providers about how to communicate medicines information and remain adherent
Principles of designing a medication label for community and mail order pharmacy prescription packages	http://ismp.org/Tools/guidelines/labelFormats/comments/default.asp	Institute for safe medication practices (ISMP)	Aim: to show a sample of a drug label in order to produce better medication adherence and fewer medication errors
Electronic programs and websites available to consumers and providers to access medicines information			
Health data.gov	http://www.healthdata.gov/content/about	A federal government website managed by US Department of Health and Human Services	Aim: "This site is dedicated to making high value health data more accessible to entrepreneurs, researchers, and policy makers in the hopes of better health outcomes for all" Lots of health related information but not drug or medication related

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Blue button health initiative, January 2010	www.healthit.gov/patients-families/blue-button/about-blue-button www.healthdata.gov/blog/leading-pharmacies-and-retailers-join-blue-button-initiative	Originated from the Markel foundation Work Group on Consumer Engagement meeting in NYC; now employed by Veterans Affairs Office and Medicare along with other agencies; trademark now lies with the US Department of Health and Human Services	Aim: Health initiative to make patient's medical history accessible to them. Blue button represents a symbol so that patients know they can view and download their personal health records
Markle Foundation	www.markle.org/about-markle	Markle foundation is a not for profit charitable organisation.	Aim: To use information technology to promote better health and health care awareness for both medical professionals and consumers
Medwatch Program: The FDA safety information and adverse event reporting system	www.fda.gov/Safety/MedWatch/default.htm	US Department of Health and Human Services - Food and Drug Administration	Aim: To allow people to report serious problems with medical products and to receive important safety information about them. Anyone can subscribe to MedWatch safety alert emails and thereby receive important alerts about drugs, medical products, and medical devices

Name of the document, year	Link to the document and link to organisation website	Responsible organisation	Notes
Drug Safety and Availability (FDA)	www.fda.gov/Drugs/DrugSafety/default.htm	US Department of Health and Human Services- Food and Drug Administration	Aim: Provides information to consumers and health professionals on "new safety information, drug label changes, and shortages of medically necessary drug products". Provides current drug shortages index. Provides drug alerts and statements (warnings and safety alerts that have already been reviewed). Provides medication guides for select medicines (on medicines which require certain information to prevent serious ADRs, medicines with a known serious side effects, medicines where patient adherences is essential to effectiveness). Provides a drug safety communications page with currently under-review drug safety issues FOR FURTHER RESEARCH http://www.fda.gov/Safety/MedWatch/ (Potential signals of serious risks/ new safety information identified from the FDA Adverse Event Reporting Systems (FAERS)) AND (Postmarked drug and biologic safety evaluations)
Daily Med	http://dailymed.nlm.nih.gov/dailymed/about.cfm	Department of Health and Human Services, National institutes of health (NIH), US National Library of Medicine	Aim: Provide "high quality information about marketed drugs". "Provides health information providers and the public with a standard, comprehensive, up-to-date, look-up and download resource of medication content and labelling as found in package inserts". It is a public service. Contains US package inserts for 59,740 drugs. Can search by drug name, NDC code, drug class, or settled. Gives package inserts from different companies. Allows person to print or download package insert

Medicines information strategies — Europe

Name of the document, year	Link to the document	Responsible organisation	Notes
EUROPEAN UNION			
Information to Patients — Non-legislative approach	http://ec.europa.eu/health/human-use/information-to-patient/non_legislative_en.htm	European Commission	Describes the work of the High Level Pharmaceutical Forum (2002-2008) and its recommendations and tools
Information to Patients — Legislative approach	http://ec.europa.eu/health/human-use/information-to-patient/legislative_en.htm	European Commission	Describes legislation on developing medicines information in the European Union Link to the **directive 2001/83/EC** on the Community code relating to medicinal products for human use
Product information: Reference documents and guidelines	http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000254.jsp&mid=WC0b01ac058008c34c	European Medicines Agency	List of the reference documents and guidelines on the quality of product information for centrally authorised human medicines, including style, terminology, use of abbreviations and the translations of standard terms into European Union languages
Product-information templates	http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&mid=WC0b01ac0580022c59	European Medicines Agency	Instructions and templates for product information for use by applicants and marketing authorisation holders for human medicines.
INDIVIDUAL EU COUNTRIES			
"Better information, better choices, better health": Putting information at the centre of health, 2004	http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4098576	Department of Health, UK	A three-year programme of action, at both national and local level, to improve access for all to the quality general and personalised information people need and want to exercise choices about their personal health and health care
The power of information: giving people control of the health and care information they need, 2012	https://www.gov.uk/government/publications/giving-people-control-of-the-health-and-care-information-they-need	Department of Health, UK	The strategy sets out plans for using information and technology to improve health, care and support – to improve experience, quality and outcomes of health and care services, putting people truly at the heart of care.

