

FORUM

Quality Use of Medicines

→ What it means for industry

MEDICINES
Australia

QUM

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Introduction

Quality Use of Medicines is a term often used by health consumer groups, healthcare professionals, government, the medicines industry, and in the trade media but what does it mean? Put simply, Quality Use of Medicines, or QUM, provides a framework through which medicines can be used most effectively.

Australia's National Medicines Policy endorses a partnership approach to improving access to and the wise use of medicines. The activities and initiatives of the medicines industry are critical to achieving all of the central objectives of this policy.

One of these objectives, 'Quality Use Of Medicines' focuses on ensuring that medicines are used judiciously, appropriately, safely and efficaciously. Here the medicines industry can add enormous value by ensuring that health practitioners have timely access to accurate information and education about medicines and their use. This in turn enables health practitioners to make good treatment choices and to effectively communicate with consumers about their medicines.

Dr Linda Swan • NATIONAL MEDICINES POLICY COMMITTEE

This means that a patient has access to a medicine that will help their particular condition at the time they need it. QUM also means that a patient understands why they have been prescribed a medicine and how to use it properly.

QUM ensures that healthcare professionals have all of the evidence-based information they need to prescribe a medicine appropriately. QUM means that if a medicine is not required, it is not prescribed and other options are provided to a patient.

QUM applies equally to prescription medicines, non-prescription and complementary medicines. It reinforces the importance of the patient and their healthcare professional having access to accurate evidence-based and balanced information to inform decisions about these medicines and their use.

So how does this affect industry? If the medicines produced by industry are not used appropriately this has a negative impact on patients and can increase costs to the health system. This has been illustrated through statistics that show over 190,000 hospital admissions in Australia annually are related to medicine misadventures. If we could reduce this number, through ensuring medicines are used safely and appropriately then the cost to the health system, patients and carers would be significantly reduced with quality of life for patients significantly increased.¹ <http://www.anzhealthpolicy.com/content/6/1/18>

This site will explain QUM and its impact. It will demonstrate industry's commitment to QUM through testimonials and case studies and show how, as an industry, we make a positive contribution to the health of Australians and the efficiency of the health system.

The consumer focus that established QUM in Australia

Where did QUM begin?

Work to establish a National Medicines Policy (NMP) began in Australia as far back as the 1950s. This was sparked by the World Health Organization (WHO) and countries around the world that were starting to implement national medicinal drug policies to ensure the availability of essential, affordable drugs of acceptable quality, safety and efficacy to be available to patients when needed.²

In Australia, the crucial period in the development of the policy supporting QUM occurred in the late 1980s through to 2000. Much of this activity was influenced by the more vocal consumer voice which commenced in May 1985 with the "Petition of reform addressed to the Minister" that called for a formal system of public

participation to be built into the national health administration. This move eventually resulted in the establishment of a Health Forum that consisted of a coalition of community and consumer groups that were to provide the consumer voice on health issues. The birth of the Consumers Health Forum of Australia (CHF) was funded through the 1986/87 Federal Budget and ensured ongoing consultation and consumer involvement in the health debate.³

To accelerate progress towards the development of a national medicines policy, the Australian Government in 1991, established the Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health and Rational use of Medicines (PHARM) Committee. PHARM then produced the National Policy on QUM in 1992 which provided a framework to improve the use of medicines in Australia.

Between 1992 and 2002 consultation occurred between many groups including PHARM, APAC and CHF which resulted in national therapeutic guidelines, consumer medicine information, academic detailing and medication management services. In 1998 NPS (then called the National Prescribing Service) was established to be the driving force behind the National Strategy for QUM. All these initiatives come under the banner of QUM and it is through the collaboration of many groups across the health sector that medicines policy and a strategy for QUM were developed.⁴

To progress this work even further, the June 1996 Council of Australian Governments meeting agreed on systems for health and community services that would meet medication and related service needs so that both optimal health outcomes and economic objectives were achieved. This formed the basis of the National Medicines Policy which was launched by the Department of Health and Ageing (DoHA) in late 2000.

[Click here for a link to the National Medicines Policy](#)

The objectives of the NMP are:

- Timely access to medicines that Australians need, at a cost individuals and the community can afford
- Medicines meeting appropriate standards of quality, safety and efficacy
- **Quality use of medicines**
- Maintaining a responsible and viable medicines industry.

