Medicines Australia | Better health through research and innovation

1 April 2021

Professor John Skerritt
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Therapeutic Goods Administration (TGA),

**Submission from Medicines Australia: TGA Consultation on Repurposing of Prescription Medicines**

Thank you for the opportunity to respond to this consultation. This submission was brought together by Medicines Australia's Regulatory Affairs Working Group (RAWG) in consultation with our broader membership, particularly the Health Economic Work Group (HEWG). Members of the RAWG and HEWG are selected for their regulatory, health economics and industry experience, and bring a whole-of-industry perspective to the consideration of issues that stand to impact our sector.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Pharmaceutical companies represented by Medicines Australia have a broad and deep pipeline of innovative medicines, diagnostics, treatments and vaccines. Our members develop, manufacture, and supply critical medicines and vaccines available on the pharmaceutical benefits scheme (PBS), the Life Saving Drugs Program (LSDP), the national immunisation program (NIP) and companion diagnostics or other treatments available through the Medical Benefits Scheme (MBS) and National Blood Authority (NBA). Our membership comprises small, medium, and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.

Medicines Australia is supportive of investigating mechanisms, and to conduct benefit/risk assessments for new indications for prescription medicines, to facilitate appropriate access to medicines for patients in the context of 'repurposing'. In many cases, well established 'off-label' uses involve older medicines which are off-patent. Consequently, the innovator may no longer supply or hold the major market share. These medicines have well-established safety profiles and an important role to play in healthcare delivery. We are strong proponents of Quality Use of Medicines and TGA initiatives to conduct rigorous assessments of all medicines routinely used within Australian clinical practice.

During 2020, Medicines Australia also provided detailed information on the goals, barriers and incentives for repurposing of medicines to an MTPConnect led project. Medicines Australia has not seen the outcome of the consultation and remains optimistic that the Medical Technology and Pharmaceutical growth centre will understand, and moreover make reasonable recommendations to address, the well-articulated barriers and required incentives for greater industry input to repurposing.

Regarding this consultation, Medicines Australia was disappointed in the TGA's apparent limited understanding of issues related to repurposing. Medicines Australia opposes, in particular, proposals

that seek to intervene in the free market, unilaterally interfere in commercial operations, extend company liabilities and impose offences for failing to comply with such government interventions. Additionally, proposals within this discussion paper give inadequate consideration to the market failure that underpins lack of access and the mechanisms that may be required to recognise and resolve these market failures.

Whilst this consultation identifies some relevant operational barriers to repurposing within the current system, it does not reflect or appreciate the more fundamental issues that result in limited industry participation. This includes the pricing and reimbursement arrangements, the resources and costs involved in registration and reimbursement application process, as well as the real-world evidence systems and other clinical data shortcomings.

It subsequently follows that the proposed solutions have been devised without full consideration of the consequences, are therefore not fit for purpose and will not realise significantly more repurposing activity. Some proposed options, particularly relating to compelling companies to act against their commercial interests and against free market principles, would unnecessarily increase risks to ongoing medicines supply and are unreasonable. Others, in the case of proposing exclusive market access or extending data exclusivity, do not fully explain their possible implementation or intellectual property implications respectively. Medicines Australia recommends that proper consultation is required with all relevant stakeholders, such as through a series of roundtables or workshops, to fully identify the barriers to repurposing, and to co-design policy, regulatory and reimbursement solutions to overcome these.

Medicines Australia strongly urges the TGA to re-initiate consultations on this important issue with all stakeholders with an appreciation of the whole environment. From the needs of patients, role of clinicians and researchers, principles of a free-market economy, intellectual property implications and the reforms required to the regulatory and reimbursement processes.

**Summary of Medicines Australia's Response**

There are numerous additional barriers to repurposing medicines in Australia to those outlined in the consultation:

- commercial considerations such as supply capacity, financial exposure, etc.
- resources and costs involved in the registration and reimbursement process
- real-world evidence systems and clinical data shortcomings

The three options outlined are not fit for purpose in motivating companies to repurpose prescription medicines in Australia:

- Option 1 - Reduce Regulatory Burden: these may engage sponsors interest, however have the potential to contribute to comparator erosion and devalue innovative products
- Option 2 - Enhance Information Access: local real-world data has many limitations stemming from the absence of electronic connectivity across the Australian health system
- Option 3 – Actively pursue registration of additional indications: this is highly problematic where there is no sponsor ownership of the molecule, no secured medicine supply and no ownership of the relevant efficacy and safety data.