Name of the document, year	Link to the document	Responsible organisation	Notes
Effective information for managing medicines. A strategy for the UK medicines information network in the NHS, 2007	http://www.ukmi.nhs.uk/ukmi/strategy/default.asp?pageRef=1	UK Medicines Information – UKMi	The UKMi strategy facilitates the service to adapt and meet the new opportunities and challenges in the evolving NHS. UKMi is an NHS service provided through an integrated network of local and regional medicines information centres.
Rational use of medicines through information and guidance. Medicines information services: current state and the strategy for 2020, 2012	https://www.fimea.fi/documents/542809/838272/21513_KAI_JULKAISUSARJA_Laakeinformaatiostrategia_1_2012_eng_links.pdf	Finnish Medicines Agency, FIMEA, Finland	A national Medicines Information Strategy which is implemented through a Medicines Information Network.

Medicines information strategies — India and South-East Asia Region

Name of the document, year	Link to the document	Responsible Organisation and link to the organisation website	Short description
National Policy for containment of Antimicrobial Resistance, 2011	http://nicd.nic.in/ab_policy.pdf	NCDC (http://nicd.nic.in/)	Describing role of registered pharmacist in promoting rational use of Antimicrobials and prevention of infection.
National Medicines Policy, 2006	http://www.searo.who.int/entity/medicines/nmp_ino_2006_gov_ok.pdf	WHO Indonesia (www.ino.searo.who.int/EN/Index.htm)	Role of pharmacist in developing policies on financing, availability, fair distribution, affordability, selection and rational use of medicines.
Guidelines for the Regulation of Herbal Medicines in the South-East Asia Region, 2004	http://pharmacy.utah.edu/ICBG/pdf/WebResources/TraditionalMedicines/WHO-TradMed-Safe-and-Effective.pdf	WHO, Regional Office for Southeast Asia, New Delhi (http://www.who.int/en)	• Serving as a reference to facilitate setting up requirements for registration and regulation of herbal medicines. • Role of pharmacists in reporting adverse events relating to herbal medicines.
Background Document on Counterfeit Medicines in Asia, 2011	http://www.whpa.org/background_document_counterfeit_medicines_in_asia.pdf	WHPA (http://www.whpa.org/)	• Extent of counterfeit medicines in Asia and its impact on health and economy • Prohibiting pharmacists from supply of counterfeit medicines
The Drugs and Cosmetics act and rules, 1940	http://www.fardodisha.gov.in/sites/default/files/pdfs/Drugs%20%26%20Cosmetic%20Act_0.pdf	Department of AYUSH, Ministry of Health and Family Welfare, Government of India (http://indianmedicine.nic.in/)	• Drug definitions, requirements for licence and regulatory requirements for Homeopathic medicines. • Role of pharmacists in storing & dispensing drugs.
National List of Essential Medicines of India, 2011	http://www.cdsco.nic.in/writereaddata/National%20List%20of%20Essential%20Medicine-%20final%20copy.pdf	CDSCO, Ministry of Health and Family Welfare, Government of India (www.cdsco.nic.in/forms/Default.aspx)	• Executive summary on process adopted for revision of NLEM and Salient features of NLEM, 2011. • Pharmacist involvement in therapeutic group discussion
Maternal Health Supplies in Bangladesh, 2010	http://populationaction.org/wp-content/uploads/2011/12/maternal-health-bangladesh.pdf	PAI, Washington (http://populationaction.org/)	• Systematic study on health care system and maternal health supplies forecasting and procurement. • Emphasising role of pharmacist as providers and recommend appropriate treatments.

