Public Consultation on Authority Required Medicines for the Post-market Review of Authority Required PBS Listings

I have been registered as a pharmacist for almost twenty years and have worked with the Authority Required system for PBS and RPBS listings throughout this period.

Relevant issues requiring attention by the reviewers are noted in below points:

Point 1
Improvement to patient safety through reduction of potential adverse risk outcomes should be an integral consideration during this Review – not just the reduction of administrative burden alone.

Point 2
A notable exclusion from this Review list of medicines is Strontium which from 01 October 2014 was moved back from Authority Streamlined to Authority Required
Authority required (STREAMLINED) to Authority Required
3036T strontium ranelate 2g granules, 28 x 2g sachets *(Protos 2g)*

The rationale for this move seems to have occurred due to the significant potential safety issues, namely the risk of cardiovascular events and venous thrombosis highlighted by the Boxed warning the TGA has required to be inserted at the top of the sponsor's Product Information. The PBS restrictions were also modified to ensure the prescriber is made aware of the issue or at least prevent them from prescribing unless other osteoporosis treatments have been unsuccessful or contraindicated.

This one change of restriction under a Quality Use of Medicine principle emphasises the need to maintain the current Authority Required system and is clearly supported by the PBAC if they act to revert back to the Authority Required system being questioned in this Review on public safety grounds which were seemingly unable to be administered by prescribers alone via the Authority Streamlined listing.

Point 3
Another concern that needs to be raised is the current ongoing prescribing of combinations of hypoglycaemics for Type 2 Diabetes already designated as Streamlined Authority where the combination (fixed dose preparation or single ingredient formulations used in combination) is not TGA approved nor within PBS restrictions.

This prescribing regimen is definitely occurring in practice and should be considered as part of this Review under both a Quality Use of Medicine framework and also in regard to outpouring of government expenditure. This would not occur if these items were to revert to Authority Required listings as the PBS staff and DVA pharmacists would identify this leakage and untrialled usage.

Tranche 1

L01XC07	**07243F**	Avastin (bevacizumab 100 mg/4 mL) injection: concentrated, vial Avastin (bevacizumab 400 mg/16 mL) injection: concentrated, vial

- **Keep as Authority Required**
- Concern that prescribers might be unaware of non-TGA indications (eg non-squamous lung cancer) and non-PBS indications (glioblastoma multiforme and ovarian cancer) and may begin to be prescribe outside funding guidelines resulting in loss of financial control and financial stability of the PBS

L04AA06	**01836P**	mycophenolate Capsule 250 mg, 50
	01837Q	mycophenolate Capsule 250 mg, 50
	02150E	mycophenolate 180 mg tablet: enteric, 120 tablets
	02193K	mycophenolate 360 mg tablet: enteric, 120 tablets
	06208R	mycophenolate mofetil 250 mg capsule, 100
	06209T	mycophenolate mofetil 500 mg tablet, 50
	06364Y	mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL
	06369F	mycophenolate 180 mg tablet: enteric, 120 tablets
	06370G	mycophenolate 360 mg tablet: enteric, 120 tablets
	08649F	mycophenolate mofetil 250 mg capsule, 100
	08650G	mycophenolate mofetil 500 mg tablet, 50
	08651H	mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL
	08652J	mycophenolate 180 mg tablet: enteric, 120 tablets
	08653K	mycophenolate 360 mg tablet: enteric, 120 tablets

- **Keep as Authority Required**
- Ensures ongoing review is occurring by transplant unit
- Potential use for non-PBS restrictions eg other organ transplant increasing PBS cost outside of projections when listed
- Items that are currently dual listed s100 HSD (management) and s85 (maintenance) will lose that distinction as GPs may pick the first one that appears in their item selection menu. Generating future scripts from incorrect patient history will then continue to reproduce the error. This will skew PBS supply data
- Pharmacists will bear the brunt of this potential confusion of code leading to potential rejection of payment by DHS – Guild may not have considered this implication for it's members

M05BA03	**06223M**	pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack
	06279L	pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack
	06286W	pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial
	06287X	pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial
	06288Y	pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial
	06289B	pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial

