BETTER ACCESS
AUSTRALIA

SUBMISSION TO THE

NATIONAL MEDICINES POLICY REVIEW

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Better health, disability and social services. Better Access Australia.

www.betteraccessaustralia.org.au

Evaluate the current NMP objectives and determine whether these should be modified, or additional objectives included. This includes consideration of the proposed principles to be included in the NMP.

A. Are the proposed principles appropriate? With regard to the proposed principles is anything missing or needing to change?

The original NMP was drafted during a time of concerns about the growth in the PBS, and was accompanied by, and the precipitous to, a suite of cost saving policies designed to reduce use of PBS subsidized medicines in Australia. The NPS Prescribing Services announced in the 1997-98 budget, proudly stated the intention to deliver

> *"savings from the Pharmaceutical Benefits Scheme (PBS) … based on improvement in GP prescribing practice which will lead to reductions in overprescribing and/or inappropriate prescribing in a number of drug groups. The drug groups that will be targeted initially include peptic ulcer treatments, antibacterials, psycholeptics, analgesics and antihypertensives*".[1]

The intentions of the original policy were broader than savings, such as timely access, safety and quality use of medicines. However, the objectives of the original policy over the past 20 years have increasingly been defined and caveated based on cost, cost cutting, and prevention of uptake of medicines alongside the fears of new treatments and an ageing population driving costs. ***It has become a policy that had multiple objectives but has been weaponized such that its focus on affordability has become almost the sole focus of its influence in the sector as statements by individual consumers and ongoing cost-saving measures funded through Strategic Agreements and NPS MedicineWise measures reaffirm***.[2] [3]

This occurs because the current NMP has not been implemented with equality of standing. It is the Australian community's policy not the Government's policy and therefore the Australian Government needs to be a stakeholder with no greater or lesser value than the consumers, suppliers, researchers and clinicians. This is not currently the case, and the lack of scientific and clinical expertise on this review panel highlights this approach of the NMP not being a community-owned policy, but a tool for government. We can do better and we must.

Therefore, the principles outlined in this consultation paper are not enough, they are a 'bolt-on' or an afterthought instead of being the foundational building blocks of a first principles policy.

For example, the proposed: **Consumer centred approach** – consumers should be informed, engaged, and empowered to participate in medicines policy, recognising their key role in supporting the achievement of the policy's objectives.

- It is not consumers jobs to support the NMP, it is the NMP that is there to support them in their healthcare. Patient-centric and consumer-centric policy is critical to a genuine review of this policy.

[1] Australian Government: '1997-98 Budget Paper 2', page 71
[2] Biopharmadispatch: 'Business owner, patient and advocate for change', 15 October 2021
[3] Biopharmadispatch: 'Government funded alliance sruiks controversial and unproven theory', 24 May 2021

- This proposed thinking is not new and in fact is reflected in most modern government service design principles. Taking New South Wales (NSW) as an example: "***Placing the customer at the centre is the core driver of our design***."[4]

If you place the consumer or patient at the centre of our NMP, our future policy framework takes on a very different shape and emphasis.

The NMP itself must do what it demands of the rest of the system, break down the silos and see medicines policy as integrated into our national health system, and not standalone. And like all health policy it MUST focus on the patient health, patient outcomes, patient access, patient need as its primary objectives. Thereafter everything else follows and can caveat, but patients as an afterthought must stop.

Medicines (and therapeutics) access is the Australian community's most common touchpoint with the health system. From over-the-counter medicines to complex cellular therapies. Australia's national medicines policy is a commitment to the community that access to quality healthcare is a fundamental right in Australia and medicines access is an integral part of that healthcare.