Name of the document, year	Link to the document	Responsible Organisation and link to the organisation website	Short description
National Medicinal Drug Policy for Sri Lanka , 2006	http://apps.who.int/medicinedocs/documents/s17121e/s17121e.pdf	WHO (http://www.who.int/en)	• To ensure the availability and affordability of efficacious, safe and good quality medicines. • Role of pharmacists in promoting pharmacy profession.
Sri Lanka Pharmaceuticals in Health Care Delivery, 2010	http://www.searo.who.int/entity/medicines/sri_lanka_situational_analysis.pdf	WHO (http://www.searo.who.int/en/)	Importance of pharmacist in shops to supervise dispensing and availability of OTC drugs and their role in stock regulation.
Indonesia's Pharmaceutical and Healthcare Report, 2010	http://xa.yimg.com/kq/groups/18751725/114222297/name/Indonesia+Pharmaceuticals+and+Healthcare+Report+Q3+2010.pdf	Business Monitor International (BMI), London (www.businessmonitor.com/)	• Importance of pharmacist professional competence certification. • Summary on BMI's Pharmaceutical industry survey and forecast series.
Access to affordable essential medicines	http://www.who.int/medicines/mdg/MDG08ChapterEMedsEn.pdf	WHO (www.who.int/en/)	Allowing pharmacists to dispense a generically equivalent product in place of the originator brand listed on the prescription for improving affordability of medicines.
The world medicines situation 2011	http://digicollection.org/hss/documents/s18063en/s18063en.pdf	WHO, Geneva (www.who.int/en/)	• Evaluation of quality, safety and efficacy of traditional medicines. • Role of the pharmacist in self- medication and self-care.
National Drug Demand Reduction Policy, 2013	http://malda.gov.in/Acts,Orders%20&%20Circulars%20related%20to%20ICPS%20,%20Child%20Protection%20&%20Social%20Welfare/National%20Drug%20Demand%20Reduction%20Policy.pdf	Ministry of Social Justice and Empowerment: Department of Social Justice and Empowerment, Department of Disability affairs, Govt. of India (http://socialjustice.nic.in/)	Educating and building awareness about drugs of abuse in general public through pharmacists.

Medicines information strategies — Africa

Ghana

Name of the document, year	Link to the document	Responsible organisation and link to the organisation website	Notes
Ghana National Drugs Policy, 2004	https://s3.amazonaws.com/ndpc-static/pubication/Drug+Policy_July+2004.pdf	Ghana National Drugs Programme (GNDP)	The policy features a section on drug information (See Section 6.3.2)
NDIRC Medium Term programme of work 2002-2006	www.ghanadruginformation.org (currently unavailable)	National Drug Information Resource Centre (NDIRC)	
Drug Information Manual, 2002	www.ghanadruginformation.org (currently unavailable)	National Drug Information Resource Centre (NDIRC)	

Rwanda

Name of the document, year	Link to the document	Responsible organisation and link to the organisation website	Notes
Guidelines for pharmacovigilance and medicine information system in Rwanda, 2011	http://www.who-umc.org/graphics/28561.pdf	The Pharmacy Task Force, Ministry Of Health. www.moh.gov.rw	The purpose of the guidelines is to help health workers in Rwanda to participate in the process of continuous surveillance of safety and efficacy of the pharmaceutical products which are used in clinical practice, thus help to achieve the ultimate goal to make safer and more effective treatment available to patients. The guideline addresses specifically the issues on what to report, why to report, when to report, where to report and how to report.

South Africa

Name of the document, year	Link to the document	Responsible organisation and link to the organisation website	Notes
South African Medicines Formulary	Available only in print	Division of Clinical Pharmacology, Faculty of Health Sciences, University of Cape Town (www.hmpg.co.za/samf)	Medicines information is developed utilising the National drug policy.
Standard Treatment Guidelines and Essential Medicines List, South Africa	http://www.kznhealth.gov.za/pharmacy/edladult_2012.pdf	Department of Health, South Africa.	The main aim of the National Drug Policy is to ensure the accessibility and availability of essential medicines to all people. The essential medicines list is developed down to the generic or International Non-proprietary Name (INN) level. Therapeutic classes indicated in the guidelines provide a list classes of medicines (in no particular order) followed by specific examples in conjunction with the ICD-10 number.
South African Electronic Package Inserts	http://home.intekom.com/pharm/	Malahyde Information System	The website provides package inserts information for South African medicines available to the public in electronic format. The package inserts are indexed in three different ways: Generic Name - the generic name is used to designate chemically equivalent medicines. Trade Name - the trade name is the name given to a product by the product manufacturer. Classifications - this is the pharmacological classification as given on the package insert.
Monthly Index of Medical Specialities (MIMS)	Available in print and as a mobile application (e-MIMS).	Avusa Media Limited (print only) (www.mims.co.za/)	MIMS is compiled from package inserts supplied by pharmaceutical companies. Drug information include the proprietary name, name of marketer, active ingredient, approved main indication, scheduling status, dosage form, usual dosage regimen, drug registration number, reference number*, NAPPI codes ‡, contraindications, side effects and precautions.

