



# Lung Foundation Australia

## Nation Medicines Policy Consultation

### Lung Foundation Australia feedback October 2021

Lung Foundation Australia (LFA) is the only national charity and leading peak-body dedicated to supporting anyone with a lung disease including lung cancer. For over 31 years we have been the trusted national point-of-call for patients, their families, carers, health professionals and the general community on lung health. There are over 30 different types of lung disease currently impacting 1 in 3 Australians.

Our mission is to improve lung health and reduce the impact of lung disease for all Australians. We will continue working to ensure lung health is a priority for all, from promoting lung health and early diagnosis, advocating for policy change and research investment, raising awareness about the symptoms and prevalence of lung disease and championing equitable access to treatment and care. As a patient representative charity, we have partnered with patients, health professionals, researchers, medical organisations and the Australian community to drive reform in the delivery of health services in Australia to benefit more than 7 million Australians impacted by lung disease and lung cancer. We have consulted with our community of patients, families, and clinicians as we strongly believe that their voice is important in this consultation, and we look forward to supporting a reinvigorated National Medicines Policy.

LFA supported the development of the National Strategic Action Plan for Lung Conditions (NSAPLC), and this is a key national action plan and is reflective of the current gaps and opportunities in ensuring the best outcomes for Australians with lung disease. This key strategic document outlines a range of actions, many of which fall within the current and future NMP.

The review of the National Medicines Policy (NMP) represents an important opportunity to drive reform of the 20-year-old policy, and ensure it enables all Australians to receive the therapeutics they need at the right time.

The NMP has served as the guiding framework underpinning all policy decisions related to access and reimbursement of medicines, safety and quality of medicines, medicine management, and industry policy. The goal of the NMP is to “optimise health outcomes for all Australians through a collaborative partnership with key stakeholders, focusing especially on people’s access to, and wise use of, medicines.” Whilst this goal remains relevant, the Department of Health discussion paper recognises that twenty years after the development of the NMP the health landscape has changed; patient voices are better informed, Australians are living longer, often with multiple chronic conditions and healthcare delivery is being transformed by digital advances.

Ongoing use of an outdated NMP in a rapidly changing health technology environment has resulted in fragmented policies and confounding regulatory processes. This context, coupled with inconsistent implementation of the outlined principles across medicine policy and decision making plus cost saving measures, contributes to significant inequities in consumers' health outcomes. As such, a review of the NMP must modernise the system and ensure it is fit for purpose, now and into the future.

## **Lung Foundation Australia have provided feedback to align with the Terms of Reference.**

LFA are a peak consumer body, and ensure that patients, their families, and the community are consulted with and have their voices heard on issues that affect them. As such, we surveyed 220 Australians living with, or caring for a loved one with, lung disease or lung cancer on their experience with medicines, and their views on the consultation's terms of reference. In addition, we sought feedback from our clinical advisory committees which include allied health professionals, respiratory physicians, general practice, researchers, and other health professionals. We have included their feedback in our response, and our commitment to ensuring that the community voice is heard aligns directly with NMP proposed Principles, particularly ensuring a consumer centred approach.

We strongly support the NMP, it is a pivotal document that guides the way Australia addresses medicines purchasing. We are pleased that this document is being reviewed and look forward to the NMP being amended to ensure it is fit for purpose and will ultimately improve options and outcomes for Australians.

- 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.**

Australians must be able to access the therapeutics they need no matter how much they earn or where they live. Recognising that the NMP is an overarching framework, LFA want the programs which are underpinned by the NMP to address the inherent and systematic issues leading to inequity and lack of access.

### **Objectives**

Lung Foundation Australia strongly support the four central objectives of the NMP, which are; 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.

While we support the objectives, we query their achievement, reporting and monitoring, and highlight that this needs to be a key consideration going forward.