With that in mind:

- ✓ a revised NMP needs to recognise the patient at the centre of everything we do.
- ✓ Patients expect seamless and ready access to the most up to date and relevant therapeutic care for them where and when they need it. This is not the exclusive remit of the PBS. It is about clinical trials, preventive health, timely diagnosis and choice to fund access themselves through a variety of sources.
- ✓ Patients expect to be the ultimate decision-makers on their treatment, to be fully consulted on their treatment journey whoever that is with and however long that may be to be.
- ✓ Patients expect to be consulted on programs, policies and reviews that impact their access to therapeutics.
- ✓ Patients expect to rely upon the quality and safety of their medicines if available in Australia.
- ✓ Patients expect their health system to be medicines-educated and informed about treatment options and be able to provide contemporary health advice tailored to them as an individual.
- ✓ Patients expect the health system to work as one to deliver the best treatment plan for them as an individual irrespective of their diagnosis, location, stage of life or cultural, linguistic or personal circumstances (this includes in the community, hospitals public or private, outreach programs, private programs, First Peoples' programs, aged care facilities and emerging modes of care delivery).
- ✓ Patients expect the system must come together to work as one to achieve this. Government, clinicians, suppliers, academics, researchers, community organisations must work together to hold our system accountable to the outcomes and key performance indicators this policy enshrines of patient-centric healthcare.
- ✓ Patients expect that what the NMP enshrines it must report upon, and reporting has to be more than savings achieved and money spent on the PBS it has to be a report card on access not just for the PBS but for choices of investment in clinical trials, research, and other programs. But most importantly, it must report based on the patient experience.

[4] https://www.nsw.gov.au/onecx/blog/what-does-it-mean-to-be-customer-centric

When you design a national health policy with the patient or consumer at the centre of it, the "principles" that emanate from this modify accordingly. With respect to the underpinning principles proposed in the consultation paper, the following comments are offered.

The current use of the term "wise" is quite dated and not consistent with the language of other modern health policies. As per our earlier statements first principle language in modern health care policy uses terms like 'patient-centric' 'optimal', and 'contemporary'. Using terminology for an ageing population denies the interest, implications and involvement of the younger generations for whom this policy will have access implications for the next 20-years and who should be equal stewards of this policy. In doing so, the NMP would be adopting concepts permeating other health consultation processes, policies, and strategies including those issued by the Australian Government Department of Health in consultation with other stakeholders.

The concept on one collaborative approach is important and should be strengthened in this Policy and protected from dilution and setting aside by governments for the purposes of savings measures or convenience.

EQUITY – all Australians receive effective, safe, high-quality, and affordable access to medicines when needed irrespective of background or personal circumstance.

- Equity is an important principle but the current drafting ignores the challenges of location, cultural diversity and access to diagnosis.
- Timely access is a fundamental principle in equity.
- Location becomes an increasing issue of equity as the state-by-state attempts during COVID to hoard medicines for their own state demanding absurd levels of stock in advance (up to 12 months), means this principle needs to be a key learning for governments in their management of medicine and therapeutic programs particularly during national crisis. [5]
- Equity also relies on diagnosis because without diagnosis there is no treatment. No point having medicines if you aren't properly diagnosed, and this highlights the need for the NMP to see itself part of the national health system not stand alone.

CONSUMER CENTRED APPROACH – consumers should be informed, engaged, and empowered to participate in medicines policy, recognising their key role in supporting the achievement of the policy's objectives.

- This language includes consumers and patients but still sets them aside as an afterthought and lesser player in the system.
- We encourage the Department to review the policy and strategy development in other parts of the health system where genuine co-design and consumer-centric focus is a feature and a strength.
- If the system wants to focus on 'sustainability' and expenditure, remember whose money you are spending or not spending – consumers' What do they want from their health system?

PARTNERSHIP BASED – establish and maintain active, respectful, collaborative, and transparent partnerships, to harness stakeholders' skills, experience, and knowledge.

- This would be appreciated across all aspects of the policy and its implementation as it is not an experience of the current approach within government.
- The ongoing lock out of consumers, patients, suppliers and groups from closed door discussions that determine future access policies and processes has to stop.