* Reference number means the product is an old medicine available for sale but still awaiting registration
‡ NAPPI codes are unique 9 digit-long product codes implemented with electronic transactions. The product name, pack size, strength, manufacturer and exclusions are incorporated.

APPENDIX 4. Bangkok 2014 session: Experiences in developing and implementing national medicines information strategies

Introduction words

Medicines information is related to many aspects of pharmacy practice. Medicines information is essential in order to empower patients in their medicine use and in ensuring rational and safe use of medicines and adherence to long-term therapies. Pharmacists should take an active role in developing medicines information practices. The strategic development of medicines information has been recognised in, for example, the USA, with a long tradition of such development, and more recently, in the European Union, in the work of the Pharmaceutical Forum (2005–2008). During this session, experiences from different countries will be described. A medicines information strategy or policy is understood as a guideline which gives suggestions on how medicines information could be developed nationally for health care professionals as well as patients.

Learning objectives

At the end of the session, the participant should be able to:

- describe how medicines information may strategically be developed
- identify the importance of multidisciplinary stakeholder cooperation in developing medicines information
- specify how policies in developing medicines information may be implemented
- define the outcomes which may be reached by strategic development of medicines information

Chair: Katri Hämeen-Anttila (FIP PIS, Finnish Medicines Agency, Finland)
Co-chair: Parisa Aslani (FIP PIS, University of Sydney, Australia)

1) Introduction to strategic development of medicines information **(20 minutes)**
   Speaker: Theo Raynor, University of Leeds, UK
   - What is meant by strategic development of medicines information
   - Why is it important?

2) USA – a pioneer in the strategic development of medicines information **(30 minutes)**
   Speaker: N. Lee Rucker, National Council on Patient Information and Education, USA
   - Public-private partnerships, regulatory challenges, emerging technologies
   - Influence of 15 years of direct-to-consumer advertising
   - For patients and caregivers, need for trusted information mediators

3) Experiences from the medicines information work in the EU **(30 minutes)**
   Speaker: Ulla Närhi, Ministry of Social Affairs and Health, Finland
   - Medicines information in European Union, including legislative actions
   - Experiences from the work in the EU Pharmaceutical Forum: collaboration between different stakeholders towards better medicines information

   BREAK (30 minutes)

4) Strategic development of medicines information in the developing countries **(30 minutes)**
   Speaker: Kathleen Holloway, WHO

5) Experiences after the first two years after establishing a national network for medicines information in Finland **(20 minutes)**
   Speaker: Katri Hämeen-Anttila, FIP PIS, Finnish Medicines Agency, Finland

6) Discussion **(20 minutes)**

APPENDIX 5. Evaluation of existing FIP policy statements in relation to medicines information (MI) — How existing statements should be taken into account in the proposed policy statement on strategic development of MI

Policy Statement	Year	How it relates to MI	How it should be included / taken into account in the proposed Reference Paper / Policy Statement on strategic development of MI	Comments in the status report (11.2.2014) from WG on FIP statements
The Effective Utilisation of Pharmacists in Improving Maternal, Newborn and Child Health (MNCH)	2013	Includes the role of the pharmacists in patient education & advice and support maternal and child health (in accordance with WHO recommendations). Global Strategy for Women's and Children's Health	A current Policy Statement which includes strategic / policy development on this specific topic-area also on medicines information --> no need to include this topic in the proposed Policy Statement, however, need to refer to this Policy Statement	
FIP Centennial Declaration	2012		Need to follow and be in accordance with the Centennial Declaration	
FIP Statement of Policy on Collaborative Pharmacy Practice	2010	No specific referral to MI, however MI is needed in collaborative practice	Need to refer to this Policy Statement?	
FIP Statement of Policy on Quality Assurance of Pharmacy Education	2009	NA	NA	Should be evaluated by FIP Education (FIP*Ed)*