We seek to comment on the first three objectives:

- i) **Timely access to the medicines that Australians need, at a cost that individuals and the community can afford**

This objective relies on rigorous and adaptable HTA processes including the Pharmaceutical Benefits Scheme and Life Saving Drugs Program. It is noted that there is strong linkage here, specifically in relation to timely access, with the House of Representatives Standing Committee inquiry into HTA processes. However, we question how well this objective is achieved in different contexts such as rural and remote locations.

Disappointingly, **10%** of survey respondents reported that they did not have timely access to the medicines that they needed, and **19%** reported that they did not have access to the medicines they needed at an affordable cost.

*"Took almost 5 months to receive prescription"*

*"Although affordable on an individual item, the total accumulates to a big monthly expense when I have several prescriptions to fill each month. How about a descending scale of PBS rates for multiple prescriptions?"*

*"When you are on multiple medicines it can be very expensive."*

*"It takes too long for new medication to appear on the PBS. There is also not enough international cooperation to produce medication in other countries, patents last too long."*

**ii) Medicines meeting appropriate standards of quality, safety and efficacy**

The TGA thorough procedures ensure the required standards of safety, quality and efficacy. Process improvements, such as those that were highlighted in the HTA review, should be evaluated to determine whether the recommendations achieved the anticipated improvements to the timely review of medicines by the TGA, to understand (if not) why not, and to implement corrective actions.

**iii) Quality use of medicines**

Medicines are one of the most common treatments used in health care, and there are growing numbers of people with multiple chronic conditions, that are prescribed multiple medications. This is especially true for patients with lung disease.

There are several partners, including patient support groups, that contribute to the mechanisms, such as monitoring usage, that ensure optimal quality use of medicines. The role of these partners should be recognised for the integral role that they play and articulated in the NMP.

*"Many have side effects that require the purchase of over the counter medicines. This adds a lot to the cost & is not recognised by Medicare or available on concession."*

*"I pay over \$1000 per month for a medication which works well for me but it is not on the PBS for bronchiectasis, only cystic fibrosis. This is unfair for sufferers of bronchiectasis."*

**Proposed Principles**

We encourage the development of a set of Principles, and are supportive of the proposed Principles. In addition, we believe a key principle should be focussed on ensuring that the NMP is *fit for purpose* meaning that it is agile and is reviewed every 5 years to ensure it keeps up to date and acknowledges that we are in the age of precision medicine.

Promisingly, **80%** of respondents agreed with the proposed principles which included LFA's additional suggestions.

*'Olive's diagnosis brought more questions than answers, we have a name but little in the way of long term outcomes. There is not a lot of information about Surfactant Protein C (SP-C) Deficiency, which is associated with Interstitial Lung Disease, and due to the rareness of the condition; there are no clear guidelines, no protocols, and limited treatments. It would be great if we could get some more research.'*

*– Rachel, Mother of Olive who lives with a rare lung condition.*

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

Lung Foundation Australia believe that the current definition of medicines in the NMP does not capture the extent of the therapeutics used to improve patient outcomes. We highly encourage expansion of the definition to ensure that new treatments, diagnostics and medical devices don't fall through the gaps.

The medicines landscape has significantly changed over the last decades, and there are a range of medicines which are essential to the treatment of Australians with lung disease or lung cancer that would currently not fit within the definition. For example:

- 3D printing
- immunotherapies, biomarkers, comprehensive genomic profiling, and liquid biopsies for lung cancer patients

*"I had to pay for my own bio marker testing for my lung cancer as it is not covered by the MBS or my public hospital"*

*"My treatment so far has involved chemotherapy, a lobectomy, immunotherapy, 30 radiation sessions and I'm now on a daily targeted therapy tablet" – Georgia who had to travel to the United States of America to receive cutting-edge testing and treatment.*

- pulmonary rehabilitation, which is essential for the treatment and management of chronic disease and is the most effective evidence-based intervention to manage breathlessness in chronic lung conditions. Expanding service delivery of pulmonary rehabilitation is action 5.1 in the NSAPLC, yet less than 10% of people with COPD have access to pulmonary rehabilitation.