Medicines Australia recommends a series of round-tables or workshops to:

- explore the full scope of repurposing that would be of benefit to Australian patients e.g. including closely related indications for oncology medicines
- fully identify the barriers to repurposing
- co-design policy, regulatory and reimbursement solutions to overcome these.

A buoyant medicine discovery and supply industry relies upon policy signals recognising the value of state-of-the-art clinical research, the value of new medicines and its workforce in Australia. This consultation is sending messages to the contrary. Please find in the attachment below further consideration of the issues raised in the consultation, including additional market and regulatory barriers to repurposing and an initial analysis of the TGA's proposed 'solutions'.

To discuss these issues further, please contact Anne-Maree Englund (Head of Strategic Policy Implementation, anne-maree.englund@medicinesaustralia.com.au) or Peter Komocki (Manger, Industry and Regulatory Policy, peter.komocki@medicinesaustralia.com.au).

Yours sincerely,

CEO
Medicines Australia

**Attachment:**

**Submission from Medicines Australia: TGA Consultation on Repurposing of Prescription Medicines**

This consultation seeks to identify the potential barriers and incentives to repurposing medicines that may influence a sponsor's decision to extend an indication for an existing medicine, specifically those indications that are:

- already approved overseas
- for a less common disease
- already accepted clinical practice albeit 'off-label'
- likely to be less commercially profitable

Both genericised and innovator medicines under patent or exclusivity are included in the consultation. Medicines not registered on the ARTG for any indication, or extensions of closely related indications (*e.g. use of an oncology medicine for a related tumour type or the same tumour type in a different organ*) are not included in the consultation. Industry considerations relevant to both patented and generic medicines are provided within this response.

**Proposed incentives**

The consultation paper proposes three options to encourage a greater number of regulatory and reimbursement applications for repurposed medicines. It is noted that some of the proposed incentives would require legislative amendments. The three options are summarised below.

**Option 1**

- Provide enhanced and structured regulatory support for applicants seeking to repurpose medicines
- Provide fees and charges relief (TGA and PBAC) and expansion of orphan designation periods for particular medicines
- Simplify/streamline simultaneous submission for regulatory and reimbursement evaluation
- Provide exclusivity periods for new indications of repurposed off-patent medicines

**Option 2**

- Facilitate open-access to "real-world" Australian medicines usage data
- Provide consolidated international regulatory and HTA/reimbursement information

**Option 3**

- Seek public expressions of interest for sponsorship of new indications of a medicine, potentially limited to non-commercial organisations
- Compel the sponsor of the medicine to make an application for the additional indication
- Approve the inclusion of an additional indication for the medicine without the need for an application from the sponsor

In Medicines Australia's view, the consultation asks two general questions:

1. **Are there additional barriers to and incentives for repurposing medicines in Australia to those outlined in the consultation?**
    a. **Answer: Yes**
2. **Are the three proposed options fit-for-purpose in motivating companies to repurpose prescription medicines in Australia?**
    a. **Answer: Categorically No**

**General remarks**

Recent history has highlighted the important role of effective regulatory mechanisms during a public health crisis, whether for vaccine evaluation or benefit/risk assessment of repurposed medicines. Mechanisms to expedite vaccine reviews have had demonstrable success and widespread community appreciation. However, the experience highlighted an existing structural gap in the regulator's ability to proactively evaluate the potential role for repurposed medicines in acute situations. Without a sponsor application to repurpose an established medicine, there is no basis upon which to initiate a formal assessment.

This is not a uniquely Australian issue as evidenced through multiple international initiatives (e.g. UK MHRA/NHS, USA/FDA Project Renewal, EU/STAMP programs[1,2,3]) that recognise the need for specific interventions to assess off-label use of generic medicines. Such intervention is required to avoid unsubstantiated off-label use and where appropriate, expand approved treatment options. This consultation differs from international market approaches in key areas, specifically the inclusion of both patent protected and generic medicines and explicit exclusion of closely related indications, such as those in oncology medicines. These differences, combined with the absence of defined priorities, limit feedback and discussion on alternate proposals.

The stated aim of this consultation is to further understand the obstacles to repurposing. However, the paper proposes solutions in the absence of an in-depth consideration of these barriers. It is Medicines Australia strong view that it is premature for this consultation to progress to solutions in advance of the full identification of the barriers. For example, enablers to facilitate the addition of paediatric indications differ significantly from those necessary to motivate repurposing applications for low cost, commodity (F2) medicines from multiple suppliers.