Policy Statement	Year	How it relates to MI	How it should be included / taken into account in the proposed Reference Paper / Policy Statement on strategic development of MI	Comments in the status report (11.2.2014) from WG on FIP statements
FIP Statement of Policy on the Quality of Medicines used for Children	2008	Encourages disseminating information about the need for rational use of medicines in children through optimal training, education and other appropriate approaches, and furthermore, developing appropriate paediatric formulations and medicines information. This Policy Statement continues to recommend according to its 2001 Statement of Principle "The Pharmacist's Responsibility and Role in Teaching Children and Adolescents About Medicines," and active role of pharmacist in medicine education in schools and counselling children in pharmacies	No need to include this topic in the proposed Policy Statement, however, need to refer to this Policy Statement	
FIP Statement of Policy on Medicines Information for Patients	2008	The topic of this Statement is MI	This Policy Statement is clearly very connected to the proposed Policy Statement. The proposed Policy Statement would, in fact, consider ways how this Policy Statement could best be implemented Need to refer to this Policy Statement or the proposed Policy Statement could cover the themes in this Policy Statement	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement on Pharmacists role in Public Health** covering the WHO/FIP joint declaration on HIV-AIDS from year 1997, the Tobacco –statement from year 2003 and the Point of care testing –statement from the year 2004, Statement of Professional standards on the Role of Pharmacists in Encouraging Adherence to Long term Treatments 2003 and Statement of Policy on the Role of the Pharmacist in the Prevention and Treatment of Chronic Diseases 2006 and possibly the statements about patient information from 2008.

Policy Statement	Year	How it relates to MI	How it should be included / taken into account in the proposed Reference Paper / Policy Statement on strategic development of MI	Comments in the status report (11.2.2014) from WG on FIP statements
FIP Statement of Policy on Control of Antimicrobial Medicines Resistance	2008	Information, advice and counselling specifically on antimicrobials use	Need to refer to this Policy Statement	
FIP Statement of Policy on the Role Of The Pharmacist In the Prevention And Treatment Of Chronic Disease	2006	MI is recognised as a part of the role of the pharmacist	Need to refer to this Policy Statement	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement on Pharmacists role in Public Health** covering the WHO/FIP joint declaration on HIV-AIDS from year 1997, the Tobacco –statement from year 2003 and the Point of care testing –statement from the year 2004, Statement of Professional standards on the Role of Pharmacists in Encouraging Adherence to Long term Treatments 2003 and Statement of Policy on the Role of the Pharmacist in the Prevention and Treatment of Chronic Diseases 2006 and possibly the statements about patient information from 2008.

Policy Statement	Year	How it relates to MI	How it should be included / taken into account in the proposed Reference Paper / Policy Statement on strategic development of MI	Comments in the status report (11.2.2014) from WG on FIP statements
FIP Statement of Policy on the Role Of The Pharmacist In Pharmacovigilance	2006	The pharmacist is recognised as a member of health care team, and thus, as a source of both information and critical evaluation of drug information. The pharmacist's expertise is recognised as vital to the application of the safety profile of a medicine to the needs of an individual patient.	Need to refer to this Policy Statement	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement on Patient Safety** covering statements Statement on Professional Standards on Medication Errors Associated with Prescribed Medication 1999, FIP/IFPMA Joint Statement on Ensuring Quality and Safety of Medicinal Products to Protect the Patient 1999, Guidelines for the Labels of Prescribed Medicines 2001, Statement of Policy on Counterfeit Medicines 2003, Statement on Policy on the Role of The Pharmacist in Pharmacovigilance 2006.
FIP Statement of Policy on Self-care including Self-Medication – The Professional Role of the Pharmacist	1996	Old information related to OTC medicines, refer to education on communication skills of pharmacist	Update on these topics may be included in the proposed Policy Statement	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement on self- care and self-medication** covering statements from the year 1996 and 1998
FIP Statement of Policy on the Pharmacist's Authority in Product Selection – Therapeutic Interchange and Generic Substitution	1997	No specific referral to MI, however, provision of MI is one of the ways the pharmacist (as the expert of medication) can show pharmaceutical judgment in a product selection	This Policy Statement put emphasis on the unique leading role of pharmacist in the development of policies and strategies which is among the proposed policy statement's objectives	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement/Policy paper on Health systems, universal coverage and pharmacists role in these** covering the Statement of Policy on the Pharmacist's authority in Product Selection – Therapeutic interchange and Generic Substitution 1997 (The biosimilars should be discussed under this topic), the Statement of Policy on Improving Access to Medicines in Developing Countries 2005