- **Keep as Authority Required**
- Reduces risk of inadvertent prescribing of these formulations/brands by GP's when treating Paget's disease – skews PBS data
- Complexity for pharmacist to ascertain correct Item code if incorrect use of Streamline code by prescriber – potentially first on list of codes will be predominantly utilised
- Potential for incorrect prescribed dose eg 90mg for Paget's

M05BA08	06371H	zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial
	09350D	zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

- **Keep as Authority Required**
- Potential incorrect dose prescribed for indication eg 4mg for Paget's or 5mg for cancers if left to doctor's to pick a code without intervention via Authority Required – have intervened with this incident in pharmacy practice
- Inadvertent prescribing of 5mg for Paget's sooner than one year between injections when different doctor's consulted at different surgeries and this would not be spotlighted without involvement/intervention by PBS staff or DVA pharmacy advisers

M05BB03	02194L	alendronate 70 mg + colecalciferol 70 microgram tablet, 4
	02224C	alendronate 70 mg + colecalciferol 140 microgram tablet, 4
M05BB04	02254P	RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets

- **NB these are RPBS listed items and outside of focus/scope of this Review**
- **Keep as Authority Required**
- Inadvertent use of these items by nonDVA patients
- Authority Required option allows prescribers to seek clarification of BMD differences in restriction by discussing with DVA pharmacy advisers when seeking approval

M05BX	09411H	teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge

- **Keep as Authority Required**
- Concern that if streamlined, inadvertent overprescribing ie beyond the 18month limit may occur especially as patients often see different prescribers resulting in potential ADR risk eg osteosarcoma per TGA boxed warning required in Product Information
- Confirm eligibility criteria (lower BMD, 2 or more fractures, 1 new fracture after 12months continuous anti-resorptive therapy etc) with prescriber as they may not be aware of the difference in restriction to other anti-resorptive agents on the PBS which may not occur with streamlined method of approval
- Concern that a GP may streamline without initiation by specialist or consultant physician

Tranche 2

A02BC05	03401B	esomeprazole 40 mg tablet: enteric, 30 tablets

- **Keep as Authority Required**
- Risk this could be streamlined for maintenance therapy of GORD which is not one of the PBS restrictions for indication nor recommended at this dose per the Product Information
- Concerns drug already being prescribed at high dose for NSAID gastro protection
- Leaving as Authority Required will prevent long term high dose usage which could result in lower magnesium and potential increase risk of fracture and from a QUM perspective is highlighted by DVA pharmacists when prescribers seek approval for higher doses or long term treatment
- Clearly the restricted benefit listing for this drug is being used beyond the restriction of Healing of GORD and is already causing considerable leakage so by allowing this item code above to slide from Authority Required to Streamlined Authority will no doubt result in further loss of financial control with reduced approval assessment by PBS staff or DVA pharmacists

A10AB02	**01713E**	insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial
A10AC02	**01711C**	insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial

- **Keep as Authority Required**
- Alerts doctor to restriction that is only for use when patient intolerant to human insulins and potential for doctor not to be aware of small risk of ADR's eg bovine spongiform encephalopathy due to being a biological agent of bovine origin. With streamlining a doctor may inadvertently just use the Streamlined code for the indication without consideration of the restriction in place.

A10BD03	**09059T**	rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56
	09060W	rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56
	09061X	rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56
	09062Y	rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56
A10BG02	**08689H**	rosiglitazone 4 mg tablet, 28
	08690J	rosiglitazone 8 mg tablet, 28

- **Keep as Authority Required**
- Leakage of PBS expenditure results when prescribed but not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1, or an SGLT2 inhibitor.
- I am confident that if moved to streamlined prescribing of these agents then prescribing contrary to these restrictions in the schedule notes would be frequent but could easily be detected if remains as Authority Required via phone requests to PBS staff or DVA pharmacists.