Of particular concern, especially when compared to international initiatives, is the exclusion of indications for closely related conditions (e.g. oncology medicine for a related tumour type or for the same tumour type in a different organ). These have been grouped as Out of Scope with no evident rationale. Cited barriers are equally applicable in this area, with comparable overseas regulators examining oncology specifically in Project Renewal[2]. As new medicines are developed through standard of care comparisons in global clinical studies, Australian participation in these studies relies upon consistency in clinical practice and approved product labels with major international markets. It is important, given the unmet need in this area, that the rationale for this explicit exclusion is shared and that planned alternate proposals for oncology are outlined.

It is also not possible to delink pricing and reimbursement from the issues relating to the repurposing of medicines. Fundamental to the supply of medicines is establishing their value, which requires an assessment of cost-effectiveness and price. Ultimately the sponsors must ensure that commercial supply is viable.

From a reimbursement perspective, any proposed changes to the process must consider the following;

- F1 medicines – there are no incentives for 'repurposing' without a period of exclusivity for the new indications. No company would likely cover the costs associated with submission, registration and supply. If exclusivity periods were applied, statutory price reductions would need to be amended to be indication specific (or exemptions made), otherwise any incentives would be lost.
- F2 medicines - there are no incentives for 'repurposing' in the situation where there is brand competition. If exclusivity periods were applied to an indication, the overall weighted price of the molecule would likely increase (due to no competition in the repurposed indication), which is counter to price disclosure polices.
- Special pricing arrangements – in many cases, companies may require the ability to have a Special Pricing Arrangement due to international reference pricing for F1 medicines.

The potential value derived from such initiatives needs to be balanced against the risks in creation of a multi-tiered system whereby older molecules are supported through the regulatory and reimbursement system without the demanding efficacy and safety data expected of new molecules. This may result in unintended consequences, not least of which is a signal to the research-based industry that state-of-the-art new medicine innovation with associated rigorous benefit/risk data is not a government priority. In this context, it is of upmost importance that there remains clear evidence of government recognition for the value of contemporary medicine discovery.

Interconnected components of a buoyant medicine discovery and supply industry rely on policies that:

- support world-leading clinical research
- recognise the industry's investment, employment and social contribution to the Australian economy
- dovetail to a well-established regulatory regime and a fair long-term focused health technology assessment system
- recognise the value and incremental nature of medicine discovery.

There is a lack of acknowledgement in this consultation of the connection between the regulatory and reimbursement environments and the challenges they pose to repurposing. As such, the options proposed do not seek to address these issues and are not fit for purpose.

**Identified barriers and context to repurposing**

Known challenges identified within the consultation are those broadly described as insecure or no investment on return, evidentiary standards and lack of expertise. Within each of the categories there may be many and varied reasons why additional indications are not included in a sponsor's local business plans.

The following remarks are shared to initiate a further discussion on the reasons a sponsor may not pursue an additional indication (or re-purpose a PI) for a given product. Considerations include:

- local market history
- data quality
- stage in life cycle
- fiduciary obligations
- financial exposure
- supply capacity
- competing priorities
- company strategic priorities.

R&D based pharmaceutical companies are reliant on a stream of investment funding to continually innovate and develop product portfolios secured by intellectual property protection. This also enables investment into areas with high unmet needs such as rare diseases and to support pressing global health initiatives (including as part of their general corporate social responsibility activities). The value of this model to overall public health has been highlighted during the COVID pandemic, with industry resources rapidly reprioritised and unprecedented collaboration leading to accelerated availability of new vaccines.

The innovator business model recognises and prepares for the post protection period where further investment in genericised products ceases. Without a reliable cycle of return there is an inevitable prioritisation of projects in markets with more secure revenue streams and stronger patent protections, including regulatory data exclusivity. Australia has a less attractive environment than in other international markets with comparable regulatory frameworks where investment may be continued for a longer period. This includes because of more competitive tax regimes, stronger intellectual property protections and health technology assessment regimes that better value innovations in medicines and treatments.

The information summarised below provides insights into the broader perspectives that impact an industry sponsor's position and drive investment prioritisation towards new *innovative* treatments. This highlights the need for an in-depth consideration of all barriers from the holistic perspective of patient access, rather than a pure regulatory context.

