Allergy & Anaphylaxis Australia

8 October 2021

Review of National Medicines Policy – A&AA submission

Terms of Reference 1: 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 within the NMP.

Objectives of the National Medicines Policy

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

Allergy & Anaphylaxis Australia accepts the current principles of the NMP but believes they could be enhanced to ensure greater reach. All Australians should have *timely* access to medicines. Although *timely* is included in the objective ''Access to Medicines" we would like to propose that timeliness is added to the existing principles as a separate principle. The word *timely* will need to be defined so all involved work toward a time frame. A&AA feels that this is an important addition, as many medicines for allergy are approved in other developed countries, but take an extended period of time to be approved for use in Australia. The word *timely* should also help to speed up approval of medicines that are already approved for one use, but are used off-label in conditions that are rare.

A&AA also acknowledges that while the principles include *all Australians* they do not speak to diversity. A consumer centred approach means we should consider people from diverse backgrounds. We need to consider language used (plain English) so consumers from all backgrounds have an opportunity to be engaged, included, and enabled. Use of terminology on consumer centricity that speaks at a level that is difficult for the majority to understand is not inviting/welcoming. If the National Medicines Policy is for ALL Australians, the language used in communicating the policy must be considered. As we have such a multicultural nation and we want consumers to engage, is it reasonable to translate information, including policy review so we are reaching people who have the most difficulty in communicating their health needs? The word *Stewardship* as a principle, for example, does not clearly reflect a consumer centred approach as many would not understand its meaning. We continue to speak of health literacy but the very people that need to improve health literacy, do not know what we mean by the term.

Innovation is also missing from the list of principles. We need to encourage innovation and make it clear that the National Medicines Policy embraces scientific advancement of medicines and devices that improve health and wellbeing. For example, an adrenaline injector without a needle has recently been reported on in the media. This sort of innovation would be life changing for those at risk of anaphylaxis.

The principles should embrace the use of off label medications where there is no other appropriate medication for a specific individuals/disease state. As these people have no/limited options, off label medications that are

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PBS listed for one disease state following set criteria should be an option for those whose quality of life is impaired. An example is Budesonide which is listed on the PBS for people with asthma but not for people with chronic sinusitis. If standard treatments, such as corticosteroid nasal sprays and even surgery are not effective for people with chronic sinusitis, then Budesonide should be available to them. The nebule can be opened into a nasal rinse solution when nasal sprays are not reaching the affected areas in the sinuses.

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

A&AA believes that the existing objectives remain relevant however we do have examples of Australians' needs not being met in relation to *Maintaining a responsible and viable medicines industry*". An adrenaline injector delivers lifesaving adrenaline to a person experiencing anaphylaxis. Australia has had one adrenaline injector (EpiPen®) since the 1990s with only one other PBS listed in 2011 for a three-year period. Due to continued shortages of EpiPen®, product recalls and short dated devices, consumers and health professionals have tried to encourage the launch of other devices with points of difference (such as a dose of intramuscular adrenaline for individuals over 50kg or under 10kg, smaller size device or audio instructions) in Australia. A collaborative approach of adrenaline injector device sponsors that included members of the TGA, health professionals and consumers may have assisted with sponsor confidence in applying for registration and then PBS listing of a much-needed alternate device listed in Australia. We note that Anapen® has recently (September 2021) been launched in Australia.

A&AA is also concerned about registered and unregistered products used for allergen immunotherapy (AIT) in Australia. While products registered are supported by years of research, health professionals are still prescribing costly unregistered products for AIT. Almost all AIT is not PBS listed so we have consumers who are unaware that their costly AIT is not registered and therefore unlikely to have met the rigor of *Quality use of medicines* and the *Quality, safety, and efficacy of medicines*. As non-registered medicines are being used in Australia, there needs to be a process that enables transparency so that consumers, who are our focus, are made aware that the medicine they are being prescribed is not registered. What process is there to review unregistered medicines that are being used once they have been used for a number of years? Should we have a process that mandates registration of products after use for a number of years/on number of patients?

A&AA is also confused about the use of products for skin prick testing (SPT) to assist with allergy diagnosis. As far as we are aware, some of these SPT reagents, although used very often, are not TGA approved. If non-registered products are used because there are not registered alternative products, A&AA believes that there should be a process for registration after a period of time of the product being used?

Equity is clearly a principle, but it does not filter through to objectives and is notably missing. Minority groups such as those with rare diseases, those from culturally and linguistically diverse backgrounds, and those in rural, remote or regional areas or of low socioeconomic status need to have fair and reasonable access to medicines, including vaccines and technologies.