A12CC05	**05146W**	magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

- **Keep as Authority Required**
- Potential for use outside PBS restriction of subsidy only for ATSI populations if streamlined

A14AB01	**01671Y**	nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe
G03BA03	**02114G**	testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes
	02115H	testosterone undecanoate 40 mg capsule, 60
	02341F	testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations
	08098F	testosterone 100 mg implant, 1
	08099G	testosterone 200 mg implant, 1
	08460G	testosterone 2.5 mg/24 hours patch, 60
	08619P	testosterone 5 mg/24 hours patch, 30
	08830R	testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets
	09004X	testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule

- **Keep as Authority Required**
- Potential for abuse and use as a performance enhancer or misuse in sport and in the general community if moved to Streamlined Authority through doctor shopping but is quickly identified by PBS staff or DVA pharmacists if left as Authority Required
- Confirmation of documented low testosterone levels by two morning samples or an established disorder when left as Authority Required reducing chance of prescribing through pressure by patient

C01CA24	03408J	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe
	03409K	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe
	08697R	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe
	08698T	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe

- **Keep as Authority Required**
- Responsible use and prescribing maintained with Authority Required listing which confirms a comprehensive anaphylaxis prevention program is in place with specialist involvement
- Reduces patient desire to have multiple injectors on hand in various locations which only increased PBS expenditure especially considering these items often have a short expiry date

C09CA02	05491B	eprosartan 600 mg tablet, 28
	08951D	eprosartan 400 mg tablet, 28
C09CA08	05492C	olmesartan medoxomil 20 mg tablet, 30
	05493D	olmesartan medoxomil 40 mg tablet, 30

- **Keep as Authority Required**
- Prescribers often unaware of the cost implications for equal efficacy which result in a Therapeutic Group Premium being designated to some drugs within a class
- Leakage of PBS expenditure if allowed to Streamline without assessment of eligibility for the TGP exemption
- Prescribers often unaware of the restrictions for the TGP exemption and when explained by PBS staff or DVA pharmacists they agree particular patient does not fit eligibility criteria for the exemption

D01BA02	02285G	terbinafine 250 mg tablet, 42
	02804N	terbinafine 250 mg tablet, 42

- **Keep as Authority Required**
- Prescribers will often prescribe outside of the PBS restrictions of proven onychomycosis (eg tinea corporis, pedis, cruris) or for non-ATSI populations
- Prescribers may not be aware of the ongoing action of terbinafine and that optimal clinical effect is not recognised visually some months after final dose and may wish to continue to prescribe.
- DVA pharmacists explain via a QUM approach of this phenomenon and that the dystrophic nail whilst mycologically cured takes considerable time to grow out.

D11AX	02546B	imiquimod 5% cream, 12 x 250 mg sachets
	02637T	imiquimod 5% cream, 2 x 2 g pump packs

- **Keep as Authority Required**
- Prescribers may want to prescribe for unconfirmed BCC or consider topical therapy to be easier option than excision, cryotherapy, or diathermy and be unaware of this PBS restriction, or disregard this restriction if streamlining with an indication code
- Prescribers may want to treat larger areas at one time with amounts higher than Product Information recommends and this leakage could not be stopped if the item was to be moved to Streamlined Authority

M05BX	09411H	teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge

- **Keep as Authority Required**
- **Duplication from Tranch 1**
- Concern that if streamlined, inadvertent overprescribing ie beyond the 18month limit may occur especially as patients often see different prescribers resulting in potential ADR risk eg osteosarcoma per TGA boxed warning required in Product Information
- Confirm eligibility criteria (lower BMD, 2 or more fractures, 1 new fracture after 12months continuous anti-resorptive therapy etc) with prescriber as they may not be aware of the difference in restriction to other anti-resorptive agents on the PBS which may not occur with streamlined method of approval
- Concern that a GP may streamline without initiation by specialist or consultant phys

J01FA09	06151R	clarithromycin 250 mg tablet, 100
	06152T	clarithromycin 500 mg tablet, 100
J01FA10	06221K	azithromycin 600 mg tablet, 8
J01MA02	01208N	ciprofloxacin 250 mg tablet, 14
	01209P	ciprofloxacin 500 mg tablet, 14
	01210Q	ciprofloxacin 750 mg tablet, 14
J01MA06	03010K	norfloxacin 400 mg tablet, 14

