WHO Discussion Paper

Essential medicines and basic health technologies for noncommunicable diseases: towards a set of actions to improve equitable access in Member States

Australia’s response

Australia thanks the WHO Secretariat for its work in preparing the discussion paper Essential medicines and basic health technologies for noncommunicable diseases: towards a set of actions to improve equitable access in Member States. We are pleased to be able to contribute to the web-based consultation on the discussion paper.

Access to essential medicines is one of the fundamental elements to achieving universal health coverage. Australia’s contribution to the discussion paper focuses on the processes used for ensuring access to essential medicines and health technologies, that are effective, costs efficient and of high quality, through our universal health care system. The comments are not specific to medicines and technologies required for treating and managing noncommunicable diseases. This is because in Australia the same process is applied across the board, regardless of the health condition.

Introductory comments – Australia’s experience with access to pharmaceuticals

In Australia, assistance with the cost of prescription pharmaceuticals dispensed through community pharmacies is provided through the Pharmaceutical Benefits Scheme (PBS). The PBS is a universal scheme available to all Australian residents within Australia. Under the National Medicines Policy, the PBS aims to provide Australians with timely access to a wide range of affordable and cost-effective medicines at a cost the community can afford.

The PBS costs the Australian Government around $AUS9 billion a year. Over 790 drugs, in over 2,000 forms and strengths, marketed in over 5,300 branded products, are listed on the Scheme. In 2013-14, over 210 million prescriptions were dispensed through the PBS (around nine prescriptions per person in Australia) – this represents around 80 per cent of all prescription medicines dispensed in Australia.

In accordance with Australia’s National Health Act 1953, medicines can only be listed on the PBS following a recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert advisory body comprising doctors, other health professionals and a consumer representative.

By law, the PBAC considers each PBS listing submission having regard to the safety, clinical effectiveness and cost-effectiveness (value-for-money) of the medicine for the intended use, in comparison with other available treatments.

In Australia, all consumers are required to make a co-payment toward the cost of their PBS medicines. However the level of co-payment reflects the ability of the consumer to pay. In 2015 this amount is $6.10 for a concessional patient (such as a pensioner or veteran) and up to $37.70 for a general patient (noting that around half of the products listed on the PBS cost less than this general co-payment amount). The actual cost of the medicine may be several hundred or even thousands of dollars per dispensing.
The PBS co-payment arrangements help to ensure that medicines remain affordable in Australia. A PBS safety net exists to ensure that the chronically ill (and their family) who require a large amount of medicines are protected from ongoing costs. For example when a concessional consumer reaches the safety net of $366 (2015 figure), no further PBS co-payments are usually required for the rest of the calendar year.
RESPONSE TO QUESTIONS

Question 1
What lessons can be learned from access programmes for the Millennium Development Goals that are relevant for access to essential medicines and basic health technologies for NCDs, at the global, regional and country levels?

Are there specific examples of best practices and successful case studies on country-led initiatives to improve access to essential medicines and basic health technologies for NCDs?

What were the critical success factors for these initiatives?

Australia has sought to introduce policies that make health investments more efficient through the provision of cost-effective and evidence-based health care. Understanding the approaches used to make coverage decisions, including disinvestment in lower value technologies, is essential to this policy analysis.

Australia supports health technology assessment as an invaluable tool to ensure that those who pay for health technologies and associated health services obtain acceptable value for money. This is because health technology assessment directly addresses the primary objective of any health care system – to improve health outcomes, and the primary constraint of any health care system – the limited ability to pay for unlimited demand.

In Australia, health technology assessments are used to define the goods and services financed collectively under universal health scheme arrangements. In 1990, Australia became the first jurisdiction in the world to systematically request information on cost-effectiveness when deciding whether to fund medicines on its PBS. This extension beyond information on comparative safety and clinical effectiveness represented the first complete health technology assessment approach applied systematically to health care resource funding decisions. Health technology assessments are now also being applied systematically to decisions to fund other types of health care interventions in Australia, such as medical services and vaccines.

The Australian Government is currently undertaking a review of the PBAC submission guidelines to ensure Australians continue to have affordable and timely access to new medicines and products. The Guidelines are used by the pharmaceutical industry to prepare submissions to the PBAC so it can assess whether a medicine or medicinal product should be included on the PBS.