*"I don't know what I would be like if I hadn't done pulmonary rehabilitation. Pulmonary rehabilitation gives you the tools that you need to be as fit as you can be. Fit to fight – maintaining fitness if critical and the effects of exercise make you feel so much better overall." Ian, lives with COPD.*

- drug repurposing

*"I need off label medication for my ILD this has caused delays in accessibility"*

- and digital future proofing including telehealth, remote monitoring and the use of Applications.

We support the broadening of the definition of medicines in the NMP, specifically we encourage adoption of language used by the World Health Organisation's definition of health technology as the '*application of organised knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life*'.

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

We want a NMP that provides a framework that is fit for purpose and enables processes that are flexible to adapt to advances in constantly evolving technology to ensure timely access for all, and has appropriate consideration of the social determinants of health.

Changes in technology and the health landscape are overtaking our system's capacity to evaluate, fund and provide access to innovative treatments and interventions.

We acknowledge the important step taken in implementing the House of Representative Standing Committee review of Australia's HTA process, and we look forward to the recommendations of this review - anticipating they will lead to improvements in the process enabling better access to treatments, improve equity of care for all Australians, and a mechanism to regain the trust of all involved.

We believe that the NMP review must work alongside the HTA review and other initiatives, in seeking improvements to ensure the system is flexible and agile.

#### Digital health

Convenience and safety in treatment can be enhanced through effective use of digital technology. This can include the My Health Record and e-Prescribing and integration of these policy areas with the NMP will be an important recognition of this.

COVID-19 has drastically changed the way we access medicines and treatments, and it is vital to ensure appropriate monitoring and reporting of telehealth and other current technologies, with a NMP that is agile and incorporates emerging health technology.

Positively, nearly **80%** of survey respondents who used digital technologies reported a positive experience.

*"You can now have a telehealth appointment with your doctor, who can give you a prescription via a QR code that is sent directly to your phone, that can be added to the Chemist app. So you can put in an order for your prescription immediately, then go pick it up or have it delivered without having to go into your doctors office to pick up a paper prescription, then go to the chemist and wait for it to be dispensed. This is great to minimise time in the community during covid out breaks, and the chemist notifies you if they do not have your medication in stock and need to order it in for you so you don't come in and have to come back the next day."*

We do note feedback of wait times and prescription issues as some ongoing challenges.

*"Currently, digital prescriptions are not supported by my chemist. Paper prescriptions had to be posted during the pandemic lockdown which added risks of delays by the postal system as services were reduced under lockdown"*

**Health Literacy** including Aboriginal and Torres Strait Islander cultural competencies  
Quality use of medicines is not only about safe and effective delivery but also about supporting and empowering consumers to build their understanding and knowledge of medicines use, leading to improved engagement with treatment and enhanced outcomes. Health literacy is a fundamental enabler for patient-centred care, and we know that higher levels of health literacy are associated with increased patient involvement in shared decision making. Advances in treatments and therapies, whilst welcome, create further challenges for consumer health literacy.

Only **69%** of survey respondents felt all their treatment options and medications were explained to them, and only **60%** felt they had sufficient understanding of their treatment and medicines.

Health literacy must be explicitly included in the NMP framework and support must be provided to consumers to find, evaluate and use health information effectively and the system must support health professionals in delivering health-literacy responsive services.

## **Equity and sustainability**

Many novel medicines have been associated with high upfront costs including investment in the establishment of system infrastructure and workforce to support treatment delivery, which comes in addition to the cost of the treatment itself. This may lead to limited options available, particularly for people living in rural and remote locations.

Ensuring equitable access to medicines is vital to reducing the health inequities. This extends to other marginalised groups including those with a disability, Aboriginal and Torres Strait Islanders, and those with a rare lung disease, to name a few. Consideration of the social determinants of health can assist in placing the NMP in a progressive lens that ensures no Australian is left behind.