[5] BioPharmaDispatch: 'Greg Hunt intervenes on hospital stockpiling', 24 April 2020

- The most recent Strategic Agreements are examples of the Government negotiating in isolation of the broad range of stakeholders impacted by the one-on-one engagements, most notably they excluded consumers and patients from the consultation processes.
- This consultation concern is also reinforced with this NMP review itself.
    - A select group was asked to review the draft terms of reference some 18 months ago, and these individuals or organisations have had the opportunity to participate and prepare for this review since that time as opposed to the majority of suppliers and consumers who have been given one month to form a view on a policy the Government regularly cites as the reason for all the actions it takes with respect to medicines access, particularly on the PBS.
    - Further the time allowed for this review compared to the time set aside for Post Market Reviews, the national lung cancer screening proposal, and the National Preventive Health Strategy all send strong signals about the level of interest the government has for consumer comment. Instead, it seems that a more honest message and the from the government is: We don't really want to know your opinions or genuinely care about this policy reform. And that's a real shame.

ACCOUNTABILITY AND TRANSPARENCY – all stakeholders are identified and accountable for their responsibilities and actions towards delivering or contributing to the achievement of the policy's objectives, within a transparent framework.

- This consultation paper sees the Australian Government as the owner, and everyone else as a stakeholder. This is the community's policy.
- These accountabilities and transparencies must apply to all in the system especially governments. No more locking people out of conversations. The medicines policy area could learn a lot from other areas of the health system and other areas of the Australian Government, Department of Health and their approach to policy engagement, consultation and transparency.
- This is not an Australian-Government alone problem, industry groups must also take responsibility for their exclusion of others in processes and negotiations.
- Transparency and accountability must not be tokenistic.

STEWARDSHIP – all stakeholders have a shared responsibility to ensure that the policy's objectives are met in an equitable, efficient, and sustainable manner, as stewards of the health system.

- Again, this must explicitly include the Australian Government and the state and territory governments as the ultimate decision-makers and program owners and designers over which all other stakeholders have limited access and input.
- 'Sustainable' is a term bandied about in many media releases and certainly in strategic agreements. It is a word of concern because it is usually used in the context of making things cheaper for government.
- Many consumers would argue a co-pay of over $40 is not sustainable access for them, particularly when the prevalence of managing co-morbidities in individuals and families is increasing, and when 1 in 3 scripts on the PBS is fully funded by a consumer not government.
- Again, governments at all levels have set aside the concept of sustainable when individual government and private sector purchasers are distorting the market with demands for access to stock in critical times of demand, setting aside sustainable access for the entire Australian community.

B. Are these four Objectives still relevant? Should any be modified, or any additional objectives be considered? If so, how and why?

The four objectives as currently drafted are as follows:

1. Access to medicines
2. Quality safety and efficacy of medicines
3. Quality use of medicines
4. A responsible and viable medicines industry in Australia.

Despite recognition that medicines include those beyond the subsidy of medicines on the PBS, the policy has been drafted and increasingly interpreted as focussing on this above all else, and it drives behaviour in a way that is perhaps overly focussed on the purchaser, rather than on the consumers and suppliers and the interactions with the broader health system that is an increasingly interdependent relationship for medicines access.

It is in this context that Better Access Australia makes the following comments on whether or not the current four objectives are still relevant and whether they should be modified.

1. Access to medicines

Access to medicines is traditionally espoused as timely affordable access to medicines wherever someone resides at a cost the community can afford. It is the linking of these four concepts in one objective that means ***our universal access health system is nothing more than a universal waiting system when it comes to treatment with medicines or therapeutics.***

The average time from ARTG registration to PBS subsidy is 820 days, compared to 50% of patients waiting only 41 days for a hip replacement and 91% completed in 279 days.[6] [7] These elective surgery statistics are still considered sub-optimal by the community and by the system. So how did we get to such a different tolerance level of delays in for medicines access?

Because over time government has linked timely access to 'the cost the community can afford' and the process and pricing negotiations have become the dominant focus of the NMP over everything else.

And to be fair, that's not all that surprising when the current content underpinning "Access to Medicines" in the NMP, cites cost to the system in various forms nine times in a section that goes for less than two-thirds of a page.