Further information about the review is available at: http://www.pbs.gov.au/info/reviews/pbac-guidelines-review/

Question 2
Are there other bottlenecks limiting access to essential and basic health technologies for NCDs not mentioned above that need to be addressed?

Which bottlenecks would you consider the three most important to be tackled?

Timely access to medicines is achieved through co-operation of key stakeholders, including pharmaceutical companies, government bodies and prescribers.

The first step in providing access to medicines in Australia is an application to the Therapeutic Goods Administration (TGA) to have the medicine or new treatment approved for use in Australia. This is done at the discretion of the sponsor; usually a pharmaceutical company.
As with the TGA, sponsors can apply, at their discretion, to the PBAC to list new medicines on the PBS or to make a significant change to an existing PBS-listed medicine. The submission needs to be received four months prior to the relevant PBAC meeting. During this time, the submission is evaluated by expert evaluators and by the PBAC’s sub-committees, where necessary.

A key factor influencing the timing of decisions is the quality of evidence provided to support the application. The rigour of the PBAC process does not advantage applications that are not adequately supported by evidence of both clinical and cost-effectiveness. It is accepted that this high standard may sometimes present a barrier and could limit the capacity for certain medicines (e.g., for rare cancers) to meet the evidentiary requirements. The ‘evidence dilemma’ is especially challenging for rare diseases. For example, it can be difficult to establish a clinical trial from the limited patient population and the resulting aggregated data may not provide sufficiently detailed evidence.

The ability to deliver timely access to medicines is also affected by the timing of the applications which, in Australia, is at the discretion of pharmaceutical companies. It is acknowledged that these companies operate in a global industry and this can affect their decisions. Sponsors often choose to apply first in the US or Europe, delaying consideration of the medicine in Australia (or in other countries that have smaller markets).

**Question 3**

*How best can governments utilize multi-stakeholder collaboration, including the private sector, to increase country capacity to improve access to medicines and other health technologies for NCDs with health systems?*

*What additional information do donors and countries need in order to understand the business case for funding medicines and other health technologies for NCDs?*

Providing business conditions that encourage the marketing and take up of generic medicines, including biosimilars, both increases the availability of medicines in the community but also reduces the total cost to government and consumers.

For example in Australia, the Government provides a financial incentive to community pharmacies to dispense a generic medicine in situations where the originator brand is more expensive. Further information on this policy (the Premium Free Dispensing Incentive) is publicly available at: [http://www.pbs.gov.au/general/pbs-access-sustainability/fact-sheet-premium-free-dispensing-incentive-1-july-2015.pdf](http://www.pbs.gov.au/general/pbs-access-sustainability/fact-sheet-premium-free-dispensing-incentive-1-july-2015.pdf)

The Australian Government has recently announced the PBS Access and Sustainability Package, including the Sixth Community Pharmacy Agreement (6CPA). This package includes measures to promote the use of biosimilars, encourage biosimilar makers to enter the market and ensure appropriate pricing policies can be applied to achieve the savings that might be gained from increased biosimilar uptake. For example, the Australian Government is also investing $20 million in awareness activities for health professionals and consumers designed to support the efficacy and safety of biosimilar medicines.

**Question 4**

*Do Members States perceive a need for the development of a bottleneck assessment tool on NCDs?*

*What assessment tools are countries and partners already using that could be adapted for assessing bottlenecks for NCDs?*

Nil comment
Question 5

What are the most pressing needs for Members States as regard the availability of standard guidelines for management of the major NCDs and rational use of medicines for the alleviation of pain during palliative care?

How can Member States strengthen implementation of existing WHO guidelines for management of NCDs at the first level of health care?

What are the outstanding needs to improve patient acceptability of adherence to medicines and other technologies

Australia’s National Medicines Policy is a partnership committed to by all participants in Australia’s medicine supply chain to bring about better health outcomes for all Australians, focusing especially on people’s access to, and quality use of, medicines. The overall aim of the National Medicines Policy is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved.

Based on the shift of emphasis from healthcare programme inputs to quality health outcomes, the National Medicines Policy likewise focuses first on people’s needs and brings individual partners’ skills, experience and knowledge to bear on these central objectives:

- timely access to the 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; and
- maintaining a responsible and viable medicines industry.


Education and support (through NPS MedicineWise and the Department of Human Services) for prescribers, dispensers and consumers also helps by improving the Quality Use of Medicines, reducing waste and the cost of prescription medicines to the community.