*"Medicine for Alpha-1 has not be subsidised so patients have been left to die"*

*"Fair & equitable is not met"*

*"There is no medication available for me re my lung disease."*

*"The augmentation therapy I need for ALPHA1 is not on PBS so not affordable for me so I am dying faster than I should be"*

## **Precision Medicine & Clinical trials and Medicines Access Programs**

We support the comments and submission made by the Australia Patient Advocacy Association (APAA) and reiterate their feedback on precision medicine and clinical trials and medicines access programs:

*The fields of genomics, biotechnology and medical science have seen advancements that enable new ways of identifying, preventing and treating disease. Precision medicine considers the variability of an individual's genes, environment and lifestyle enabling a tailored and targeted approach to preventing, managing and treating disease.*

*Currently MSAC considers genetic and genomic tests for public funding through the MBS. The National Medicines Policy must recognise that therapeutics has a wide definition that includes, but is not limited to, medicines.*

*Access to clinical trials and medicines access programs are not discussed in the current NMP despite the obvious implications for patient treatment options. It is our recommendation that these are explicitly included in the refreshed NMP.*

#### 4. Consider the centricity of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.

Patients must be at the centre of the NMP with a policy that empowers informed patient participation, ultimately closing the gap between patients and decisions.

Consumer involvement in Australia's therapeutics policy is not a desired principle; it is, and should be, a core fundamental of the NMP and applied to each and every program, policy and service. We echo feedback by APAA, we too no longer want to see decisions that are being made with consumers at a distance or not wholly consulted and informed. Critical to this is ensuring that the community and patients are appropriately informed about the NMP, it is transparent, and outcomes focused, and decisions are made with community by co-design and involvement in policy. People living with lung disease and lung cancer are unfairly subjected to an association with current or prior tobacco use. It is well acknowledged in literature that bias and nihilism are strongly associated with lung disease and the NMP must ensure that all decisions or policy frameworks applied are done so without any conscious or unconscious bias or judgement in the access to or approval of medications or treatments for patients.

The 2020-25 Nationally Cohesive Health Technology Assessment provides a commitment by all governments to work together on long-term system wide reforms to provide patient-centred care in the most appropriate setting. The standard will be set through this review process with a comprehensive consultation process required to ensure patient views are heard, reflected on, and placed at the core of the NMP. LFA continue to ensure that our community are informed and can provide input and share their experiences in all facets of our work. This can be evidenced by our commitment to surveying patients, their families, and our clinical advisory committees, and relaying on their perspectives in our response to the NMP consultation.

We do recognise that considerable work has been done to date to increase the inclusion of the consumer voice. However, more can and should be done to strengthen this, evidenced by the contributions heard at the recent House of Representatives Standing Committee inquiry into HTA processes, specifically looking at the need for inclusion of consumer in the early stages of policy discussion and in providing greater transparency in the decision-making processes.

*"As a single older person, far from family, a recent exacerbation saw me relying on neighbours and an ambulance, after a disastrous telehealth consult with a doctor unknown to me."*

*"When I have been very sick it has been difficult process to get a script from a doctor and have it sent to a chemist and then have it delivered because I live alone"*

*"Bronchiectasis is definitely manageable. I chose to be an equal partner in staying informed and understanding the nature of my illness. I continue to find ways to support myself and the care that is needed to stay healthy."*

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

LFA believe that this is an important opportunity to ensure that the NMP is communicated, implemented, and evaluated appropriately.

We encourage the NMP to be reviewed every 5 years, as this will ensure that it is fit for purpose and provides a suitable timeframe for identifying further opportunities for improving communication and implementation and presents an opportunity to be evaluated and reviewed. This aligns with the NSAPLC action 6.1, *invest in ongoing surveillance to monitor the quality of healthcare and to understand and monitor the epidemiology and burden of lung conditions*, which includes a recommended time period of 5 years.