***Indications already approved overseas***

- previously unsuccessful PBS listing of earlier molecule indications result in investment write-offs and diminished exclusivity periods and so personnel are diverted to more secure projects
- local pricing negotiations (F1 medicines) compared to global company expectations reach an impasse
- low confidence in achieving a positive PBS outcome does not justify further investment in pursuing extending an indication (noting that the average combined TGA application & PBS listing fees to

secure a new indication costs approximately $1 million, based on an average 1 TGA application fee and 2 PBAC cycles)

- ongoing company investment is shifted to more preferential markets that provide a higher probability of product launch
- significant differences in Australian data exclusivity provisions compared to overseas jurisdictions influence the business case for extending (or not) indications later in a product's life-cycle
- insufficient business case with a single indication to secure supply of stock and adequate in-house resources to support a launched product
- in the case of generics, overseas approval may have been supported through specific health authority initiatives alleviating sponsor data and investment expectations.

***Indications for a less common disease***

- orphan fee waiver provisions may not be available due to additional *non orphan* indications. As indicated above, fees alone regularly exceed over $1 million with no guarantee of positive outcomes
- limited efficacy and safety data for rarer patient populations present challenges for the innovator sponsor, as they do for the health authority, in making a positive benefit/risk assessment. Even in the event of adequate data to meet Core Data Sheet inclusion criteria[4], it is accepted that meaningful patient access relies on success in both TGA approval and PBS listing. While the capacity of the TGA to manage benefit/risk assessments with limited datasets has been demonstrated, similar mechanisms are not yet apparent within the Department of Health's Pharmaceutical Evaluation Branch. This results in high-risk investment with low probability of a meaningful gain for patients
- Against a back-drop of high costs, high uncertainty and an approximate 2-3 year timeframe for combined TGA approval/PBS listing, the Special Access Scheme presents a more meaningful patient-centric solution.

***Already accepted clinical practice albeit 'off-label'***

- generally applies in the case of generic medicine availability so there will be limited interest in a local sponsor submitting an application
- accepted clinical practice for a given medicine/indication in the Australian context relies generally on an established funding mechanism (e.g. PBS general listing) or very low cost items sourced through hospital and/or pharmacy channels
- in situations where clinical guidelines are updated and patient access is achieved, there are generally no requests from colleges/clinicians/patients to sponsor TGA applications
- off-label repurposed medicines may have long term evidence of safety/tolerability but long-term efficacy may be less clear
- no change to usage patterns should the indication be extended so not commercially viable

- imperfect data sets to support a TGA registration and PBAC application
- insecure investment due to F2 price insecurity. Low margins are vulnerable to ongoing erosion with every price disclosure cycle
- exclusion of innovators from F2 price disclosure calculations signals a government intention to separate the innovator's *know how* and global safety database from a generic medicine supply market
- within the current system, resource and financial investment undertaken by a single sponsor may be readily leveraged by all other suppliers at minimal cost and effort.

***likely to be less commercially profitable***

- any and potentially all of the circumstances identified in the other categories equally may apply in this case.

Importantly, Medicines Australia members acknowledge their role within a broader healthcare delivery system and the community. While a repurposing exercise may not on its own withstand scrutiny as a secure R&D investment, the industry recognises the value of their safety and efficacy databases, the role for established medicines within healthcare and their capacity to create scope for future medicines funding. Engagement with industry in this context will prompt constructive, long term solutions that look at both medicine repurposing priorities and timely access to new medicines, acknowledging that there is a valid place for both within a successful and cost-effective health delivery system.

**TGA Proposed Options**

As stated already, the below options are not fit for purpose as they are not based on a full understanding or appreciation of the global commercial realities faced by R&D-based companies.

**Option 1**

- **Reduction of regulatory burden for repurposing medicines**
- **Provide fees and charges relief**
- **Simplify/Streamline simultaneous submission for regulatory/reimbursement evaluation**
- **Provide exclusivity periods for new indications of repurposed off-patent medicines**

As a general observation, reduction of regulatory burden, fee relief, TGA/PBS process simplification and exclusivity periods would all engage sponsors' interest. A key issue is in what public health circumstances the Department of Health intends to exercise such options. This is an important area for further clarification as the existence of a multi-tiered system has the potential to undermine Australia's regulatory, reimbursement and intellectual property frameworks.