Thus QUM is one of the four objectives of the NMP, highlighting its importance to the health system. The Government then developed a National Strategy for QUM which provides a framework on how these principles apply across the health sector. [Click here for a link to the National Strategy for QUM](#)

Defining 'Quality Use of Medicines' or QUM

[Click here for the National Strategy definition of QUM](#)

QUM means:

- Selecting management options wisely by:
 - Considering the place of medicines in treating illness and maintaining health, and
 - Recognising that there may be better ways than medicines to manage many disorders.
- Choosing suitable medicines, if a medicine is considered necessary, so that the best available option is selected by taking into account:
 - The individual
 - The clinical condition
 - Risks and benefits
 - Dosage and length of treatment
 - Any co-existing conditions
 - Other therapies
 - Monitoring considerations
 - Costs for the individual, the community and the health system as a whole

- Using medicines safely and effectively to get the best possible results by:
 - Monitoring outcomes
 - Minimising misuse, over-use and under-use, and
 - Improving people's ability to solve problems related to medication, such as negative effects or managing multiple medications.

Put simply:

- Medicines are not always necessary or the first choice for treatment
- Where medicine is the appropriate choice, patients should receive medicines appropriate to their clinical condition and in doses or formulations that meet their own individual needs
- Consumers and prescribers must have the knowledge and skills to use medicines to their best effect.

Working in partnership is fundamental to Quality Use of Medicines. This is rarely easy or straightforward as organisations and individuals have different ways of working and sometimes different priorities. What I have learnt over many years of doing this is that we always achieve a better result for consumers when we work together, bringing all the expertise and perspectives together and dealing with the drivers and barriers for each player. Many times it is possible to fully align their goals and when this isn't achievable being explicit about what is agreed (or not) is critical to successful QUM partnerships.

Lynn Weekes • CEO, NPS

QUM applies equally to decisions about medicine use by individuals or entire populations. In this context, medicines include prescription, over-the-counter and complementary products.

This definition demonstrates the focus on how medicines are to be considered as part of a treatment plan for a patient. Medicines play an important role in health, but need to be considered on a patient-by-patient basis to be most effective.

Industry supports QUM by providing information to healthcare professionals and consumers that is based on the latest evidence and includes balanced information on the benefits and risks of the medicine.

QUM Stakeholders and what they contribute

The principles of QUM were developed to improve health outcomes for patients, thus all industry activities should incorporate these principles to ensure that their outcomes translate to positive patient benefits. Equally, all organisations and individuals that work or interact within the health sector have a role to play in QUM. Some of the key players are listed below together with a short description of their QUM role.

The National Heart Foundation of Australia commented positively on the importance of working collaboratively with a range of stakeholders to be able to improve the cardiovascular health of all Australians. "The Heart Foundation has established the Heart Foundation Pharmaceutical Roundtable in an effort to bring together leading pharmaceutical companies to work together with the Heart Foundation to support cardiovascular research and increase awareness of cardiovascular disease, and the risk factors associated with its development. More recently the Roundtable members have focussed on Quality Use of Medicines by seeking ways to improve adherence to pharmaceutical and lifestyle-based interventions".

Dr Lyn Roberts CEO • NATIONAL HEART FOUNDATION

Consumers:

Consumers have a central role to play in QUM. It is vital that consumers understand why they have been prescribed a medicine or had a non-prescription or complementary medicine recommended to them. Consumers need to know what the medicine is for, how to take it properly and for how long. In addition it is important that consumers advise their healthcare professional of all other medicines (including non-prescription and complementary medicines) that they are taking so that any decision to prescribe or recommend an additional medicine takes into consideration all of this relevant information. The consumer contribution to QUM focuses on appropriate, safe and effective treatment so that if a medicine is necessary, the consumer is well informed on how to take the medicine safely and knows what to do if they experience any problems.

Health consumer organisations (HCOs) represent the interests of consumers and patients. They may participate in the development of patient information materials about a medicine, lobby relevant authorities for access to medicines, and raise awareness about particular therapeutic areas to ensure that treatment regimens are balanced and include non-medicinal therapies. For example, it is in the interests of consumers who have cardio-vascular disease to be informed about a range of treatment options. Whilst they may be prescribed a statin to reduce their cholesterol, it is equally important that these patients also follow a balanced diet and an appropriate exercise regime to build fitness and lower their cardiovascular risk.

Healthcare professionals:

Whether a GP, specialist, pharmacist, nurse or any other kind of healthcare professional, all have a role to play in ensuring that their patients have access to evidence-based balanced information on any medicines they are taking. They also need to ensure that a medicine is one part of the total treatment regimen and, where appropriate, they consider other options that may include diet, exercise or other therapies to provide the best possible health outcomes.

