Media Release
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BETTER ACCESS AUSTRALIA

ON WORLD RARE DISEASE DAY
PROOF THAT #100DAYS FROM DRUG REGISTRATION TO PBS SUBSIDY IS POSSIBLE

On Friday 25 February the PBAC released advice that it had found the drug molnupiravir used to treat COVID infection to be clinically effective and cost effective for listing on the PBS in the community setting. In doing so they ensure pharmacists will be fairly remunerated for dispensing, and patients can purchase the product with the full protections of PBS co-payments and safety nets.

After being told by the National Medicines Policy Review team that faster times to listing were simply not possible in Australia's immovable Health Technology Assessment system, the Minister, the Pharmaceutical Benefits Advisory Committee (PBAC) and the Department of Health have defied their own Review panel and shown that when the Minister asks, the impossible is possible.

For patients – this is the window of opportunity we have all been waiting for. But only if industry and community hold the system to account for its decisions.

"This record assessment process for recommending and subsidising a medicine should be welcomed by everyone in Australia waiting for access to a medicine on the PBS" BAA Chair Felicity McNeill said

"Today the PBAC and Department have shown that their HTA process can take a medicine provisionally listed on the Australian Registry of Therapeutic Goods (ARTG) on a limited dossier and assess it for cost-effectiveness under the National Health Act and find it suitable to list and deliver into a patient's hands with a PBS co-payment in less than 40 days. It truly is a miracle.

"It's the miracle in the application of HTA in Australia we have all been waiting for, and the model of HTA application we should set as the benchmark for reform as part of the forthcoming HTA review.

"When listings on the PBS are taking on average 820 days post ARTG registration, this is the innovation we have all been waiting for.

"Having pre-negotiated pricing with the manufacturers for putting the drug in Australia's national medical stockpile, the final component of access within the community has been a quick and simple process.

"It's proof systems like those in Germany and France can be readily translated into the Australian environment and ensure quick access for patients and ongoing pricing and HTA review – after that access is provided. It's all about that usually insurmountable first step when going through the PBAC - setting the price. With molnupiravir the government did that before the PBAC even looked at the medicine... it's a lesson for us all."

Better Access Australia first commenced advocating for a #100days from ARTG to subsidy process as part of its submission to the Zimmerman Inquiry, and again called for this reform as part of our 2022-23 pre-budget submission.

"28 February is World Rare Disease Day. We can only hope that the waiting times for breakthrough treatments for diseases such as cystic fibrosis, spinal muscular atrophy, Pompe, X-linked

hypophosphataemia (XLH) and Leber congenital amaurosis might now be given this same expeditated process to make *#100days* a reality," Ms McNeill said.

"Of course, if this is not genuine reform, then we need to ask, why now, why this medicine, why this disease?

"Why do patients who need lifesaving drug treatments wait years to navigate the HTA process? Why did migraine and eczema patients wait over two years for treatment access? Why are patients diagnosed with rare cancers still waiting years for subsidised access?

"And how does this action on molnupiravir compare to the Minister's decision to deny financial equity to patients accessing PBS medicines via the Opioid Dependence Treatment Program (ODTP)?

"Why must a pharmacist still dispense an ODTP medicine without remuneration? Why must patients still meet those costs out of their own pocket? Why are these patients still not protected by the PBS safety net and co-payment? Why does it take three years to consider this issue for the ODTP but less than 40 days for a covid treatment?

"Maybe if we called it the COVID-based ODTP, the Minister, Department and the PBAC might behave differently.

"Maybe if it was a migraine treatment for use in anyone that had a positive COVID test over the past two years, the patients in desperate need of access to treatments would be treated differently.

"We can all smell the politics. Question is – will the industry, community groups and patients use this to demand equality or simply go back to the mouse wheel they are all allowed to ride and wait to be told what to do?

"This is not just about medicines access; it is about devices and pathology too.

"Imagine if all the newborn screening tests registered in Australia were made available to babies within #100days of being listed on the ARTG. How many more babies would be protected from the devastation of untreated rare and life-threatening diseases? How many lives could we save and change. Because without diagnosis there is no treatment

It is time to demand genuine reform from first principles, because Friday's advice shows us it's all entirely possible. No more nibbling at the edges as is the usual approach in this sector – because all that's delivered is poorer outcomes for patients. *#EnoughisEnough*.

"Better Access Australia will shortly be inviting individuals and organisations to work with us in designing the new #100days to subsidy roadmap. If we want better access, then we must show the system how it can be done.

"It's time to not just *#MindTheGap* but show how to end it."

Any individual or organisation interested in this project should contact Tim Davies.

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