The Australian Government funds NPS Medicine Wise an independent, not-for-profit and evidence-based organisation. It provides practical tools such as medicines lists or the Diabetes Health Tracker, evidence-based information and continuing professional development educational activities, with the aim to improve the way health technologies, medicines and medical tests are prescribed and used.

NPS MedicineWise works across Australia and throughout the Asia-Pacific region to positively change the attitudes and behaviours which exist around the use of medicines and medical tests, so that consumers and health professionals are equipped to make the best decisions when it counts.

NPS MedicineWise has a significant impact on the way health technologies are used in Australia, so much so that its work has become a benchmark for similar organisations overseas. Its educational programmes reach over half of all Australian General Practitioners, and through its website, resources and campaigns consumers are now able to access important health information which previously didn't exist.

Further information is available at: http://www.nps.org.au/about-us
Question 6

What constraints do Member States face in accessing accurate and transparent information about procurement process and quality of essential medicines and other health technologies for NCDs?

How useful do stakeholders consider an initiative on knowledge sharing to be?

The Australian Government does not procure medicines dispensed under the PBS. However, it reimburses pharmacies for the cost of the medicine, less any co-payment made by the patient.

Innovative Medicine Pricing issues

Value-based pricing of medicines in Australia has its ethical foundations in the concept of utilitarianism (doing the best for the most amount of people within current constraints) and its economic foundations in the concept of opportunity cost (the allocation of a resource to one use denies its allocation to its next best use).

With this as a starting point, most medicine pricing decisions for PBS listed medicines in Australia are made with reference to the relevant incremental cost-effectiveness ratio (ICER). The ICER estimates how much more therapy involving the medicine will cost over its comparator divided by how much more health outcomes will be gained. Health outcomes are quantified as improvements in both quality and quantity of life through use of a consolidating metric called “quality-adjusted life-years (QALYs) gained”. These are based on the different strengths of preference expressed by people to avoid being in different health states or to be in them for different durations of time.

The ICER per QALY intentionally sends a message to medicine innovators, investors and developers that greater pricing rewards are achieved by greater improvements in health outcomes.

Comparative health improvements are a primary objective of health care systems, so this is a sensible starting point to define the “right” innovations. However, health policy makers and payers are not limited to this objective alone. But whenever pricing is used to achieve other objectives, the concept of opportunity cost dictates that this also results in diminished improvements in health outcomes overall.

There are three main alternative objectives for the Australian health care system which have impacted on subsidy medicine listing and pricing decisions:

- **equity of access**: the Australian health care system seeks to diminish differences in accessing worthwhile medicines, for example due to geographical remoteness
- **rule of rescue**: an increased price is likely to be paid for a medicine that substantially improves the health of (“rescues”) individuals who have a rare, severe medical condition for which there are no alternative therapies
- **potential versus realised health improvements**: an increased price is likely to be paid for a medicine that has stronger evidence supporting the estimate of improved health outcomes.
This last point addresses the issue of the “right” time. A trend in recent years has been towards seeking marketing approval and subsidy listing earlier in the development of new medicines. The earlier that this occurs, the less confidence there is in the evidence to demonstrate any improvement in health outcomes. However, the consequent pressure to reduce prices is in conflict with traditional pharmaceutical business models to maximise medicine prices at launch. “Fast-track” and “adaptive” pathways are being designed on the premise of simply showing that the health gains (“benefits”) due to a new medicine are likely to outweigh the health losses (“harms” or “risks”) due to the medicine. Typically, this has proven to be inadequate in estimating the extent of these differences, which, as described above, is the evidentiary basis for back-calculating the extent of any increase in price.

In relation to the “right” conditions, incremental cost-effectiveness analyses are typically designed to illustrate the consequences of applying different conditions in the context of subsidy listing. As a general observation, the Australian subsidy arrangements for medicines rely less on developing such conditions compared with overseas jurisdictions which rely to a lesser extent on aligning the value of medicines with the improvement in health outcomes.

In general the trend in the development of new medicines in the last few decades has seen increasing costs of development, and diminishing marginal returns in health outcomes for medical conditions where effective therapies already exist. Seeking to reduce costs of development has resulted in the trend towards seeking earlier approvals based on less convincing evidence.