When discussing medicines with patients, healthcare professionals need to ensure that they obtain as much information as possible from the patient on exactly what else they are taking prior to making any prescribing decisions or recommending a non-prescription or complementary medicine. It is also important for healthcare professionals to evaluate each patient's capacity to accurately follow their treatment regimen. For example:

- If the patient is elderly and already taking multiple medicines for chronic conditions
- If the patient comes from a non-English speaking background and needs patient information in another language
- If the patient has a carer which means that someone else monitors their medicines.

All of these different examples highlight the importance of understanding each patient's particular situation and then prescribing appropriately.

QUM principles ensure that healthcare professionals can provide balanced information to their patients so that whatever their background or clinical condition, patients can take their medicines with confidence.

TGA (Therapeutic Goods Administration):

The TGA is responsible for regulating the quality, safety and efficacy of therapeutic goods which includes medicines, medical devices, biologics, blood and blood products. The products the TGA regulates are as varied as prescription medicines, vaccines, implants, blood products and sunscreens. All of these products need to be evaluated by the TGA before they can be marketed in Australia and the TGA also conducts ongoing monitoring and surveillance activities once medicines are on the market to ensure their continuing positive risk/benefit profile.

TGA's role also extends to the regulation of therapeutic goods manufacturers to ensure high standards of manufacturing quality are maintained, whether a product is manufactured in Australia or overseas. This forms the basis of the TGA's contribution to QUM through the provision of a system that ensures high quality, safe and effective products for consumers through consistency of production. Information on the TGA can be found at www.tga.gov.au.

PBAC (Pharmaceutical Benefits Advisory Committee):

The PBAC was established in 1954 and is an independent statutory committee formed under Section 101 of the National Health Act of 1953. PBAC was established to make recommendations and give advice to the

Health Minister about which drugs and medicinal preparations should be made available as pharmaceutical benefits. In addition, the PBAC recommends whether new vaccines may be made available through Australia's National Immunisation Program or through the Pharmaceutical Benefits Scheme.

PBAC's primary contribution to QUM is providing access to medicines, via the PBS, that the consumer, community and government can afford. The Committee also contributes to QUM through its evaluation of submissions to ensure that any medicines listed on the PBS are cost effective and provide a benefit when compared to alternative therapies. The Committee can also recommend maximum quantities and repeats and can also recommend restrictions to the indications where PBS subsidy can be provided.

A PBAC submission consists of a number of sections and these are:

- Section A – details of the proposed drug and its intended use on the PBS
- Section B – clinical evaluation for the main indication
- Section C – translating the clinical evaluation to the listing requested for inclusion in the economic evaluation
- Section D – economic evaluation for the main indication
- Section E – estimated extent of use and financial implications
- **Section F** – options to present additional relevant information (this is the primary section where QUM related activities are included. However it must be noted that QUM principles apply and should be incorporated across every Section of a PBAC submission).

Additional information on the PBAC can be found on the Department of Health and Ageing website www.health.gov.au

NPS:

Established in 1998, NPS provides both consumers and healthcare professionals with balanced evidence-based information on medicines. NPS was established to be the driving force behind the National Strategy for QUM and it is funded by the Department of Health and Ageing. NPS conducts educational campaigns for consumers to promote understanding about the medicines they are taking (which includes prescription, non-prescription and complementary medicines). NPS also targets healthcare professionals with education and clinical audits on a variety of therapeutic areas, focusing on appropriate medicine prescribing.

NPS's contribution to QUM is through the supply of evidence-based balanced information to consumers and healthcare professionals to inform decisions on medicines. This information should result in the judicious use of medicines and thereby improved health outcomes for patients and lower costs to the health system. More information on NPS can be found at www.nps.org.au

The Australian Government Department of Health and Ageing (DoHA):

DoHA oversees the implementation of the National Medicines Policy and the National Strategy for QUM. It has also established the National Medicines Policy Committee which provides advice to the National Medicines Policy Executive on emerging NMP issues and conducts, oversees or considers projects and/or research that has been endorsed by the Executive. Members of the NMP Committee are appointed on the basis of their individual skills, knowledge and expertise in certain areas. [Click here for a list of current members.](#)

The Federal Government has a commitment to QUM and this Committee provides a voice from across the health sector. DoHA also funds the NPS and the work they undertake in the implementation of the National Strategy for QUM. More information on DoHA can be found at www.health.gov.au

Industry:

The medicines industry has a key role to play in QUM with the main responsibilities being:

- The development of safe and effective products
- Marketing products in a way that facilitates QUM
- Providing high quality, evidence-based information relevant to all stakeholders
- Discouraging any activities that are not conducive to QUM

Industry has a history of implementing activities that promote QUM and this includes playing a role in early patient access to innovative medicines; partnering with Government and other stakeholders to shape

healthcare policy which supports QUM; and pursuing new opportunities that add value and address unmet needs of healthcare professionals and patients. There are case studies included within this document that demonstrate how industry puts QUM into action.