Policy Statement	Year	How it relates to MI	How it should be included / taken into account in the proposed Reference Paper / Policy Statement on strategic development of MI	Comments in the status report (11.2.2014) from WG on FIP statements
FIP Statement of Policy on Good Practice in Donations of Medicines	1997	NA	NA	MEPS could be nominated as the experts to evaluate the statements
FIP Statement of Policy on Good Pharmacy Education Practice	2000	MI / communication shortly mentioned	More detailed description of communication skills need to be included in the proposed Policy Statement? Need to refer to this Policy Statement	Should be evaluated by FIP*Ed*
FIP Statement of Policy on the Role of the Pharmacist in Promoting a Future Free of Tobacco	2003	NA	NA	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement on Pharmacists role in Public Health** covering the WHO/FIP joint declaration on HIV-AIDS from year 1997, the Tobacco –statement from year 2003 and the Point of care testing –statement from the year 2004, Statement of Professional standards on the Role of Pharmacists in Encouraging Adherence to Long term Treatments 2003 and Statement of Policy on the Role of the Pharmacist in the Prevention and Treatment of Chronic Diseases 2006 and possibly the statements about patient information from 2008.

Policy Statement	Year	How it relates to MI	How it should be included / taken into account in the proposed Reference Paper / Policy Statement on strategic development of MI	Comments in the status report (11.2.2014) from WG on FIP statements
FIP Statement of Policy on Counterfeit Medicines	2003	NA	NA	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement on Patient Safety** covering statements Statement on Professional Standards on Medication Errors Associated with Prescribed Medication 1999, FIP/IFPMA Joint Statement on Ensuring Quality and Safety of Medicinal Products to Protect the Patient 1999, Guidelines for the Labels of Prescribed Medicines 2001, Statement of Policy on Counterfeit Medicines 2003, Statement on Policy on the Role of The Pharmacist in Pharmacovigilance 2006.
FIP Statement of Policy on Point of Care Testing in Pharmacies	2004	NA	NA	
FIP Statement of Policy on Improving Access to Medicines in Developing Countries	2005	NA	Promoting access to medicines is essential before developing MI practices. Thus, this Policy Statement need to be recognised in the proposed policy statement	There seems to be need for some new statements which could then cover the rest of the existing statements not listed elsewhere in this document. **Statement/Policy paper on Health systems, universal coverage and pharmacists role in these** covering the Statement of Policy on the Pharmacists's authority in Product Selection – Therapeutic interchange and Generic Substitution 1997 (The biosimilars should be discussed under this topic), the Statement of Policy on Improving Access to Medicines in Developing Countries 2005

APPENDIX 6. FIP Statement of Policy on Medicines Information for Patients (2008)

Introduction

There is a range of various sources of information that users of medicines may access on their own. The effectiveness of this information is of importance to the patient, as well as prescribers, pharmacists, the health regulatory authorities and the industry that manufactures the medicines.

Providing unbiased and effective medicines information to patients and carers must be a priority for pharmacists. People who use medicines need oral and or written medicines information. As medication experts, pharmacists are a key information resource for the patient and other health-care providers. This Statement addresses the objective information that patients need about their medicines. The key challenge for the pharmacist is getting such information to the patient in forms that meet their needs, as well as the needs and abilities of health professionals and the health systems.

The purpose of patient medicines information

The primary purpose of patient medicines information is to assist the patient and health professional in achieving safe and effective use of medicines. This includes providing information that allows the patient to make an informed decision as to the appropriate selection and use of the medicines. Patients value information about the range of treatments available, relative effectiveness of each, inherent risks if any, and effect on life style of the treatments. Further, they need information for ongoing decisions about the management of medicines. While not every patient wishes to receive written information, those who do want sufficient detail to meet their needs. Patients value the idea of information that is adjusted to the individual patient, and contains a balance of benefit and risk information. Most patients also want to know about the possibility of adverse reactions.

Sources of patient information

It is important that there is a range of sources of information that the patient can access, and that health-care professionals are available to assist them in understanding this information.
(Raynor *et al*; Health Technology Assessment 2007; 11 Number 5). Effective patient information is defined as: "Information which improves patients' knowledge and understanding of treatment, self-management of illness and improves health outcomes."