Additionally, evaluation and performance measures must be established in the NMP to ensure it is working where it matters. It is vital that we ensure all relevant policies are effectively delivering on the principles outlined in the NMP. To ensure this, the NMP must include performance measures that are evaluated on a regular basis.

Through our consultation process we found a large proportion of the community were unaware of the NMP and its purpose, which alone highlights that communication needs to be improved. Effective and clear communication will contribute to increased transparency in the process and improved engagement by consumers.

A multi-stakeholder committee to monitor the implementation of the NMP may be an effective way to deliver this in practice and ensure the patient voice is at the centre of decisions. In addition, we encourage consideration be given to an advisory board overseeing the NMP and the achievement of objectives, meaning this should be completed independently from government.

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

End-to-end transparency must be a core principle of the NMP to ensure trust in the system that supports access to the medicines Australians need. A lack of transparency in the way the NMP policy comes to life is a considerable barrier to the trust that patients and other stakeholders have in the NMP. This can be addressed by the development of public facing annual reports of the impact, achievement of objectives and include consumer engagement as a measure.

This will go a long way for the community to better understand how decisions are made and why, and at what cost. Transparency must be the rule, not the exception.

The importance of partnership is a key theme in the overarching NMP framework. We note that the lessons learned from the pandemic have resulted in negotiated strategies to facilitate a guaranteed supply chain which is greatly welcomed and reflects the importance of partnership. Implementation of the policy framework is reliant on partners and we note that this can present challenges in delivering an integrated approach. There is recognition that the need to address replication and gaps in the current NMP will contribute to greater transparency and accountability for all partners.

We would like to acknowledge that there has already been work progressing in this space, with the House of Representatives Standing Committee inquiry into HTA process. We are pleased that the NMP Expert Advisory Committee will consider the findings of this work in the context of the NMP review, and LFA has been vocal on these issues.

## **Summary**

LFA are pleased that the NMP is being reviewed, and welcomes the opportunity share the feedback received from the consultation with our community of patients, carers and clinicians. We are committed to ensuring that the 7 million Australians living with lung disease are given the best possible opportunity to thrive with the use of medicines and technologies in Australia, so they are able to lead healthy and productive lives.

Australia should have the fastest, most efficient, and safest medicines system in the world. We reiterate the above feedback, and hopes the revised NMP:

- ensures that consumers are at the centre of decisions
- broadens the definition of medicines
- enables all Australians to have equitable access to the therapeutics they need no matter their location, condition or background
- increases transparency, agility, communication and evaluation

Lung Foundation Australia hopes the Australian Government adopts this feedback, as it will ultimately benefit all Australians, and ensure that the community are able to live healthy lives. We strongly support the NMP, it is a pivotal document that guides the way Australia addresses medicines purchasing. We are pleased that this document is being reviewed and look forward to the NMP being amended to ensure it is fit for purpose and will ultimately improve options and outcomes for Australians.

*“Current medication impedes my quality of life. Whilst effective for my condition alternative medicine approved overseas remain unatable here”*

*“Need to plan in advance when ordering hospital pharmacy-based medicines by post, especially since my hospital now requires up-front payment.”*

*“While very grateful for compassionate access, approvals do take time. Please keep working on getting more medicines and tests (eg: NGS) listed on PBS/Medicare.”*

*“Due to insufficient consumer competition, my local chemists own both stores and often I have to wait for my regular script due to over selling to tourists.”*

*“Feel that long term / chronic need for medication should not have a need for a consultation process.. Needs to have in place a safety step to allow the patient to access a repeat script without clogging the already over worked medical system”*

*“.. if you get pseudomonas which is a common bacteria in immunocompromised.. there is no help nor alternative for expensive medicine aka Tobramycin to treat.. you either end up with repeating hospital visits while helplessly watching your health decline. Only those financially well off will survive.”*

*“I am fortunate to be on a Pension & also have some assistance through my Health Fund in regards to cost of medicines, this of course does not relate to natural therapies which I am finding very helpful”*