Media:

Although it may not be immediately apparent, the media plays a key role in QUM. Responsible reporting is the media's contribution to QUM. By reporting the facts about medicines, the media can ensure that unnecessary consumer concern is not caused by misleading headlines. Many publications are trusted by consumers to provide accurate information and what is written in the media can outweigh information that comes to consumers from other sources. Thus journalists have a responsibility to be balanced in their reporting, only state known facts and not speculate, check sources prior to going to print, and as much as possible report without bias.

Your role in QUM

The good news is that a lot of the work we do in the medicines industry aligns with the principles of QUM. These activities would be what we call 'business as usual' but we may not identify them specifically as QUM activities. These types of activities include:

- Developing medicines that improve the health of patients by either targeting specific diseases or by acting in a preventative capacity so that patients do not develop illnesses
- Contributing to the development of a submission to provide access to innovative medicines
- Ensuring manufacturing processes result in high quality production
- Providing balanced and evidence-based information to consumers (when they have been prescribed a specific medicine) and to healthcare professionals
- Partnering with a health consumer organisation to raise awareness about a specific therapeutic area and the various treatment options available, including options other than medicines
- Partnering with Government and other stakeholders to shape healthcare policy that is QUM focused
- Ensuring packaging is easy to use for consumers, especially the elderly and that labelling is clear and unambiguous.

QUM applies right across the medicines pathway, from the discovery of the molecule through to market entry and beyond. The medicines pathway covers:

- Discovery:
 - The selection of the molecule
 - Pharmacology and toxicology
- Clinical Trials:
 - Phase I
 - Phase II
 - Phase III
 - Phase IV
- Market Entry:
 - Regulatory approval
 - Scheduling and re-scheduling
 - Reimbursement approval
 - Marketing
- Post Market:
 - Post-marketing studies and monitoring
 - Patent expiry

The following examples will take you on a journey along the medicines pathway, further illustrating the QUM connection.

Discovery: selection of the molecule, pharmacology and toxicology – the search for active substances and preclinical testing

Research efforts here are focused on discovering and developing molecules that can meet an unmet clinical need. During this stage intensive pharmacological studies are done to determine the effect of these compounds and what side effects they may have. Studies are conducted to ascertain the dose and effect relationship i.e. what dosage is required to get the desired effect and how this impacts on any side effects. This work includes testing on animals and very detailed biochemistry, the result of which is hopefully the identification of a compound that has therapeutic potential and can be produced in a dosage form and regimen that assists patient compliance.

The link to QUM here is the identification of an unmet medical need and conducting research that results in developing products to address that need.

CASE STUDY

Addressing a high clinical need

Raltegravir was the first of a new type of HIV-1 antiretroviral treatments called integrase inhibitors. As well as increasing the choice of effective medicines for patients with HIV, its development brought benefits to patients in two important areas.

“Raltegravir works in a completely different way to other HIV medicines,” said Professor Andrew Carr of the HIV, Immunology and Infectious Diseases Unit, St Vincent’s Hospital, Sydney. “It is active where other medications have failed and therefore provides us with an important new option in the treatment of HIV.”

International studies suggest that resistance to at least one type of HIV (antiretroviral) treatment may be as high as 76 percent.

Another important benefit of raltegravir is that its side effect profile is comparable to placebo. It is well recognised that HIV medicines have a complex and varied range of side effect profiles which can significantly affect the ability of patients to adhere to their medication regimen. Poor adherence is a factor in a patient developing resistance to treatment.

Due to its significant benefits and the high clinical need, Raltegravir received accelerated approval from the TGA and was listed on the PBS in 2008.