These proposals have the potential to contribute to comparator erosion and devalue innovative products. Under the proposals, medicines used off-label and later repurposed, could be considered a comparator for reimbursement purposes, even though they may not be the best reflection of the 'treatment most likely to be replaced' or have the best evidence base, but could now be considered a

substitute in the treatment mix. The repurposed medicines may have long term evidence of safety/tolerability, but long-term efficacy may be less clear.

The specific subset of proposed measures outlined under Option 1 are addressed below:

- Support for clinical trial design – the vast majority of international pharmaceutical studies are designed to satisfy global regulatory environments where market exclusivity (should the trial succeed) is secured. Through the establishment of the current local regulatory framework recognising EMA guidance, Australian requirements are generally addressed through the EMA's early advice pathways. In the infrequent event of a uniquely Australian priority indication extension, early advice and agreement on a sponsor's clinical trial design would be of assistance (subject to adequate investment justification). There is also ample opportunity for collaboration with the TGA in the design of non-industry sponsored studies funded through NHMRC grants and the Medicines Research Future Fund to ensure outcomes are suitable for health authority assessments
- Literature review assistance - marginal benefit may be realised as literature review experts are routinely employed by sponsors for PBAC applications
- Repurposing medicine guidance – this would provide limited assistance where evidentiary standards remain unchanged
- Facilitating access to overseas evaluations – support in this area would assist sponsors', and potentially the TGA's, resource concerns cited within the consultation. International collaboration has proved to be a useful tool in addressing key public health issues. Sponsor access to a corresponding submission dossier may remain a hurdle where overseas approvals are through clinical college/academia/HA collaboration
- Multi-country submission coordination – potentially a resource efficient approach for sponsors and regulators, subject to agreement on dossier content expectations in each market (e.g. USA/EU repurposing initiatives may not be traditional industry sponsor dossiers)
- 3-5 year payment plans – this would rarely change the viability assessment for a sponsor
- Expansion of orphan indication – this proposal may stimulate increased activity as it recognises the TGA and PBS cost hurdles for non-viable indications where a data set is available. However, there remains a barrier if multiple rounds of PBAC review are required
- Department intervention to prioritise retrospective evaluation and PBS listing, based on different (lower) levels of evidence, can erode trust in a global system that relies on risk capital investment to support new medicines. Proposals to extend regulatory data exclusivity (i.e. regulatory data protection (RDP)) for non-commercial sponsors is interesting and we propose that government align RDP with comparable overseas jurisdictions such as the European Union.

**Option 2.**

**Further support the development of repurposed drugs through enhancing information access**

These concepts may support industry in identifying the potential scale of the market within Australia, or may provide insight for research organisations in gathering evidence.

- **Facilitate open-access to "real-world" Australian medicines usage data**
- **Provide consolidated international regulatory and HTA/reimbursement information**

Local real-world data (or rather Real-World Evidence (RWE)) has a number of inherent limitations, stemming predominantly from the absence of electronic connectivity across the Australian health system. In the case of SAS data, for example, while it exposes request numbers, there is no information available on efficacy outcomes, nor specific linkage at a patient level to adverse event reports. The capacity to measure established off-label use is fraught with system limitations. They rely on survey extrapolation or indecipherable data due to general PBS item codes that do not allow indication differentiation. While overseas RWE could support re-purposing applications if sourced from jurisdictions with evolved e-health environments, this capacity must exist within our own health system.

Further to RWE availability, the Australian system needs an RWE assessment framework for both regulatory and reimbursement decision making, not limited to repurposing exercises. Medicines Australia welcomes the opportunity to work with the government in the continued developed of an effective integrated e-health system.

Facilitating access to benefit/risk assessments conducted by clinical colleges can add system efficiencies, as would centralised access to international health authority and reimbursement reviews. Co-ordinated international approaches may enable a process that accommodates multiple sponsor involvement. Drawing from global experience reduces unnecessary duplication of both regulatory and health technology assessments and usefully progresses international harmonisation.

**Option 3.**

**Actively pursue registration and potential PBAC review of additional indications for medicines**

In cases where there is no commercial party interested in submitting a repurposing application, subject to further exploration, the following options could be considered. It is acknowledged that legislative amendments would be required to implement these options.