Timely access must be a standalone objective.
Affordable access must be a standalone objective.

When timely access is standalone, the setting of Key Performance Indicators, program objectives and patient- access design all flow from a different approach, which today is exclusively about cost and timeliness is the collateral damage at every step.

Timely access as a standalone objective allows the health system to contemplate the cost of delayed access to treatment and the interventions and priorities.

[6] Elective surgery waiting times 2018-19, Supplementary data tables, Table 4.7, Australian Institute of Health and Welfare

[7] Better Access Australia, 'Submission to House Committee review of Processes for access to novel technologies, attachment A', November 2020

Timely access allows the system to acknowledge access to therapeutics is more than the PBS.

- ✓ It is the PBS.
- ✓ It is clinical trials.
- ✓ It is input into the defining and participation in translational research in Australia contributing to the priorities of our Medical Research Future Fund.
- ✓ It is reliant on and demands for early diagnosis and appropriate testing. Because without diagnosis there is no treatment, and this is a continuing theme across multiple patient groups, noting presentations at the Medicines Australia PharmAus 2020 event highlighting the impact of delayed cancer diagnoses, through to our own current advocacy on the loss of children year after year from diseases with subsidised treatments because we do not have a contemporary national newborn screening program in Australia.[8]
- ✓ It sets aside antiquated restrictions demanding patients experiment with outdated therapies or ensure unnecessary surgical procedures in order to "qualify" for access to a treatment
- ✓ It sets aside outdated thinking that fails to recognise diseases such as cancer becoming an area of chronic treatment and concepts of "once-in-a-lifetime".
- ✓ It is the defining of KPIs that set the system targets of #100days from ARTG registration to subsidy that are reported upon annually.
- ✓ It is KPIs that drive genuine innovation in processes for subsidy and evaluation based on disease across multiple clinical pathways and interventions not siloed slow reviews of medicines versus surgical versus other interventions that work at five different speeds in the health system.

It makes timely access an equal policy and program consideration in our NMP. Then and only then can you consider the second objective of affordability.

1.1 AFFORDABLE ACCESS

Affordable access will always have a strong system-centric view of cost. How much will this cost government, the system?

Better Access Australia again highlights that the general co-payment in Australia is now over $40 a script. For over a decade now multiple groups have been raising concerns about the increasing costs of the general co-payment for the management of chronic and acute disease in the Australian community. [9] Changes to the PBS safety nets following the 2019 federal election show the ongoing tension this will represent for the community, and it must remain front and centre in the defining of affordability in the future NMP.

This does not however set aside the very real issue of the affordability of our health system. In a two-year period of unprecedented spending on vaccines and health interventions in the primary and acute care setting, the value of not having timely healthcare treatment has been made a stark reality for all, and one the system has invested significantly in.

With disease management increasingly a multidisciplinary, multivariant clinical intervention experience covering many years of a patient's life, the cost of treatment with a medicine, versus a scan, versus surgery, versus preventive interventions in ***a finite health budget is important but not the singular focus. Further our medicines policy must increasingly grapple with the cost of delayed treatment due to delayed subsidy and delayed diagnosis.***

[8] https://www.medicinesaustralia.com.au/media-events/pharmaus20-digital-forum/
[9] Consumers Health Forum: 'Submission to the Senate Community Affairs Inquiry into PBS medicines co-payments' , 2014

These conversations must be had but cost must not have a greater value in our policy principles than the other objectives. ***The NMP as currently drafted does and has allowed the universal waiting system for medicines in Australia to reach unacceptable levels.***

2. Quality Safety and efficacy of medicines

The work of the TGA continues to be paramount in the community expectations of the safety of treatment in Australia

With the increasing prevalence of clinical trials in Australia, and in fact the increasing reliance upon them by clinicians in providing contemporary and best standard of care to their patients, the broader remit of this objective has increased in its importance in a future NMP.

3. Quality Use of Medicines

This objective has been used as the basis to fund many billions of dollars in expenditure through community pharmacy programs, the NPS MedicineWise, and NHRMC and ARC grants.