Clinical Trials: Phase I, II, III and IV

This next stage in the medicines pathway journey covers clinical trials which are divided into four stages:

Phase I

- The clinical plan for a compound is developed
- The first studies are conducted on humans; these studies consist of around 50–150 healthy individuals
- Tolerance studies are conducted with the dose being gradually increased to monitor the effects and any adverse events. These studies inform further research
- Studies on toxicology and carcinogenicity are continued on animals

Phase II

- This phase is where research is first conducted on those patients that have the target disease
- The research focuses on the effects seen in these patients, including any adverse events which are closely monitored
- The number of people included in the research groups is expanded to around 100–200 and the research further refines the relationship between dose/effect and tolerance
- Animal testing still continues at this stage to determine longer term toxicology and carcinogenicity

Phase III

- This is where comparative controlled studies are conducted with the new medicine being measured against conventional therapy
- These studies will generally include a larger number of participants in order to document the effect and safety of the medicine in long-term therapy
- Researchers are seeking to confirm clinical efficacy, comparative efficacy and effectiveness, any contraindications and the adverse events profile, and also identify any drug interactions and what the final form of the medicine will be (tablet, solution etc), final indications and dose
- This stage is also where the manufacturing teams should be planning packaging and labelling design to ensure patients can safely use the medicine as intended

CASE STUDY**Making treatment easier for patients**

ELONVA, or corifollitropin alfa, is a first in class sustained recombinant follicle stimulating hormone (rFSH) which is used in IVF treatment.

Undergoing IVF treatment has a major impact on people's lives, and involves an invasive schedule of daily injections.

Due to its prolonged mode of action, a single injection of corifollitropin alfa can replace the first seven injections of the alternative daily rFSH.

A reduced injection burden may lessen the impact of the ART cycle on the patient's quality of life and could reduce the potential for errors associated with administering the medication (Huisman et al. 2009).

CASE STUDY**It's all about the right process for Mundipharma**

Mundipharma's process for managing people who are participating in their clinical trials includes:

- Adherence to ICH Good Clinical Practice and local law
- The target population (research participants) are clearly identified
- Informed Consent by the target population to participate in trials
- Participants full history is taken and they are maintained on standard therapy
- Participants are monitored throughout the trial and followed up 30 days after completing a trial
- All adverse events are recorded and reported
- There is full documentation of quality and safety
- A web-based system has been devised for each trial for the random allocation of treatments to eligible participants, to manage medicine distribution so that if required, immediate un-blinding can occur
- Reporting is undertaken every six months to an ethics committee
- A Toll Free number is established for Australian and New Zealand participants to provide 24 hour medical access
- Controlled medicines are kept under secure and safe storage
- All participants are provided with a sufficient quantity of the product to ensure a continuous supply
- All used and unused medicines (in this specific example patches were used) are returned to the warehouse and then sent for destruction according to the local legislation (Australia utilises high heat incineration, New Zealand utilises sterilisation, compaction and burial)

This is typical of companies' processes in the medicines industry.

Phase IV

Phase IV clinical trials are undertaken after the medicine has been approved for the treatment of a particular disease. Phase IV trials are undertaken to compare the new medicine to a wider range of existing medicines. These trials are used to establish where, in the range of treatment options, the new medicine is best used. Phase IV studies may be required by regulatory authorities or may be initiated by the sponsor for competitive (finding a new market for the medicine) or other reasons e.g. the medicine may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women.

Phase IV trials include Post Marketing Studies, which involve safety surveillance (pharmacovigilance) and ongoing technical support of a medicine after it is approved. The safety surveillance is designed to detect any rare or long-term adverse events in a much larger patient population and over a longer time period than was possible during any of the Phase I to Phase III clinical trials.

CASE STUDY

sanofi puts QUM principles into practice

sanofi developed the MOTIF trial looking at side effect management and patient compliance. This Australian trial was developed to identify the impact of concomitant use of modafanil in docetaxel treated patients suffering from fatigue. If favourable, the concomitant use of modafanil may enable patients to gain greatest efficacy from docetaxel treatment, whilst minimising the side effects experienced by patients. Such an outcome would improve the number of cycles of treatment patients receive bringing the average duration of real-world treatment closer to the evidence base from large randomised clinical trials.

Market Entry: regulatory approval, scheduling, reimbursement and marketing

This stage of the QUM journey is when the medicine moves through:

- regulatory approval by the Therapeutic Goods Administration (TGA)
- consideration for reimbursement under the Pharmaceutical Benefits Scheme (PBS)
- promotion to healthcare professionals once the medicine is approved.