There are many possible sources of patient medicines information:

- Spoken (from health professionals).
- Medicine leaflets supplied with individual medicines.
- Written medicines information for patient and health professional organisations, health organisations and other organisations that communicate with health care consumers.
- Internet and other electronic tools.

There is a need for alternate languages and special formats (large type, pictograms, audio versions, Braille) to meet the needs of specific patient populations. Direct–to-consumer advertising of prescription medicines is a controversial subject and is only allowed in a few countries. FIP is opposed to direct-to-consumer advertising of prescription medicines.

Best practice in information design

Improving the effectiveness of written medicines information can be addressed by applying key principles of good writing and design. It is important to emphasise that good design and layout are as important as easy-to-understand content. The level of health literacy (people being able to understand health information) varies by country and even by region within a country. This variation should be reflected in the writing and presentation of health information. Attention should be given to methods of communication other than the usual written or spoken, where appropriate.

Impact on adherence

If relevant and customised information is provided to the patient then adherence may improve.

Expanding regulatory function

Increasingly, authorities are creating guidelines and information about medicines. For example, the European Union (EU) requires comprehensive patient leaflets in all medicine packs, which are written according to strict guidelines. These now have to be tested to ensure they are usable by patients. There are similar requirements in the Western Pacific Region. Also, the USA FDA is now developing a more interventionist role in ensuring high quality of information, and providing more information itself to the public (largely via its website).

Need for further research

Generally, it is observed that there is a lack of research in the area of patient medicines information. There is a need to determine the content, layout, delivery method and timing of medicine leaflets that best meet patient' needs. Also, there is a need to find out how to better incorporate individualisation, and benefit and risk information into such leaflets.

Role of the pharmacist

The pharmacist will continue to play a pivotal role in the provision of reliable and valid written and oral medicines information to patients. As patients increasingly access information from the Internet, pharmacists can act as a guide and interpreter. Spoken information remains the priority for patients, but should be closely linked to written information. Both spoken and written information should be tailored to reflect the health literacy of the patient and/or care giver. Pharmacists should ensure that written information is not used as a substitute for discussion. They should also encourage patients to use written medicines information and welcome any questions this may raise.

National initiatives can encourage patients to engage with pharmacists and ask questions about their medicines. Pharmacists should also ensure that they collaborate with fellow health professionals, to make sure that patients receive appropriate, consistent, and correct information. It is the pharmacists' responsibility to ensure that the information they provide is objective, understandable, non-promotional, accurate and appropriate. Further, the pharmacists can use written material with the medicines as a reminder document to support the spoken information that is given to the patient. Pharmacists should encourage patients to seek objective and accurate information.

Against this background FIP recommends that:

Pharmacists should help patients and carers to obtain and critically analyse information to meet their individual needs. Special attention should be given to topics such as:

- Applying the same critical analysis to direct promotion by governments and health insurance plans that they do to other information sources.
- Sources of all information to be available.
- Educating patients on how to use web-based health-care information (including medicines information) and to strongly encourage them to speak to a pharmacist regarding information they find online.
- Informing patients who do not come into the pharmacy to receive their medicines.
- Encouraging and assisting patients on how they can educate themselves.
- Installing private areas for patient care in pharmacies.
- Patient empowerment and patient responsibility for personal health.

In addition, pharmacists should:

- Engage in public-private partnerships that produce and disseminate objective and valid medicines information for patients.
- Provide information in formats accessible by people from special groups.
- Provide both risk and benefit information.
- Provide patients or carers with critical assessment of medicines information sources.
- Use written information to augment the spoken information provided to a patient.

FIP member organisations should:

- Develop strategies that encourage pharmacists and other health-care providers to provide high quality medicines information as well as take an active role in assisting the patient to manage the use of medicines.
- Motivate computer software developers to provide systems, which can give access to accurate and readable medicines information that is customisable so as to be relevant to the specific patient and therapy.
- Organise and promote campaigns on medicines information.
- Work with allied health organisations to develop guidelines for production and use of medicines information materials.

Governments should:

- Develop policies whereby pharmacists are key in informing patients about medicines and encourage people to seek advice from their pharmacists regarding medicines and their use.
- Give pharmacists economic incentives that recognise the pharmacists' value in providing patient medicines information.
- Provide or encourage the development of medicines information guidelines that assure quality information, which is consistent amongst all health-care providers.
- Prohibit direct-to-consumer advertising of prescription medicines.

This statement originated with the Board of Pharmaceutical Practice.

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