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AMA SUBMISSION – POST-MARKET REVIEW OF AUTHORITY REQUIRED PBS LISTINGS

The AMA supports the independence and transparency of PBS listing and pricing functions through the Pharmaceutical Benefits Advisory Committee (PBAC).

The PBAC plays a fundamental role in ensuring that the PBS subsidises safe, effective and affordable medicines. It is an equitable system for providing affordable, sustainable access to cost-effective medicines for all Australians.

In the interests of patient safety, the AMA supports measures to control access to certain medicines that are prone to addiction and misuse.

The AMA also accepts the need for measures to ensure high cost pharmaceuticals are used appropriately in the interests of effective PBS expenditure.

However prescribing regulations and measures, such as the PBS Authority policy, should not pose a barrier to medical practitioners treating their patients or impose an administrative burden without evidence that they are effective and necessary.

PBAC's primary tenet is that decisions to list medicines must be based on evidence of effectiveness and cost-effectiveness. This same tenet is not applied to its decisions to apply an Authority requirement.

It appears that in many, if not most, cases a decision to apply an Authority requirement to a PBS medicine has been made on the basis of a 'just in case', conservative judgement rather than actual evidence that lack of an Authority will lead to misuse.

Rather, there is evidence to the contrary. There has been no rampant, inappropriate prescribing of medicines following a move from Authority Required to streamlined arrangements. Since 2007, the Department of Health has only identified a very small number of medicines, e.g. antipsychotics, where prescribing rates do not conform to those expected after they were streamlined. It should be noted there has been no investigation of potential reasons why prescribing patterns may have changed.

Further, PBAC does not undertake any cost-benefit analysis when making decisions about Authority requirements that compares the potential costs to the PBS of misuse, to the financial and opportunity-cost impact on government, doctors and patients resulting from administering and complying with additional regulation.

Based on statistics provided to us from the Department of Human Services (DHS) between October 2012 and June 2014, doctors undertake anywhere between 20,000 and 35,000 less consultations per month due to time spent waiting for calls to be answered by the Authority Freecall Service. Our conservative calculations over three periods are attached at pages 7-8 so that they can be made publicly available when this submission is published.

During July and August this year the phone line service failed completely several times due to 'technical' problems. AMA members reported having to send patients home without a script.

And yet during 2013-14, out of over 5.7 million calls only 2.2% were rejected (DHS letter dated 9 July 2014). The reasons for 'rejection' are not recorded.

This is an appalling waste of time and resources, with a serious impact on patients. Consider what could be achieved with an additional 20,000 to 35,000 consultations a month? How many more patients treated, how much extra time spent on quality care, how much more quickly patients would be able to see a doctor?

We understand that DHS is doing its best with a limited budget to support the Authority Freecall Service. We also understand that realistically the resourcing of the phone line will never be a priority for government and will never be adequate to prevent the sorts of failures described above.

This inadequate resourcing is directly transferred to cost on medical practice. The review must consider this significant impact on patient care. If appropriate resources are not available the PBS Authority policy should be scrapped.

If the purpose of the Authority policy is to control PBS spending, to reduce misuse, or to monitor prescribing, then there are alternative approaches to achieve this. The Authority system imposes an administrative burden on the vast majority of medical practitioners who do the right thing, in order to potentially defer the few who may seek to prescribe outside the PBS requirements.

The Government has stated that the primary objective of the review is to reduce red tape. We are not aware of any restriction arising from the Government to limit the scope of the review or to retain any particular features of the Authority policy and process.

The following alternative approaches are currently available and should be better resourced.

Practitioner audits

The Department of Human Services' compliance program identifies individual medical practitioners with prescribing habits different to their peers, and audits prescribing of PBS medicines to patients who do not meet the PBS conditions.

Practitioner education

The National Prescribing Service (NPS) funded by the Government to improve the quality use of medicines, provides individual medical practitioners with information to compare their prescribing patterns with those of their peers, based on Department of Human Services data. It also collects and analyses detailed information about how and why medicines are prescribed in medical practices and whether prescribing aligns with recommended best practice, as part of its MedicineInsight program. This information informs policy and clinical practice and the effectiveness of the PBS, particularly how new PBS medicines are used. The NPS also promulgates evidence-based guidance on prescribing safely and appropriately within a 'quality use of medicine' framework.

Medicine utilisation monitoring and evaluation

The Department of Health has other means than the authority system to allow tracking and monitoring of medicines prescribed and dispensed under the PBS. The prescription coding system introduced in 2011 allows detailed information on utilisation to be collected and analysed. This information could inform NPS activities, and highlight risk areas to be audited by DHS. Also, since the beginning of 2014, pharmacies now provide information on Authority medicines dispensed to the Department electronically, allowing real-time tracking to occur.

AMA recommendations

In recognition that abolishing the Authority policy at this stage may be a bridge too far for the Government, in the interim the AMA proposes the following approach, which will also achieve the collection of important data and evidence to support informed policy decisions.

Firstly, assessment criteria should be debated and developed to guide consistent and evidence-based consideration of individual medicines; secondly, the majority of existing Authority Required medicines should be either removed from Authority listing or moved to streamlined arrangements until there is evidence of unjustified changes to prescribing behaviour.