- **Keep as Authority Required**
- Per QUM and worldwide concerns of inappropriate prescribing of antibiotics, the Authority Required restriction is essential for these items
- Without approval controls in place by PBS staff or DVA pharmacists these strong antibiotics could be prescribed for non PBS indications and long term use eg:
    - azithromycin prescribed for chronic bronchitis and bronchiectasis where there is little evidence of it's efficacy in reducing exacerbations
    - ciprofloxacin prescribed for immunocompetent patients or for mycobacterium where no HIV infection is present
    - norfloxacin for travel reasons resulting in PBS funding leakage
    - concerns for prolonged use of antibiotics resulting in overgrowth of nonsusceptible organisms and this is reduced by controlled authority approval
- DVA pharmacists seem to play a crucial QUM role and discuss evidenced base antibiotic rationale in discussions with prescribers at the time of approval
- Concern for antibiotic resistance increasing within the Australian community when not safely or correctly prescribed without approval assessment by PBS staff or DVA pharmacists

J02AC03	09363T	voriconazole 50 mg tablet, 56
	09364W	voriconazole 200 mg tablet, 56
	09452L	voriconazole 40 mg/mL oral liquid: powder for, 70 mL
J02AC04	09360P	posaconazole 40 mg/mL oral liquid, 105 mL

- **Keep as Authority Required**
- Due to increased cost versus fluconazole financial control of PBS expenditure needs to be maintained by confirming fluconazole is inappropriate failed or not tolerated (per each relevant restriction/indication) prior to commencing this therapy – prescribers may not be aware of this funding restriction and want to use as first line agent
- Multiple indications exist for voriconazole and with Streamlining prescribers may not choose correct four digit indication code and just select the first one on the list which skews PBS data for monitoring expenditure

J04BA	01982H	rifampicin 150 mg capsule, 100
	01983J	rifampicin 300 mg capsule, 100

- **Keep as Authority Required**
- Requires confirmation of Leprosy per PBS restriction but often prescribed in combination with other antibiotic for alternate indication
- Loss of financial control for specific PBS restriction impacting on PBS expenditure

J05AB11	06280M	valaciclovir 500 mg tablet, 100

- **Keep as Authority Required**
- Prescribers may be unaware of PBS restriction for this quantity and inadvertently prescribe for genital herpes infection resulting in skewed PBS data and resulting in vastly increased PBS expenditure due to differences in cost between this 100 pack versus the other Streamlined amounts

N02AA01	08453X	morphine sulfate 200 mg tablet: modified release, 28 tablets
	08454Y	morphine sulfate 200 mg granules: modified release, 28 sachets
N02AA59	08785J	codeine phosphate with paracetamol Tablet 30 mg-500 mg, 20

- **Keep as Authority Required**
- Reduces risk of drug diversion and doctor shopping whereby prescriber can be alerted to this behaviour which would not happen if each doctor utilising Streamlining method – reducing risks and impact on community of such patient requests
- Gives the prescriber some support in dealing with abuse/diversion of narcotic items and pressure from these patient's to prescribe narcotics where not appropriate
- Increased quantity maximums can be controlled under QUM framework for codeine+paracetamol – some prescribers still prescribe at more than 8/day
- DVA pharmacists that identify high dose and/or frequent approval seem to apply QUM principles and request further information in writing from prescribers for the clinical rationale for the prescribed regimen where necessary recommend a pain specialist review – this would not occur if the items were made Streamlined Authority listings thereby affecting positive patient outcomes in reducing the patient's opiate burden

N03AE	02732T	nitrazepam 5 mg tablet, 25
N03AE01	01805B	clonazepam 500 microgram tablet, 100
	01806C	clonazepam 2 mg tablet, 100
	01808E	clonazepam 2.5 mg/mL oral liquid, 10 mL
N05BA01	02669L	diazepam 1 mg/mL oral liquid, 100 mL
N05BA04	03134Y	oxazepam 15 mg tablet, 25
	03135B	oxazepam 30 mg tablet, 25
N05BA12	02130D	alprazolam 250 microgram tablet, 50
	02131E	alprazolam 500 microgram tablet, 50
	02132F	alprazolam 1 mg tablet, 50
	08118G	alprazolam 2 mg tablet, 50
N05CD02	02732T	nitrazepam 5 mg tablet, 25
N05CD07	02088X	temazepam 10 mg tablet, 25
	05375X	temazepam 10 mg tablet, 25
	05376Y	temazepam 10 mg tablet, 25