With innovative pipelines in medicines predominantly focussed on the hospital setting for access, the education of primary care by the pharmaceutical industry is rapidly diminishing. ***The value of organisations such as the NPS MedicineWise to conduct genuine education programs (not savings programs) is an increasing unmet need meanwhile the prevalence of chronic diseases and multiple co-morbidities continues to increase in Australia***.

Defining education and quality service principles in health care is important. Defining it to help improve the cost of these current education and review services would benefit from a research driven by the refresh of this policy.

4. A responsible and viable medicines industry in Australia

The principles of stewardship and partnership are important as articulated earlier. But so too is the expertise and capacity of the full medicines and therapeutics supply chains operating in or delivering into Australia.

Consider the definition of medicines and whether the NMP needs to be expanded to include health technologies.

A. Should the current NMP definition of medicines be expanded to include medical devices and vaccines? Why or why not? How would a change in definition of medicines be reflected in the policy's high-level framework?

Australia should consider a National Therapeutics policy rather than just a national medicines policy. It should cover the vaccines and other emerging technologies as the blurring of lines of traditional medicines versus treatments continues to evolve.

Vaccines

- Vaccines are an excellent example of needing the NMP to be less focussed on the PBS and being about access to therapeutics that support optimal health outcomes for all Australians. The current NMP places great stock in the value of preventive health (mostly to avoid the cost of medicines) but if that principle is genuine, vaccines are an intrinsic part of the consumer experience of medicines policy in Australia: no jab no play, no jab no pay and a priority of access to vaccines for certain groups in the community.
- Most people in the community do not differentiate between a medicine and a vaccine with respect to the importance of access and being fundamental to the quality of their health and quality of their health care access in Australia.
- Some vaccines used to be listed on the PBS until the creation of the NIP and so recognition of these important therapeutics as a 'medicine' for subsidy has been long assumed by the community, suppliers and clinicians.

Medical Devices

- There is a growing complexity in the delivery of health to Australians. Cellular and genetic therapies and changing scope of blood products make the simple molecule approach to what is a medicine covered by the NMP, results in the policy lagging behind the access needs of the community.
- Complex food substitutions also increasingly appear on the PBS even though they are not technically medicines but are considering lifesaving access by the patients that access the food products via PBS scripts.
- There is a need for the definition of medicines to take on a new term. This may not be legally possible given the importance of the linkages to the Therapeutic Goods Act of the NMP, and therefore the concept of "therapeutics" has increasing merit and applicability.
- Better Access Australia acknwoeldges that decisions regarding where a medical device should be included in the policy are challenging and we note the issues of Over-the-Counter (OTC) versus PBS may arise in this domain.
- For example a glucose test strip, syringe, needle, sterile wipe and gloves, an EpiPen®, insulin, or IVF device for auto-injecting a medicine are all examples of important components of therapeutics access and policy that cudl readily be argued are integral to medicines Ithreapuetics) access. But does that extend to a Continuous Glucose Monitor, or a stent? What about digital health devices for recording and sending data to determine changes in dose administration immediately and changes in prescribing?
- Does the term need to encompass the administration relationship with the therapeutic (medicine, cell, gene therapy) that is the primary focus of the NMP? These devices improve the health outcomes of the therapeutic, through either compliance, convenience, or efficacy of the

therapeutic. Better Access Australia considers this is an important area for extensive consultation with the community and clinical sector, and broader areas such as private health insurance (PHI), but are concerned the brevity of this review process does not lend itself to such review and robust policy development to ensure the NMP stands the test of time for another 10 years. If the review team were of a mind to do this, it would be welcomed.

- Finally, the reality of without diagnosis there is no treatment. Diagnosis is the gateway to clinical pathways of treatment- whether that be medicines and therapeutics (dominant) or surgical or other allied health or social services support interventions.
- The NMP and medicines sector has been pontificating about the concept of co-dependent technologies and one test one drug for 15 years. In doing so have they overlooked the basic science and revolutionary science of diagnosis being the pathway to all treatments and clinical pathways at a basic and comeplex level.