Seeking to identify niche populations to address residual unmet clinical need has resulted in medicines for very small populations where the reduction in eligible patients is greater than the improvement in health outcomes, resulting in disproportionately large medicine costs per patient. Changing the balance in the tension should be assessed for unintended consequences as much as maintaining the balance existing in each jurisdiction and across the world.

In relation to medicines not subject to brand competition, the Australian Parliament recently passed legislation to apply a one-off statutory price reduction of five per cent to all brands of pharmaceutical items on PBS formulary 1 (F1) after they have been listed for at least five years;

- the one-off reductions will commence 1 April 2016 and will be applied each April until 1 April 2020 as different medicines on the F1 formulary reach their five year anniversary on the PBS.

**Pricing of medicines subject to brand competition**

The prices paid by the Government for multi branded PBS-listed medicines are being reduced in several ways, including through statutory price reductions and price disclosure. The objective of price disclosure is to ensure that the prices at which the Government subsidises multiple-brand medicines listed on the PBS reflect more closely the prices charged in the market. Since their inception in 2007, reforms to the PBS are estimated to save over $15 billion by 2018–2019. Price disclosure is a large component of this.

Price disclosure works by taking into account the actual price paid by pharmacists for multi-branded medicines and any incentives provided by pharmaceutical companies.
Information is disclosed at regular six monthly intervals and is used to work out the price at which the PBS brands are sold. There is a six month processing period following each data collection period. Any medicine with a difference of 10 per cent or more between the existing PBS price and the weighted average price disclosed for sales by companies incurs a reduction to bring the Commonwealth price closer to the average price they are supplied in the market.

Price disclosure reductions occur in addition to the 16 per cent reduction that occurs on entry of the first competitor brand for a medicine.

Further information of the pricing of PBS listed medicines can be found at: http://www.pbs.gov.au/info/industry/pricing

As part of the recent legislative package of reforms passed by the Australian Parliament further changes have been made to improve price disclosure arrangements:

- Removal of the originator brand from price disclosure calculations, which will see the price of generic medicines for consumers reduce as much as 50 per cent from October 2016, delivering $2 billion worth of efficiencies for taxpayers and savings for consumers.

- Closing loopholes around the way combination drugs – where two separate drugs are combined to create a new patented drug – are subsidised under price disclosure reductions. This will deliver proposed efficiencies of $610 million over five years and savings for consumers.

More information about the full PBS Package, including changes to pricing arrangements is available on the PBS website at: http://www.pbs.gov.au/6cpa

Australia sees merit in sharing information about the pricing of medicines subject to Government reimbursement and improvements in the transparency of prices and pricing policies.

**Question 7**

*Are there any gaps in current tools available to Member States need to addressed to adequately capture the quantification of needs for essential medicines and basic health technologies for NCDs?*

*How best can Member States build and sustain capacity for effective national surveillance and data collection to forecast needs for medicines and other health technologies for NCDs?*

Nil comment

**Question 8**

*How best can Members States ensure the availability of safe, effective and quality-assured medicines and other health technologies for NCDs?*

*How can Member States strengthen quality assurance capacity for insulin, asthma inhalers and other more complex NCD essential medicines and health technologies?*

Developing the regulatory capacity of Member States to allow for active monitoring, surveillance and enforcement provides a solid foundation for ensuring that medicines and health technologies meet suitable standards of quality, safety and efficacy.
The effective regulation of medicines by developing countries is an issue of global and regional concern. Every Member State has a responsibility to effectively regulate the quality of medicines in order to protect public health interests of their own citizens. It is equally important to consider opportunities to foster regional collaboration on regulatory practice to strengthen effective regulation and reduce the trade in substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

Convergence of national regulatory systems, where technical information, knowledge and processes are shared and capacity in developing countries is built, can reduce time to market and improve access for patients to effective therapeutic products. There are a number of established global initiatives which align with the overall objective of strengthening regulatory systems and harmonising regional standards and in doing so, contribute to the overall goal of improving access to essential medicines including those relevant to noncommunicable diseases. The Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific Region is an example of such a mechanism.

**Question 9**

*What are the best ways to increase awareness of the importance of essential medicines and basic health technologies to prevent and control NCDs?*

*What other measures can be taken to enhance advocacy efforts to improve access to essential medicines and basic health technologies for NCDs in countries?*

Please refer to response to Question 5.

**Question 10**

*What key knowledge gaps are present for NCDs and how can these gaps be bridged using research?*

Nil comment