- **Keep as Authority Required**
- Reduces risk of drug diversion and doctor shopping whereby prescriber can be alerted to this behaviour which would not happen if each doctor utilising Streamlining method – reducing risks and impact on community of such patient requests
- Gives the prescriber some support in dealing with abuse/diversion of benzodiazepine drugs and pressure from these patient's to prescribe them when not clinically appropriate
- Encourages doctors to recognise the addictive potential and discuss with PBS staff and DVA pharmacists about withdrawal for patients in aged care facilities or home carers
- Allows prescribers to be informed of the PBS definition of palliative care where they may not be aware of this interpretation

N06BA02	01165H	dexamphetamine sulfate 5 mg tablet, 100
N06BA04	02172H	methylphenidate hydrochloride 27 mg tablet: modified release, 30 tablets
	02276T	methylphenidate hydrochloride 20 mg capsule: modified release, 30 capsules
	02280B	methylphenidate hydrochloride 30 mg capsule: modified release, 30 capsules
	02283E	methylphenidate hydrochloride 40 mg capsule: modified release, 30 capsules
	02387P	methylphenidate hydrochloride 18 mg tablet: modified release, 30 tablets
	02388Q	methylphenidate hydrochloride 36 mg tablet: modified release, 30 tablets
	02432B	methylphenidate hydrochloride 54 mg tablet: modified release, 30 tablets
	03440C	methylphenidate hydrochloride 10 mg capsule: modified release, 30 capsules
	08839F	methylphenidate hydrochloride 10 mg tablet, 100
N06BA07	08816B	modafinil 100 mg tablet, 60
N06BA09	09092M	atomoxetine 10 mg capsule, 28
	09093N	atomoxetine 18 mg capsule, 28
	09094P	atomoxetine 25 mg capsule, 28
	09095Q	atomoxetine 40 mg capsule, 28
	09096R	atomoxetine 60 mg capsule, 28
	09289X	atomoxetine 80 mg capsule, 28
	09290Y	atomoxetine 100 mg capsule, 28

- **Keep as Authority Required or should revert back to Authority Required**
- Reduces risk of drug diversion and doctor shopping whereby prescriber can be alerted to this behaviour which would not happen if each doctor utilising Streamlining method – reducing risks and impact on community of such patient requests
- Gives the prescriber some support in dealing with abuse/diversion of stimulant drugs and pressure from these patient's to prescribe them when not clinically appropriate
- Some stimulants are prescribed by psychiatrists and other doctors for indications outside of TGA and/or PBS restrictions eg depression, somnolence, weight loss and this can only be controlled by Authority Required pathway

N06DA02	**08495D**	donepezil hydrochloride 5 mg tablet, 28
	08496E	donepezil hydrochloride 10 mg tablet, 28
N06DA03	**08497F**	rivastigmine 1.5 mg capsule, 56
	08498G	rivastigmine 3 mg capsule, 56
	08499H	rivastigmine 4.5 mg capsule, 56
	08500J	rivastigmine 6 mg capsule, 56
	08563Q	rivastigmine 2 mg/mL oral liquid, 120 mL
	09161E	rivastigmine 4.6 mg/24 hours patch, 30
	09162F	rivastigmine 9.5 mg/24 hours patch, 30
N06DA04	**08770N**	galantamine 8 mg capsule: modified release, 28 capsules
	08771P	galantamine 16 mg capsule: modified release, 28 capsules
	08772Q	galantamine 24 mg capsule: modified release, 28 capsules
N06DX01	**01956Y**	memantine hydrochloride 10 mg tablet, 56
	09306T	memantine hydrochloride 20 mg tablet, 28

- **Keep as Authority Required**
- Potential would otherwise exist for no specialist involvement or use outside of PBS MMSE restrictions
- Inaccurate diagnosis by GP of Alzheimer's Disease may result in delay to specialist review and accurate diagnosis