A standalone NMP that is siloed and insular will continue to miss these opportunities and also likely boast about the savings achieved from poor diagnosis.[10] [11]A new contemporary NMP would recognise the interdependencies of the system and embrace it and be a leader in this long discussed but poorly executed area of health service.

B. Does the policy's current title, the "National Medicines Policy", reflect the breadth of health technology developments within the policy's scope? If not, how best can these and future health technologies be better represented in the policy's title?

Better Access Australia supports the concept of a National Therapeutics Policy, noting it should encourage a broader focus on the different inputs to therapeutic access, the different funding and access pathways both public and private, and challenge the increasing emphasis of old-school health technology assessment (HTA) to consider the relative costs and savings of medicines compared to other interventions in the health system to achieve improved health outcomes at the population and individual level.

Medicines have until recently stood alone with the use of HTA and some other health sectors have been too quick to see the ability to cut access with its application in broader health areas, rather than challenging the construct and funding principles behind how we treat diseases at a concept level, instead of an individual intervention level.

Denying access through protracted HTA processes is not optimal. Valuing and purchasing based on population need and value of health outcomes is supported. Australia is weak in its readiness for real world evidence and timely access to medicines. Setting KPIs for access would demand the system lift and transform itself, just as the policy principle enshrined in the 1990s transformed the PBS into the system we have today.

Digital health, multiple disease registers, in principle support for population-based screening, unprecedented investment in translational research through the MRFF – these are policy transformations to be led by the NMP and program transformations to be demanded.

Finally, Better Access Australia notes once more that without diagnosis there is no treatment. Timely access to medicines and therapeutics increasingly relies on timely access to diagnosis. The current rural health upper house inquiry in NSW highlights the computing of access issues for rural and remote communities (medicines or procedures) and but it is a compounding of concerns in the

[10] MSAC, Screening for SMA co-dependent technology 2019 Public Summary Document, page 4, para 1 20
[11] Microsoft Word - 1573 - Final PSD_Jul2020.docx (msac.gov.au), p.3

general health system and therefore must be understood as a fundamental underpinning of inequity in healthcare in Australia.[12]

For example a baby born with Pompe takes on average 90 days to be diagnosed in metropolitan Australia but 180 days in rural or remote Australia. This compares to 6 days in Taiwan or the US. One drug equally subsidised for all eligible patients

This is not exclusive to rare diseases, it a fundamental failing in optimal cancer treatment as well, from breast cancer to endocrine cancer.

12 Health outcomes and access to health and hospital services in rural, regional and remote New South Wales (nsw.gov.au)

Assess the NMP's utility in the context of rapidly evolving treatment options, population changes, interconnected relationships, and system-wide capacities.

A. How has the NMP been able to maintain its relevance and respond to the changes in the health landscape?

Whilst the discussion paper focusses on many programs and deliverables including recent new initiatives about to be implemented in the PBS side of the medicines sector, these alone do not necessarily demonstrate that the policy itself has been able to remain relevant and respond to changes in the health landscape.

Once again, this all stems from the time in which the original NMP was established and the failure of governments to regularly review the policy which we consider should be standard practice in any sector or organisation, public or private. This avoidance of regular review and contemporary reflection is a disrespect to an important policy.

Most of the evolving work we have seen with respect to medicines has been at the individual program level, and the NMP is an afterthought if referenced at all, except for its "affordability".

The strong messaging that comes through the current policy is about taxpayer money, savings and avoidance of costs and the priority of HTA in the medicines system above all else. ***This is not acceptable and is not contemporary***. Does it drown out access, affordability for consumers and the sector, does it drown out innovation, and investment for the future, contingency planning and alternative ways of doing things?

Hence Better Access Australia's recommendations about timely access being an equal and driving principle for the policy, and the calibration of objectives of the policy to de-emphasis the over importance the system places on cost to government at the expense of patient need.