TGA Registration:

Australia has a rigorous system to ensure that when medicines get to market they are safe and fit for their intended purpose. Thus there is a high level of evidence required for a medicine to enter the market which incorporates a very high standard of data and analysis to be undertaken. The TGA's regulatory standards for medicines include the following features:

- Classifying the medicine based on different levels of risk to the patient
- Implementing appropriate regulatory controls for manufacturing of medicines
- Medicines assessed as having a higher level of risk (prescription medicines, some non-prescription medicines) are evaluated for quality, safety and efficacy. Extensive data and reports are submitted to the TGA by the company
- Medicines having a lower risk (medicines purchased over-the-counter, including complementary medicines) are assessed for quality and safety
- Medicines determined to be available for lawful supply by the TGA can be identified by either an AUST R number or an AUST L number on the outer packaging
- Once available for supply, medicines are subject to monitoring by the TGA which includes a comprehensive adverse event reporting program.⁴

Labelling and Packaging:

Significant resources are devoted to the development of medicines that are safe and effective. Companies also devote significant time, effort and resources to ensure that the labelling and packaging is designed in a way that facilitates correct dispensing and appropriate use of medicines by those who need to take them. When designing packaging and labelling for medicines companies will consider the prominence, location, clarity and legibility of things like the brand name, active ingredient name, dosage, storage requirements and instructions for use. Companies will do this with reference to a number of official guidelines and regulatory requirements developed by government agencies both in Australia and internationally.

Companies may use symbols to explain to patients how a medicine should be taken. For example, some medicines need to be taken once in the morning and once in the evening. To assist patients some companies utilise graphics on blister packs to clearly show a 'sun' over the blister for the tablet to be taken in the morning and a 'moon/stars' over the blister for the tablet to be taken in the evening. This illustrative method is also of assistance to those with English as a second language.

Equally as important, some elderly patients have difficulty in opening bottles and more recent bottle design has incorporated features that enable those with conditions such as severe arthritis to open these bottles more easily. Individual companies have undertaken a number of initiatives over the years to improve the legibility and clarity of packaging and labelling of medicines. For example, many companies have moved away from 'corporate' style packaging for prescription medicines and moved to packaging that better differentiates medicines and doses within a company's product line. All of this aligns to QUM principles in ensuring that medicines can be taken safely.

However labelling and packaging can be contentious as the following issues highlight:

- Confusion can arise from multiple names for the same active ingredient
- Pharmacist labels can obscure critical information such as active ingredient, product name, batch and expiry date, when they are placed on the packaging
- The product name and strength generally only appears on one panel of the box which can sometimes be obscured when packed on pharmacy shelves which may result in the wrong box be taken from the shelf and thus the wrong strength of the medicine being issued

Industry has invested considerable resources into ensuring that packaging and labelling facilitate appropriate use of a medicine. However, there are many intermediate steps between a medicine leaving a pharmaceutical company warehouse, being stocked in a pharmacy and ultimately being used by a patient. There have been many projects undertaken to determine where further improvements can be made in labelling and packaging, most recently a review currently being driven by the TGA.

The TGA takes an active role in monitoring and reviewing the adequacy of packaging and labelling of medicines and consults broadly with relevant stakeholder groups. From time to time, the TGA will recommend changes to guidelines and/or regulations.

Any changes will have an impact on industry and how labelling and packaging is designed in the future.

Product Information (PI) and Consumer Medicine Information (CMI):

QUM principles have influenced the development of both the PI and CMI through the use of appropriate language for the intended audience, usability and clarity of information. Product Information provides health professionals with relevant clinical information for the appropriate use of a medicine. Consumer Medicine Information provides consumers with plain language explanation of a medicine and its use.

[Click here for link to core CMIs on the Medicines Australia website](#)

PRODUCT INFORMATION

The PI is developed by the Regulatory Affairs/Medical Information teams in companies in consultation with the TGA. The PI must contain clear, balanced and scientifically validated information for healthcare professionals so that accurate and informed prescribing decisions can be made. The PI content is highly regulated and provides information to the clinician to ensure they have access to a summary of the data that was the basis for the TGA approving the medicine and the TGA must also approve the content of the PI. More recently, the industry has supported initiatives to provide health professionals with more information such as publication of PIs on the TGA website and the development of Australian Public Assessment Reports (AusPARs) which publicise the reasons for the TGA's decision on a medicine.

CONSUMER MEDICINE INFORMATION

As the information contained in the PI has a scientific focus, this can sometimes be too technical or confusing for patients. Thus information about a product needs to be presented in a format and written in a style that patients can readily understand. Regulatory Affairs/Medical Information teams develop the CMI which contains clear, balanced, evidence-based information for consumers to ensure they understand both the risks and benefits associated with the medicine. Many companies test their CMIs with patients to confirm that the information contained within the CMI is clear and can be easily understood by patients.