Terms of Reference 2: 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?

A&AA believes that medical devices and vaccines should be included in the NMP. Medical devices, vaccines and medicines are used to prevent, diagnose and treat health conditions and therefore all should be included in Australia's NMP.

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?

It is important that the name of the policy reflects the breadth and scope of its content as we move forward now that health technologies continue to improve medical outcomes. The TGA could consider *National Medicines and Medical Technologies Policy*

Terms of Reference 3. 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?

Changes in the health landscape reflect a NMP that has not been able to maintain its relevance/response. The below example explains why:

Food allergy has increased in prevalence; the impact it has on quality of life is significant as we all need food to survive and to date, the only way to prevent a reaction was complete avoidance of the allergen. Although death is rare, life-threatening anaphylaxis is not and the impact on the individual and their family is huge. Food allergen oral immunotherapy (OIT) is now considered a treatment in the US and other countries. The US Food and Drug Administration have registered a drug, Palforzia, for use to decrease the sensitivity of people with peanut allergy, increasing their threshold so that minute amounts of peanut will not trigger anaphylaxis. Palforzia is simply measured amounts of powdered peanut flour in a capsule, that is opened and mixed with food. Individuals with peanut allergy still have to avoid peanut but are given the freedom to eat foods with a precautionary allergen labelling statement such as *May contain peanut.* They continue to carry an adrenaline injector with them because of the risk of anaphylaxis so the ''dose'' of peanut is a treatment (just like a daily medication), not a cure.

While this drug has been registered, many in the US, including Australian's who relocate in the US for 6 months to undergo the treatment, are using foods such as milk, egg and peanut, taken daily as a medicine to increase their threshold and therefore decrease their sensitivity to that particular food. People experience more allergic reactions on OIT (using Palforzia or simply food) compared to avoiding the allergen completely but many say anecdotally that quality of life is improved. While OIT using food remains in research phase in Australia there is consumer demand for it to become a treatment. We currently have several OIT trials underway in Australia with more planned for the future. What is being used in OIT trials thus far is simply food, not medication such as Palforzia in the US, however, the food is being used as a medicine to build tolerance and not cure food allergy.

A&AA is concerned that food (not registered medications such as Palforzia in the US) used to make people less sensitive to a food could cause harm as it is not classified as a medication/medical treatment although it is used as such. Some doctors in Australia are progressing OIT outside of research trials and our concern is that people desperate to improve their lives, do not understand the risks associated with OIT.

With medicines being used in different ways A&AA believes that it is important that the NMP has the scope to guide these changes with added safety. Trials of monoclonal antibody drugs such as Omiluzimab which are sometimes used in conjunction with oral immunotherapy to improve outcomes and decrease food allergic reactions during treatment are an example of innovative use of medicines to improve quality of life and decrease episodes of anaphylaxis.

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?

The NMP needs to be refreshed to meet the needs of consumers at a level that consumers understand. As a multicultural society with people at every step of the social ladder, a framework that includes, and is inviting to consumers will assist in achieving optimal outcomes. Information written in plain English, translated as required, shared as a short video and delivered in a way that meets the needs of specific populations will assist with optimal health outcomes.

Marginal groups as well as those more informed should be able to contribute to improved healthcare. If we have learned anything from Covid-19, it has been how to approach Australians to give them the tools they need to increase understanding, make informed decisions and improve health and wellbeing.

We cannot speak to transparency, equity, health literacy, partnerships, respect and a consumer centred approach if the language used in the NMP currently is not understood by everyday Australians. If it is for Australians, it needs to be understood by Australians and not only those at professional levels.

Terms of Reference 4: Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' 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 NMP focus on centricity of the consumer can be strengthened by improved data collection on health conditions and medicine/medical technology use. The existing data collection on vaccine administration/adverse events is an example of how information can be used to optimise healthcare in Australia. The ability to capture real world data that can be shared with key stakeholders to improve understanding and healthcare, and decrease burden on consumers, health professionals and possibly the economy because we can have a more targeted approach to care needs to be considered. Data collection, such as a registry of people at risk of anaphylaxis and anaphylaxis events (no matter the cause), can assist government, health professionals, policy makers, researchers, industry and others in understanding current needs/burdens and assists with future developments/innovations for specific allergic disease states. This trusted data would improve engagement and assist in keeping the consumer central to progression of healthcare at every level.

Collection of data improves our ability to engage with consumers from diverse backgrounds across Australia and not simply those with the loudest voice who are motivated and confident.

Terms of Reference 5: 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?

