Submission to the Remuneration Tribunal
Pharmaceutical Benefits Advisory Committee: remuneration for new office of Deputy Chair and changes to remuneration for existing offices

The request for review of the Pharmaceutical Benefits Advisory Committee (PBAC) by the Remuneration Tribunal is necessary as the role and function of the office have changed.

The Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package announced by the former Minister for Health, the Hon Sussan Ley MP, in May 2015 introduced a new PBAC Deputy Chair position and a PBAC Executive. In addition, the remuneration for members of the PBAC has not been reviewed since 2005. The Remuneration Tribunal is asked to consider the remuneration of the PBAC for the purpose of:

(a) increasing the remuneration for the PBAC Chair in light of the increased responsibilities of this position over recent years.
(b) making a determination as to the appropriate remuneration for the office of the Deputy Chair of the PBAC.
(c) increasing remuneration of part-time members to reflect the depth of technical expertise required for the role, and to provide appropriate recompense for the time commitment required to contribute to the PBAC’s deliberations.
(d) providing additional remuneration for part-time members who have increased responsibilities as members of the PBAC Executive.

Legislative details and functions of the PBAC:
The PBAC is an independent statutory body established under section 100A of the National Health Act 1953 (the Act). The PBAC makes recommendations and advises the Minister about which drugs and medicinal preparations should be made available as pharmaceutical benefits. In addition the PBAC recommends to the Minister vaccines for funding under the National Immunisation Program. No new drug can be made available on the PBS unless the Committee has made a positive recommendation. The Committee also advises on other matters relating to pharmaceutical benefits, as referred to it by the Minister.

The PBAC is required by the Act to consider the efficacy, safety and cost-effectiveness (‘value for money’) of a proposed benefit compared to existing alternative therapies. To do this, the Committee must evaluate lengthy and complex clinical and economic information provided by sponsor pharmaceutical companies.

As the Minister must have a positive PBAC recommendation in order to list a medicine on the PBS, the PBAC’s advice is subject to more intense scrutiny than many other advisory bodies. Should the PBAC determine to not recommend a medicine to the Minister, the implications of that decision (delayed access for patients and reduced income for pharmaceutical companies) are often the subject of intense scrutiny and political campaigning.

Changes to the PBAC:
Over recent years, there has been a marked increase in the number and complexity of submissions made to the PBAC. Several years ago, the average number of major submissions considered at each meeting was 25. In last two years the PBAC has rarely considered less than 30 major submissions per meeting. The agenda for the March 2015 meeting included the largest number of major submissions ever with 40 major submissions. Over the last two years, the PBAC has at each regular meeting considered submissions with a
potential total cost to the PBS of on average $4 billion (over the forward estimates), with the highest being in the region of $7.5 billion in March 2015.

The Government’s current policy position is to list all medicines recommended by the PBAC. It is therefore important that the PBAC has the capability and capacity to provide Government with high-quality and robust advice.

Submissions for new medicines increasingly relate to complex new technologies, biological products, drug/genetic test combinations, often with very high treatment costs. Assessing the comparative cost-effectiveness of these therapies requires detailed consideration by Committee members skilled in assessing matters relating to health economics, epidemiology, clinical decision making and patient outcomes. In addition, pharmaceutical companies have become increasingly sophisticated in how they scientifically argue the effectiveness and cost-effectiveness of their medicines and in how they seek to mobilise stakeholder expectations for PBS subsidised medicines.

The Streamlining of PBAC Processes included in the PBS Access and Sustainability Package (and the supporting legislative changes that commenced in 2015) acknowledged the increasing workload of complex matters the PBAC is regularly asked to consider, while at the same time providing flexibility in the appointment process to enable the best experts in Australia to serve on this committee. Changes to the Act provided for:

- an increase to the maximum number of members of the PBAC by three (from 18 up to 21 members),
- a Deputy Chairperson position,
- nomination of an industry member, and
- nominations for consumer members to be made by a broader range of consumer organisations and individuals.

At the completion of a current appointment/reappointment process, the PBAC will have 19 members (PBAC Chair and 18 members). In addition, under the Streamlining of PBAC Processes measure a PBAC Executive has been established to improve the capacity, efficiency, flexibility and operations of the Committee through triaging and advising on some of the less complex applications.

Further, other measures introduced through the PBS Access and Sustainability Package have substantially increased the workload of the Committee. These changes included seeking more meaningful input from consumers and clinicians to enhance decision making in the PBAC process, and the introduction of Managed Access Programs to enable early reimbursement for high-value medicines.

(a) Chair
The submission requests an increase to the remuneration of the PBAC Chair for the following reasons:
- increased volume and complexity of work required, including the additional work of the PBAC Executive. Submissions considered by the PBAC have become further technical, often with high treatment costs;
- to acknowledge the high level of public scrutiny directed at the PBAC Chair. The PBAC receives significant parliamentary and media attention. As the most publicly visible representative of a very high-profile Committee, the Chair necessarily bears a high level of pressure in dealing with external stakeholders on the Committee’s
behalf. Both the expenditure implications and public attention have increased in recent years;
- managing more PBAC members (from the PBS Access and Sustainability Package in 2015);
- to attract and retain quality, highly skilled professionals to the role;
- to create equity compared to other holders of public office with a similar level of responsibility and expertise. Table 1 outlines public offices that have a similar level of responsibility to the PBAC Chair.