The CMI can play a key role in outlining the risks and benefits of a medicine and assist patients taking their medicines appropriately. Thus a CMI should be:

- Accurate and up to date
- Easy for patients to use and find all the information they need, including clear information on the risks of the medicine
- Consistent with the PI

A CMI should assist patients in making informed decisions about their medicines and foster discussions between a patient and their healthcare professional on the place of medicines in their treatment regimen. However, CMIs need to be promoted to patients to ensure they ask their pharmacist to print one out for them whenever they are prescribed a new medicine.

Over the years the industry has worked with regulators and other private service providers to improve the usability of CMIs for the community. These initiatives include publication of CMIs in multiple languages, the development of Braille and audio versions for hearing and visually impaired patients, and supported measures to have CMIs published on the TGA website. Industry has a long history of partnering with other stakeholders to improve the quality of CMIs and thereby enhance the quality use of medicines.

Scheduling:

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety. The Scheduling classification is as follows:

- S2: a pharmacy only medicine, this can be sold by a pharmacy assistant
- S3: a medicine that is available without a prescription from a pharmacist
- S4: a prescription only medicine
- S8: a prescription medicine which requires additional restrictions to reduce abuse, misuse and physical or psychological dependence

The Scheduling recommendations are based on safety and efficacy data and include:

- Evidence from comparable overseas countries
- Previous Australian scheduling considerations
- Post-marketing surveillance data both local and international
- Adverse drug reaction reports
- Education

PBS Reimbursement:

To obtain reimbursement through the PBS a company needs to ensure that their submission to the Pharmaceutical Benefits Advisory Committee (PBAC) contains detailed information that supports the clinical need, comparative cost-effectiveness, health outcomes, cost and expected utilisation of a particular medicine. The PBS reimbursement process identifies the medicine's appropriate place in therapy and the target population resulting in maximum cost effectiveness thus providing the best incremental health outcomes. The principles of QUM apply right across a submission but are particularly highlighted in Section F.

Once a medicine is in the community:

When a medicine is ready for distribution and promotion it is of utmost importance that these activities are conducted with complete compliance to all relevant industry codes which have been developed by:

- Medicines Australia
- Australian Self-Medication Industry (ASMI)
- Generic Medicines Industry Association (GMiA)
- Complementary Healthcare Council (CHC)
- Therapeutic Goods Advertising Code Council (TGACC)

The Medicines Australia Code of Conduct sets the standard for the ethical marketing and promotion of prescription pharmaceutical products in Australia. It complements the legislative requirements of the Therapeutic Goods Regulations and the Therapeutics Goods Act. The Code covers standards for appropriate advertising, the behaviour of medical representatives and relationships with healthcare professionals.

[Click here for a link to the latest edition of the Code of Conduct](#)

Some of the activities that companies will be involved with at this stage are:

- Promotion and education to healthcare professionals
- Media awareness campaigns and
- Patient support programs.

For the past five years at least, consumer organisations (including CVA) have worked closely with the industry to improve information to patients. In conjunction with the Consumers Health Forum and Medicines Australia the information now available to our constituency is vastly improved.

For cancer patients specifically, our ability to meet directly with individual companies provides us with current data at the local and international level which is of major benefit to our constituency. This information may assist cancer patients and their families with access to other treatment options.

John Stubbs • EXECUTIVE OFFICER, CANCER VOICES AUSTRALIA

The onus on these teams is to produce material that is accurate, clear and balanced which will assist sales representatives to appropriately inform healthcare professionals about the medicine, its appropriate use, patients that it is best suited for, risks and benefits, and in what circumstances it should not be used. This balanced approach to information provision assists healthcare professionals in making appropriate prescribing decisions.

A number of companies also offer patient support programs to consumers once they have been prescribed a new medicine, in which the patient may choose to participate. These programs play an important role in encouraging adherence and compliance to their medication regime and aim to support the best health outcome. Such programs can provide information to patients about their illness, the medicine they are taking to treat it, potential side effects and living a healthy lifestyle. Some programs can also offer ongoing monitoring, support and information services.

When a patient is prescribed a medicine, any support programs or patient information they receive needs to provide balanced information on the therapeutic area, including available treatment options. For example, if a patient has been prescribed a medicine for diabetes, then information needs to be provided on the importance of taking the medicine exactly as prescribed and for the time period recommended by their healthcare professional. In addition, information should be provided on appropriate lifestyle and dietary choices that can also improve a patient's overall health and thus reduce their risk.

Companies review the benefits of patient support programs against the costs to the company to ensure that such programs are achieving appropriate and sustainable outcomes.