Improved data collection can assist with NMP governance as we have real time information and further clarity on current and possible future needs of consumers, government, industry, support organisations and more. Availability and interpretation of trusted data can assist with communication, implementation and evaluation of the NMP.

We acknowledge the TGA has consumer representatives on working groups that help make decisions on many issues including registration and PBS listing of medications. However, it is critical that the TGA seek expert consumer involvement when decisions are being made on specific medications/policies. A consumer that has little or no understanding of allergic disease cannot advocate for consumers with allergic disease as effectively

as a consumer representative that lives with the disease or is from a credible, evidence-based organisation with a focus on allergic disease.

We speak to equity however, we remain concerned that several (sometimes many) health professionals and others with specific expertise are involved in decision making processes, often with a single consumer representative who may not have depth of knowledge in the health condition being discussed. It would be fairer for the infrastructure to allow a consumer with expertise in a specific health area, to be co-opted into PBAC and other committees to help communicate consumer needs, where possible.

The NMP's success should be measured and an annual report be made available for all Australians. Key performance indicators need to be established to reflect the objectives of the NMP. Evaluation measures of the objectives need to be included in the NMP so we can capture success of the NMP:

- timely access to the medicines that Australians need, at a cost that 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

Serious consideration needs to be given to computer software used by the government and others in the health space. Software that is compatible is needed to improve consumer safety. As we move further into the digital space with limited resources, it is critical that current, trusted health information in communicated with Australians and their range of treating health care professionals in a timely manner. The disconnect in computer software often leaves consumers chasing busy health professionals for crucial information needed for their ongoing care. The disconnect in medical software is a safety issue as health professionals cannot easily transfer information to others, including to patients through My Health Record, who need it for optimal care. We believe that some software used in medical clinics allows for brands of medicines to be prescribed interchangeably. This is an issue for the adrenaline injectors EpiPen® and Anapen®. These devices both deliver adrenaline, but their mechanism of action is different and specific, and patients need training to know how to use the device in an emergency. The device should be kept with an ASCIA Action Plan which is also specific to the device prescribed so software that might allow for substitution of the device could be dangerous as the patient may not know how to correctly use their adrenaline injector in an anaphylaxis emergency.

The NMP also needs to have a review date set and included in the NMP so that timely review can be executed.

B. How can communication about the NMP be enhanced or improved?

It would assist peak body's that represent consumers, such as A&AA, if the TGA shared simple, easy to understand information on proposals/reviews/consultations etc so that we, as the conduit to people with specific health needs, can then reach out to our members/subscribers/social media followers allowing them to voice their needs and concerns. Often, organisations such as A&AA with the equivalent of 4.6 fulltime staff nationally, do not have the time/resources to interpret and then seek input from members on specific aspects of healthcare as required. This has been done with a PBAC pilot project for medicine sponsors (through the TGA Consumer Evidence and Engagement Unit) to include information on medication registration and PBS listing proposals for particular medicines to be written in plain English. This allows consumer organisations/consumers to provide informed quality feedback/submissions that effectively communicate their thoughts and needs or those of the people they represent.

Consideration could also be given to provision of tools such as social media posts, a short survey that each consumer organisation could share with their membership to improve TGA engagement with consumers and assist peak organisations with gathering important data to help inform their submission. Consumers often feel

intimidated and/or lack confidence in communicating their needs because the language used in reviews/proposals is not in plain English. Giving people the option to respond to a quick survey in plain English that captures the most important/critical points could help people and organisations provide feedback.

C. What would be effective mechanisms to support communication about the policy?

Direct communication with individuals and organisations that have a vested interest in healthcare is important as is provision of materials for their varying communication channels (e.g. newsletters/social media) to help communicate outcomes of the NMP review in a consistent manner.

Terms of Reference 6: 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?

Until reading the NMP discussion paper, A&AA did not realise the organisation is considered to have responsibilities for advancing the NMP objectives. That said, as we advocate for consumers, our vision and mission capture the NMP objectives. The NMP needs to clearly define what is meant by the term partner and then engage with organisations/individuals that are considered partners so there is clarity on roles, responsibilities, scope, expectations and ability to fulfil the title of a partner.

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?

A&AA believes researchers should be included in the NMP reference to partners as they contribute greatly to bringing medicines and medical technologies to market and are innovators and health economists.

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

We need to have improved monitoring, greater accountability and be able to capture information to help increase understanding of the current landscape. This data gathered in post market monitoring of medicines and medical technologies will in turn help to inform needs and help to further define partner accountability.

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?

Conflicts of interest need to be clearly communicated at every step from working groups through to submissions lodged. It is critical that we have transparency so that consumers can trust in the NMP and all it speaks to/for.

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