Finally, the fact we are discussing whether vaccines should be included, cell and gene therapies, and the prevalence of PHI in the document despite it still being a largely untapped source for early access to therapies is a strong signal to the community and patients this policy this supposed to serve and protect. It suggests that the lack of regular review the lack of forward-looking horizon scanning by the policy, not just the programs, needs to be contemplated.

B. How could the NMP be refreshed so that the policy framework is able to better address current and future changes in the health landscape? What is missing and what needs to be added to the policy framework, and why?

If the concept of stewardships and partnerships are genuine, the patient-need and patient-centric design must be foremost in the policy itself, and as a result all stakeholders become partners in the stewardship of the policy.

It is time for the NMP to be more than an afterthought for engaging with select stakeholders when savings are needed. ***Consumers, academia, clinicians, suppliers and government administrators are all equal partners in the stewardship of this policy – but all with patient-need foremost driving their input.*** Policies need targets, expectations, deliverables, outcomes. Better recognition of the operating environment current and emerging. Understanding the impact and access for medicines and therapeutics in the community – where are the touchpoints, where are the impacts. One ecosystem – from the consumer to the manufacturer and everyone in-between.

Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers, and their needs and expectations.

A. How can the NMP's focus on consumer centricity and engagement be strengthened? Is anything missing, and what needs to change?

The assumption that the current NMP is consumer focussed is an inherently flawed starting assumption for this consultation as we have repeatedly asserted through this process. Unfortunately, the NMP is a systems-focussed document, that does not reflect the current consumer expectations of co-design and genuine consumer centricity.

Once again, the discussion paper refers to the appointment of consumers (all from the Consumer Health Forum (CHF)) on the key HTA bodies. Medicines access is more than HTA assessments. And consumer associations are different to consumers and different again to patients with patient-needs.

An analysis of the groups and individuals invited to participate in strategic agreement reviews, post market reviews, and even the consultation on these terms of reference, where they have actually been disclosed, reflects a small cabal of consumer groups and industry representatives allowed to participate in the design and development of the system.

An injection of youth and new perspectives would be welcomed by many. An injection of patients not professionals, a landscape of patient-centric design. Unlike so many other areas of government, the medicines policy and programs are tragically behind their other health counterparts. The disempowerment of all but a few selected consumer organisations is wrong. Individual patients and individual patient needs are of equal importance in this policy and system, alongside the new ideas and new perspectives they bring.

After 20 years, this needs to be drafted on first principles, not a track changes approach:

- ✓ What is the community and consumer expectation of access to health care in Australia?
- ✓ What does that translate into for the medicine/therapeutic access expectations?
- ✓ What support systems and principles drive that access?
- ✓ How will we know when we are achieving it?

To do so requires a start from scratch, first principle design and re-drafting of the NMP for the next 20 years. Take the blank slate and make something extraordinary.

Identify options to improve the NMP's governance, communications, implementation (including enablers) and evaluation.

A. What opportunities are there to strengthen governance arrangements for the NMP? What would these be, and why?

The Review team needs to acknowledge there are no governance arrangements for the policy. It has been left to languish while government got on with the doingdoing. The focus on strategic policy has been lost and citations of health reform agreements and TGA and HTA consultative committees, have nothing to do with the protection and enforcement of the NMP principles.

Committees for committees' sake for token consultation are not the answer. ***Genuine stewardship such as the former NMP Committee would be a good start.***

But it must be based on a policy that sets goals, has KPIs and principles that must be followed. There must be some empowerment of that committee to oversight the work of the various groups claiming the protection of the NMP for their actions and programs.

It must have environment scanning and reform as part of its remit, not be another program development body.

It must have genuine representation with rotation of membership, from consumers (not just the CHF, Patient Voice Initiative (PVI) and Rare Cancers), researchers clinical, state and territory, industry and pharmacy in multiple settings, TGA and state regulators, and not just the people already on Technology Assessment and Access Division (TAAD) advisory bodies.

It must have a minimum inclusion of demographics – age, culture, location. The full environment.

Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

A. How should the NMP's 'partnership-based' approach be defined

Make it genuine not lip service with the usual crowd.