CASE STUDY

Tailor-made solutions

Baxter Healthcare's compounding pharmacies produce individualised intravenous drugs and parenteral nutrition products for hospitals across Australia and New Zealand. Shelf life ranges from 1.5 hours to 12 months depending on the product and is assigned by Baxter's extensive stability library after exhaustive studies. The highest standard of sterility is required because the finished products are administered to patients intravenously and many have the potential for serious harm or death if prepared incorrectly. The pharmacies are licensed by the TGA and must operate according to a code of Good Manufacturing Practice. The entire aseptic compounding process – including ordering, storing, equipment management, staff training and retraining, environmental and safety activities (hoods, gowns and a sterile environment), labelling, stability testing, calibrations, release, packaging and delivery to the point of use – must comply with the strictest Quality Use of Medicines standards. Each step involves a complex set of procedures, checks and re-checks to ensure compliance.

Many pharmaceutical companies embark on projects with partner organisations to educate patients and healthcare professionals on a specific therapeutic area. Partnership is a key element of QUM and patient programs developed in conjunction with a partner, for example a health consumer organisation, can provide great benefits to the patient, the organisation and the pharmaceutical company.

An example of such a partnership is the Heart Foundation Pharmaceutical Roundtable where a group of pharmaceutical companies work with the Heart Foundation to promote the quality use of cardiovascular medicines and fund collaborative projects that improve the cardiovascular health of Australians. The operating principles of the Roundtable are based on:

- Openness
- Transparency
- Fairness
- Achieving and maintaining trust and
- Respect for the Heart Foundation's independence.

All of these principles are aligned to QUM and follow the tenets of the Working Together Guide which was developed jointly by Medicines Australia and the Consumers Health Forum to provide guidelines for industry partnerships with health consumer organisations.

[Link here to the Working Together Guide section](#)

In this section of the medicines journey, the key QUM focus is on quality, safety, evidence and balanced information. By ensuring the patient is at the centre of all activity, decisions along the medicines pathway naturally have a QUM focus as the intended result is better health outcomes for the patient.

Post Market: post-marketing studies, monitoring and patent expiry

Once the medicine is widely available there are still ongoing studies to gather additional information on the medicine as it is being used across a very broad range and an increased number of patients. Phase IV clinical trials continue measuring comparative effectiveness, tolerability and any new indications. There are also post-marketing surveillance studies to monitor safety and toxicity, ongoing monitoring of adverse event reporting and the continuation of quality assurance and quality control activity to ensure the quality of manufacture of the product. These activities support QUM as they are focused on product quality and safety.

Once a medicine comes off patent, generic versions are able to be released in to the market. The TGA is responsible for evaluating a generic medicine's bioavailability, manufacturing methods, stability, quality, and the labelling and packaging, before it can be made available to patients.

CASE STUDY

Generically speaking, quality is the best policy

The importance of following QUM principles applies equally to patented and generic medicines at Pfizer. The Established Products team developed an e-learning module for GPs regarding treatment options for patients on anti-depressants based upon the Cochrane Review produced by the Cochrane Collaboration. This organisation is an international, independent, not-for-profit made up of over 27,000 contributors from more than 100 countries and is dedicated to the provision of accurate information about the effects of health care. Basing the content of an e-learning module on such a high-level evidence base aligns with QUM principles and promotes the appropriate use of medicines.

Working Together Guide

Pharmaceutical companies have collaborated with health consumer organisations for many years on a vast number and variety of projects and this is expected to continue and expand over the coming years. The Consumers Health Forum of Australia and Medicines Australia have jointly developed the Working Together Guide to provide a comprehensive set of guidelines and principles for all potential partners. The Guide focuses on open and transparent relationships that benefit all parties and it covers topics such as developing agreed objectives, negotiation, and sustainability. As partnership is a key QUM principle this Guide is a practical aid for all parties to use with confidence.

[Link to the Working Together Guide](#)

Feedback

If you would like to share an industry or company QUM story or example, please send your comments to Diana.Terry@medicinesaustralia.com.au

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1 Australian Government Department of Health and Ageing (2002). The National Strategy for Quality use of Medicines. Commonwealth of Australia: Canberra, AUS

2 Consumer Health Forum website www.chf.org.au/history

3 Australian Government Department of Health and Ageing (2002). Quality Use of Medicines: Statement of Priorities and Strategic Action Plan 2001–2003. Commonwealth of Australia: Canberra, AUS

4 TGA website www.tga.gov.au