- **Seek public expressions of interest for sponsorship of new indications of a medicine, potentially limited to non-commercial organisations:**
- **Compel the sponsor of the medicine to make an application for the additional indication:**
- **Approve the inclusion of an additional indication for the medicine without the need for an application from the sponsor:**

Non-commercial academic institutions certainly have a potential role in assembling, assessing, or sponsoring literature-based submissions or nominating candidates for rigorous safety and efficacy assessment where off-label use is emerging. Their involvement may alleviate the TGA concerns on resourcing such initiatives and build additional product evaluation expertise within local institutions. As with a number of the overseas initiatives[1,2,3], there are collaborative arrangements involved from which we can draw experience to develop local options.

However, a key question is the circumstances under which the department would recommend that an indication be added to a medicine as a *public health initiative*. Under specific circumstances, (e.g. *health pandemic or vulnerable patient cohort)*, there may be merit, but this requires further consultation.

That said, Medicines Australia is strongly concerned that this option would create a multi-tiered medicine evaluation system that interferes with free market principles, devalues robust contemporary medicine development programs and stifles investment in a research and development-based industry.

The TGA must elaborate how this can be achieved where there is no sponsor ownership of the molecule, no secured medicine supply and no ownership of the relevant efficacy and safety data. Suggestion of such extraordinary measures would indicate that there is an extraordinary issue to be addressed, reinforcing the value of a broader stakeholder discussion. Even where there is no initial sponsor, eventual forced linkage to a medicine supplier is inevitable as is the requirement for company headquarters to accept the same benefit/risk proposition as the TGA and accept pharmacovigilance responsibilities, including liabilities, to facilitate supply.

This course of action is unacceptable, but is also neither effective or feasible. The proposal for the government to intervene in the market is an extreme suggestion and quite unprecedented. It demonstrates a fundamental change to the government's acceptance of free market principles.

Compelling a private business to seek approval and accept responsibility for a medicine indication claim that may; not be sanctioned by their own company for benefit/risk reasons; be costly; be resource draining; and may also not be aligned with the company's business strategy, all under threat of sanction, is an extraordinary proposition.

Unilaterally extending company liability for indications against their commercial wishes or interests is an unacceptable proposition. Companies already argue in many drug and device product liability cases that TGA approval of a drug or device and, where applicable, its PI limit the scope of plaintiffs to argue that the product is per se unsafe or that the warnings given in relation to it are inadequate. The current state of the law in Australia is that the TGA's consideration of relative safety and approval of the PI is relevant to, but not determinative of, such questions. This is in contrast to the US, where FDA approval of a product "pre-empts" many types of product liability claims in respect of the product. If this proposal were to be implemented, there would be a strong case for legislative change requiring the government to assume a greater degree of liability in respect of a regulatory decision, particularly liability in respect of strict liability defective product claims.

The notion of compelling a sponsor to make an application has numerous difficulties. It assumes that a local sponsor has ready access to the data necessary to support the application, as well as the expertise to assemble a submission on the basis of that data. This is often not the case. Local sponsors will depend on expertise from other companies (which may or may not be part of their corporate group) to provide such a submission. It would be extraordinary overreach to attach a criminal consequence for failure to make an application in such circumstances. The proposal is also silent on the question of how the significant costs of such an application (both in terms of application fees and the costs of assembling the application) would be met. A company could be compelled to incur the costs of a registration application and the ongoing regulatory activities (including pharmacovigilance) for a product or indication that it cannot sell profitably. Medicines Australia position is that this proposal is, in the strongest possible terms, unacceptable and outrageous.

Medicines Australia is entirely opposed to any approach which involves compulsion, free market intervention and severe consequences for resisting such extreme government encroachment. Such approaches will be a blunt instrument, unduly harsh on local sponsors and will not achieve their intended effect. Approaches that involve incentives for the repurposing of medicines and the removal of barriers, including costs, are more likely to be effective.

Also, these proposals may impede processes for better, safer and more efficacious medicines coming through the pipeline for Australian patients. This would be detrimental to patient access in Australia and further undermine Australia's reputation for being a 'first wave' country for the launch of new medicines.

The separate proposal of self-initiated TGA approvals appears similar to the current approach of agreed claims for listed medicines which sponsors may or may not choose to adopt. Given the higher acknowledged risk of prescription medicines, further information is necessary to expand on:

1. the situations where the TGA would adopt this approach
2. the public health concern it is seeking to address.

The merit in this proposal is the discretion that remains with medicine suppliers to adopt the indication and engage in supply. However, there is a question of ultimate benefit in circumstances where the opportunity is not pursued or PBS listing costs and pricing render the proposal not viable.

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