These steps are described below.

Proposed assessment criteria

The AMA is disappointed that the Department has called for submissions on current Authority Required medicines in the absence of developing and consulting on proposed assessment criteria, as specified in the review terms of reference.

It is also disappointing that the Department has not at least published on the review website the current 'reasons' that PBAC considers a medicine for Authority Required or restricted benefit listing. According to the PBAC 'guidelines for industry':

A medicine or medicinal form is considered for restricted benefit or authority required listing [by PBAC] for the following reasons, to:

- *limit PBS usage so that this is in accordance with the approval and registration granted by the TGA*
- *allow the controlled introduction of a medicine in a new therapeutic class*
- *limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons*
- *alleviate concerns about adverse reactions, possible misuse, overuse or abuse*

Rather than adopt an ad hoc, inconsistent approach as encouraged by the call for submissions in the absence of any assessment framework, the AMA proposes the following criteria should be applied when considering if a medicine should be considered for Authority listing:

- there is a history of **misuse***, and there is evidence that an Authority listing will prevent or significantly reduce the misuse and that the potential benefits will outweigh the financial and opportunity costs of an Authority listing; or

(*'misuse' includes abuse, overuse, inappropriate use, use outside PBS indications, high risk use, redirection, etc)

- there is a high **financial cost** to the PBS of misuse, and there is a history of misuse, and there is evidence that an Authority listing will prevent or significantly reduce the financial costs of misuse and that the potential benefits will outweigh the financial and opportunity costs of an Authority listing.

<u>Current Authority Required medicines</u>

The AMA's recommendations for current, individual Authority Required medicines are provided at pages 9-11. They are grouped in three categories.

(In the AMA's submission to PBAC in July 2013, we proposed that some medicines might justify an initial Authority but not subsequent prescriptions to the same patient for the same condition. This option has also been discussed by the Review Reference Group, however we understand that the current PBS software does not allow this option. Given this, the AMA has not considered this option as a category in this submission. However, the Department should scope and cost this work and provide a timeframe for completion to better inform the Reference Group whether it is a viable option and, in particular, whether it can be implemented within a reasonable timeframe.)

Remove from Authority requirements altogether

These medicines are low cost and of low risk to patients in terms of adverse reaction or misuse.

Move to streamlined arrangements

Given that there is no evidence available to support the effectiveness of a phone call to clerk in positively modifying prescribing behaviour, the AMA proposes that all other current Authority Required medicines be moved to streamlined arrangements (with the exceptions in the third category below).

These medicines should then be monitoring using existing mechanisms to provide an evidence base for moving the medicine back to full authority if necessary.

Controlled medicines and other medicines

The AMA considers there should be further discussion regarding the management of controlled medicines. The AMA recognises these medicines are at high risk of misuse and diversion. On the other hand, their prescription and dispensing are already controlled by State and Territory legislation and it is likely that overtime each jurisdiction will implement real-time electronic recording and reporting of controlled drugs. The AMA believes the Review Reference Group should give these medications particular consideration informed by data from the States and Territories.

There are a small number of additional medicines which for a variety of reasons, e.g. antimicrobial risk, should be discussed by the Review Reference Group and may justify stronger regulation if there is sufficient evidence to support it.

Additional red tape reduction measures

Following monitoring, if there is evidence that some medicines should be returned to Authority Required arrangements, or there are new medicines that meet the agreed assessment criteria, then there are additional measures that should be taken to reduce the administrative burden imposed by the Authority system.

- Increased quantities – where an initial Authority has been obtained for increased quantities of a medicine, subsequent authorities should not be required for the same patient for the same condition.

- Palliative care – when Authority medicines are used in palliative care circumstances, after an initial authority no subsequent authority should be required for subsequent or increased quantities for the same patient for the same condition. However as noted above the Department has advised that the current PBS software does not allow for this option.

- Repatriation Pharmaceutical Benefits Scheme (RPBS) medicines – some medicines only require an Authority if they are prescribed under the RPBS. For example, nicotine can be prescribed under streamlined arrangements if prescribed under the general PBS but requires an Authority if prescribed under RPBS. Medicines streamlined under the general PBS should also be streamlined under the RPBS. There are also a number of medicines only available under the RPBS which require an Authority, for example, finasteride and podophyllotoxin. RPBS medicines have been omitted from this review but the additional red tape burden should be re-assessed in the same way as general schedule medicines.

- Review or lapse – all Authority listings should be reviewed within 5 years or automatically lapse if they are not reviewed. If cost is the primary reason for an Authority listing then it should be also automatically removed once the price falls below a pre-determined threshold.

- Streamlined Authorities efficiency – the streamlined Authorities process must be as efficient as possible. The software needs to be redesigned to make it easier for prescribers to select the correct streamlined code, and the overly verbose indication descriptions need editing to improve clarity and comprehension.