Define roles and responsibilities in the supply chain wherever medicines/therapeutics are accessed by or delivered to consumers. Make them jointly responsible for the oversight and delivery against tangible outcomes, KPIs etc.

Do not see partnership as an afterthought or the justification for increased compliance or service provision.

Do not continually exclude consumers/suppliers/partners from the table when designing new programs and negotiating program-wide or policy-wide initiatives.

The increasing use of confidentiality agreements within the TAAD to exclude stakeholders has to stop. The recent HTA consultative committee who decided themselves who could and could not participate in consumer consultation using government funds – egregious and symptomatic of a

system captured and controlled by the same people, same groups, same processes. Let the sunlight in. Let real people in. Let new people in.

The Review committee is reminded that this is not the experience in other areas of the health department or the national health system. This policy suffers from capture by the administrators of the programs. This is sub-optimal governance. This policy should not be consulted upon, developed, or maintained by the same people whose primary focus is containment of the system. Leave them free to do their jobs and empower policy and forward thinkers to do theirs.

B. What is missing from the policy's reference to the NMP partners? Are there other partners that should be included in the policy? Who would they be and why?

Responsible and accountable are not interchangeable. Better Access Australia notes it earlier comments on the concept of patient need timely access, constrained by poorly defined and interpreted terms, such as affordable and sustainable, in order to reflect an increasing passion for HTA and savings priorities and at the expense of the genuine access needs and interests of the community.

The risk of identifying some partners over others, can lead to the ongoing risk of exclusion, but there needs to be a significant improvement in the consultation environment of the custodians of this policy in the Department of Health.

C. How could the NMP be refreshed to support greater accountability amongst the NMP partners? How could the partnership approach be improved?

As per our original statements as Q.1A, start with a blank sheet of paper and design from first principles, not tweaking what you have. Empower everyone to do better and think better and work together in genuine partnership not just across the medicines sector but the full health sector.

The sceptical in the community might consider that the cursory, expedited and forecasted and exclusionary nature of this truncated process reflects the pre-determined outcomes and unfortunately perpetuates the approach to the policy and partnership within government. This is both concerning and disappointing given the original engagement and vision for this policy when first established.

The Review Team should lead by example and model the governance, consultation and development processes stakeholders are looking for.

KPIs and annual reporting on the state of the policy and its impacts across the broad range of healthcare it impacts (PBS, clinical trials, hospitals, patient support programs, private health etc) would be a tremendous start as it would lift the programs to respond and report to the achievement of those outcomes, just as a portfolio budget submission aligns outcomes with outputs and KPIs.

D. How are conflicts of interest currently managed and should more be done to address this amongst the NMP partners? What approaches could be taken?

The Government/Department is quick to make accusations of conflicts of interest for industry, and consumer groups who are in receipt of any funds from industry.

We note that government itself has a raft of its own conflicts of interest and in fact consumer organisations that are predominantly funded by government or receive funding from government have equal perceived, potential or actual conflicts of interest to manage and declare.

It could also be argued that the greatest conflict of interest resides within the Department at this time given its program and savings imperatives may be at odds with the objective of a National Medicines/Therapeutics Policy and the value of access and partnership in that policy.

To address this ongoing conflict of timely access to address patient need and government obsession with limiting new spending, Better Access Australia recommends the Minister place the ownership of this policy in the Population Health Division of the Department. This would make the policy truly independent of all participants, and cognizant of the need for consultation and recognition of all interdependencies in the broader health system that are relied upon to achieve better preventive health outcomes, better chronic disease health outcomes, better cancer prognosis health outcomes, better acute treatment and supply chain sustainability outcomes.

It's time to recognise that the administration of the PBS is also a potential conflict of interest and empower the Division responsible for the PBS, and HTA and pricing negotiations for PBAC and MSAC to focus on that work.

This would allow the policy owners in another Division to raise the profile and importance of the NMP by capturing it in the broader health policy areas, just as the inclusion of Quality Use of Medicines was added as a national health strategy.