N07BA	**08465M**	bupropion hydrochloride 150 mg tablet: modified release, 30 tablets
	08710K	bupropion hydrochloride 150 mg tablet: modified release, 90 tablets

- **Keep as Authority Required**
- Could be prescribed for depression which is outside of PBS restriction specifically for smoking cessation
- Confirmation of smoking cessation between each listing approval reinforces to prescriber on a QUM perspective that ceasing smoking should have occurred

C01CA24	**03408J**	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe
	03409K	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe
	08697R	adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe
	08698T	adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe

- **Keep as Authority Required**
- **Duplication from Tranch 2 above**
- Responsible use and prescribing maintained with Authority Required listing which confirms a comprehensive anaphylaxis prevention program is in place with specialist involvement
- Reduces patient desire to have multiple injectors on hand in various locations which only increased PBS expenditure especially considering these items often have a short expiry date

Tranche 3

S01LA01	**01349B**	verteporfin 15 mg injection, 1 x 15 mg vial
S01LA04	**01382R**	ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial
S01LA05	**02168D**	aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial

- **Keep as Authority Required**
- Massive cost blowout already with repeated use beyond PBAC expectations only worsened if financial control is released further by allowing move to Streamlined Authority
- Numerous ophthalmologists want to prescribe/inject within the four week between injection interval
- Rejections result when ophthalmologists want to prescribe for indication outside PBS restriction eg areas outside of subfoveal region which would not be identified during a Streamlined code for indication being added to an Authority prescription
- Attempts to prescribe for conditions not per restriction where ophthalmologist signs PBS paperwork but indication seemingly differs to fluoroscein angiogram and report
- Circumstances where the wrong eye was prescribed for and was only identified by DVA pharmacists during the Authority Required approval process and this intervention would not have occurred had the item been Streamlined
- Authority Required ensures the ophthalmologist is involved at some stage of the prescription process when approval needs to be given direct to them, otherwise it appears in some circumstances that Authority prescriptions are prepared by orthoptists or clerical staff and just signed (before or after) by the ophthalmologist. An ophthalmologist made statement once that it is below him to have to write the prescription when clarification of the item prescribed was sought.

It is important to note that appropriately trained and experienced staffing levels should exist at DHS and DVA to ensure Authority approvals are assessed in a timely manner be it a telephone approval or posted application for Authority prescription.

Thought should be given to utilising more pharmacists at DHS to provide a similar level of clinical expertise during the approval process as what DVA currently provides. The DVA pharmacists provide speedy answering of calls into the Department, and quality advice provided without the caller having to be placed on hold while counsel is sought and are able to clear up pharmaceutical queries immediately and even apply a QUM framework to enhance patient safety.

Considering the cornucopia of relevant, valuable input from the pharmacists at the coal face of administering the Authority Required program, I find it implausible that the Department of Human Services pharmacist employees' input has not been highlighted or requested and perhaps disallowed as employees of the APS. I call on the Chairman of this Review to consider this matter and to request and facilitate de-identified confidential submissions from all DHS pharmacists to ensure the integrity and wholeness of this Review.

I reiterate statements made in the Terms of Reference submission.

As much as we all strive for efficiencies within the workplace, should they come with the potential reduction of accepted high levels of quality patient care and safety now and into the future?

Should we accept a reduction of monitored restrictions now, to find this only results in an increased PBS budget in the future and at what safety cost to the community?

The net effect of consequential increased PBS expenditure can only end with financial restrictions placed on future community access to necessary subsidised medicine and will merely be due to budget leakage from loss of financial control because it was placed into the hands of only the prescribers because these items were moved to Streamlined Authority designation.

Patient safety and potential increased adverse risk profile should be investigated and be of paramount concern when considering movement to Authority Streamlined listing, with the recent case in point, clearly demonstrated in my Point 3 above, involving strontium Authority listing tightening due to the increased risk of serious adverse outcomes that became evident and were less controlled when the item was a Streamlined Authority.

Yours sincerely

Name withheld B.Pharm ACP (submitted on Cover sheet)