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WAITING TIME AND IMPACT STATISTICS – PBS AUTHORITY PRESCRIPTION AND AUTHORITY FREECALL SERVICE PHONE LINE

Department of Human Services phone line statistics extrapolated to consultations lost per week

March – June 2014 period*

% of callers and waiting time (seconds)	Number of callers per month (based on **451,000** calls per month)	Average seconds assumed	Average minutes lost per month (av seconds x number of callers per month / 60)	Average consultations lost per month (based on av minutes lost; 15 minutes consultation)
76% < 30	342,760	15	85,690	5,713
18% 30-120	81,180	90	121,770	8,118
5.5% 120-300	24,805	210	86,818	5,788
0.5% > 300+	2,255	300	11,275	752

Due to time spent waiting for calls to be answered by the Authority Freecall Service, doctors undertake an average of **20,371 consultations <u>less</u> per month**.

*Source: Department of Human Services letter dated 9 July 2014

October 2013 – February 2014 period**

% of callers and waiting time (seconds)	Number of callers per month (based on **440,000** calls per month)	Average seconds assumed	Average minutes lost per month (av seconds x number of callers per month / 60)	Average consultations lost per month (based on av minutes lost; 15 minutes consultation)
50% < 30	220,000	15	55,000	3,667
34% 30-120	149,600	90	224,400	14,960
15% 120-300	66,000	210	231,000	15,400
1% > 300+	4400	300	22,000	1470

Due to time spent waiting for calls to be answered by the Authority Freecall Service, doctors undertake an average of **34,497 consultations <u>less</u> per month**.

**Source: Department of Human Services letter dated 22 April 2014

September – October 2012 period***

% of callers and waiting time (seconds)	Number of callers per month (based on **500,000** calls per month)	Average seconds assumed	Average minutes lost per month (av seconds x number of callers per month / 60)	Average consultations lost per month (based on av minutes lost; 15 minutes consultation)
60% < 30	300,000	15	75,000	5,000
30% 30-90	150,000	60	150,000	10,000
10% > 120	50,000	180	150,000	10,000
.06% 300+	300	300	1,500	100

Due to time spent waiting for calls to be answered by the Authority Freecall Service, doctors undertake an average of **25,100 consultations <u>less</u> per month**.

***Source: Minister for Human Services letter dated 19 November 2012

CURRENT AUTHORITY MEDICINES – AMA RECOMMENDATIONS

TRANCHE 1 MEDICINES

These medicines include those used to treat cancer, multiple sclerosis, rheumatoid arthritis and other arthritis.

The AMA recommends all these medicines are moved to streamlined arrangements.

They carry some risks (as do all medicines) and most are high cost. However they require diagnosis/assessment by a specialist medical practitioner with periodic reassessment; have a narrow therapeutic use; and therefore are of low risk of diversion.

In addition, a significant number are already streamlined if prescribed in a public hospital setting. If they can be safely and appropriately prescribed under streamlined arrangements in a public hospital, they should be regulated in the same way in a private setting.

TRANCHE 2 MEDICINES

These medicines include ocular, psychiatric and cardiovascular disease medicines.

The AMA recommends most of these medicines are moved to streamlined arrangements, with the exceptions noted below.

Some carry risks and are of high cost. However many of these, for example medicines to treat ADHD, require diagnosis/assessment by a specialist medical practitioner with periodic reassessment; have a narrow therapeutic use; and are of low risk of diversion.

Many medicines in this tranche, such as most anti-infectives, are only Authority required in a private setting; they should be regulated in the same way as in the public system.

The AMA recommends the following medicines falling under tranche 2 should be removed from Authority requirements altogether:

- adrenaline
- imiquimod
- pimecrolimus
- amoxycillin
- rifampicin
- atovaquone + proguanil
- artemether + lumefantrine
- misoprostol

The AMA recommends further discussion regarding the following medicines falling under tranche 2, however, for those marked with an asterisk, we consider there is a

strong argument for streamlining after an initial authority when they are used in palliative care circumstances:

- bupropion
- varenicline
- naltrexone
- nicotine
- alprazolam
- nitrazepam*
- temazepam*
- diazepam*
- oxazepam*
- clonazepam*
- morphine*
- sildenafil
- tadalafil
- epoprostenol
- ofloxacin
- ciprofloxacin
- voriconazole
- vancomycin
- levodopa+carbidopa anydrous

TRANCHE 3 MEDICINES

These medicines include all remaining Authority required medicines, including specialised medical foods, ophthalmologicals and those requiring an authority for palliative care.

The AMA recommends most of these medicines are moved to streamlined authority arrangements with the exceptions noted below. Most require diagnosis/assessment by a specialist medical practitioner with periodic reassessment; and have a narrow therapeutic use and are of low risk of diversion.

The AMA recommends the following medicines falling under tranche 3 should be removed from Authority requirements altogether:

- diclofenac sodium
- pimecrolimus

The AMA recommends further discussion regarding the following medicines falling under tranche 3. We consider there is a strong argument for streamlining or no Authority after an initial Authority is obtained when prescribed in palliative care circumstances. However we note that the PBS software does not allow for this option:

- morphine sulphate
- fentanyl
- methadone
- clonazepam
- diazepam
- oxazepam

- nitrazepam
- temazepam
- ciprofloxacin