Table 1: Public offices that have a similar level of responsibility to the Chair of the PBAC

<table>
<thead>
<tr>
<th>Office</th>
<th>Base salary (per annum)*</th>
<th>Total remuneration for office (per annum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair, Tax Practitioners Board</td>
<td>$292,460</td>
<td>$417,800</td>
</tr>
<tr>
<td>Chief Commissioner, Australian Transport Safety Bureau</td>
<td>$292,460</td>
<td>$417,800</td>
</tr>
<tr>
<td>Chair, Australian Accounting Standards Board</td>
<td>$285,930</td>
<td>$391,680</td>
</tr>
</tbody>
</table>


While the PBAC Chair does not have staffing responsibilities or responsibilities for managing a Commonwealth agency, the expenditure implications of Committee recommendations and public attention generated are significant. It is for these reasons that the comparators in table 1 are considered appropriate. The roles of the Chairs of other health benefits advice committees within the Health portfolio (e.g. Medical Services Advisory Committee and the Prostheses List Advisory Committee), which are non-statutory, are significantly different as these committees have less meeting days and a lower volume of less complex work. Consequently it is not possible to make a valid comparison between these part-time positions and the full-time PBAC Chair role. Further details of comparison to other related offices in the Department of Health are available at Appendix 1.

Further, while the PBAC makes recommendations rather than decisions, the Government has committed to respect the Committee’s advice and recommendations without fear or prejudice. It is critical therefore that the PBAC’s advice remains of the highest standard, underpinned by the best available evidence, in order to maintain the Government’s high level of trust.

Legislation permits the PBAC Chair to be appointed on a full-time or part-time basis. Where the PBAC Chair role is appointed on a part-time basis, the salary would be pro-rata. The last time in which the Remuneration Tribunal considered a submission relating to the PBAC Chair remuneration was in 2005.

The Chairs of the Australian Accounting Standards Board and the Tax Practitioners Board (both statutory bodies that provide advice to Government) have similar level of roles and responsibilities as the PBAC Chair. Therefore, it is proposed that the remuneration for the PBAC Chair be increased to that of the Chair of the Tax Practitioners Board:
- from a base salary of $247,810 (total remuneration for office $339,460) per annum
- to a base salary of $292,460 (total remuneration for office $417,800) per annum.
This increase will align the salary of the PBAC Chair to other public offices that have a similar level of responsibility and will ensure the ability to attract and retain quality, highly skilled professionals to the role.

(b) **Deputy Chair**
This new position will enable the aforementioned changes to the PBAC, which are set out in further detail in Appendix 1.

The Deputy Chair of the PBAC will be a prominent and well-respected position. The Deputy Chair would need to be a person well-known and highly regarded by pharmaceutical industry, academia, the medical profession and patient groups. The Committee is subject to significant public, media and industry scrutiny, including in the general media and the trade press.

There is high demand for people with such expertise, who could receive significantly higher remuneration in the private sector. Further, given the Conflict of Interest requirements of PBAC membership (which are outlined in the *National Health (Pharmaceutical Benefits) Regulations 1960*), Committee members are precluded from accessing payments, (honoraria, travel expenses for attendance at international conference, etc.) that they may otherwise receive from pharmaceutical industry.

Remuneration of the Deputy Chair PBAC office is sought on a full-time basis. Legislation permits the PBAC Deputy Chair to be appointed on a full-time or part-time basis. The ‘*Remuneration and Allowances for Holders of Full-Time Public Office*’ Determination enables remuneration for holders of full-time public office, who have been approved by the employer to perform duties on a part-time basis where the proposed hours are 60% or greater of a full-time equivalent basis. In this circumstance, the remuneration would be calculated on a pro-rata basis of the full-time rate.

Tier 1 travel allowances currently apply to the PBAC Chair and all PBAC members. Therefore, it is proposed that Tier 1 travel allowances also apply to the Deputy Chair.

It is proposed that the Deputy Chair be remunerated at 75% of the salary of the Chair, consistent with the ‘*Remuneration of Public Offices: Part-time Offices Report, October 2013*’, which states “Where there is a requirement for a specific deputy chair fee, the appropriate chair: deputy chair fee ratio is considered to be 75%.” Further, this would be in line with the ratio of Deputy Chair to Chair salary for many other Commonwealth offices. Therefore based on the requested increase to the PBAC Chair salary of $292,460 per annum (total remuneration of $417,800 per annum), the base salary for the Deputy Chair will be $219,345 per annum (or total remuneration of around $313,350 per annum, including benefits and superannuation).

(c) **Remuneration of part-time PBAC members**
PBAC members are highly skilled in the assessment of clinical and health economic information and this mix of skills is rare. Finding members with the requisite skills who do not have conflict of interests is very challenging. In addition to this role, PBAC members simultaneously engage in clinical and research roles which in many cases are of international significance. The PBAC may currently consist of up to 19 part-time members (excluding the PBAC Chair and Deputy Chair).
A comparison with the responsibilities and remuneration of other similar offices is provided in Table 3 for completeness.

Table 3: Comparable remuneration arrangements for members with similar levels of responsibility

<table>
<thead>
<tr>
<th>Basis of appointment</th>
<th>Part-time base salary (per annum)</th>
<th>Travel Tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Digital Health Agency Board</td>
<td>$56,150</td>
<td>Tier 1</td>
</tr>
<tr>
<td>Private Health Insurance Administration Council</td>
<td>$53,280</td>
<td>Tier 1</td>
</tr>
</tbody>
</table>


It is proposed to increase the annual salary of part-time PBAC members to be comparable to the part-time office holders from the Private Health Insurance Administration Council. The last time in which the Remuneration Tribunal considered a submission relating to the PBAC member remuneration was in 2006.

Therefore, it is proposed that the remuneration for the PBAC members be increased:
- from a base salary of $41,780 per annum
- to a base salary of $53,280 per annum.

(d) Additional remuneration provision for members who are on the PBAC Executive Committee

The announcement of the *PBS Access and Sustainability Package* in May 2015 made provisions for the establishment of a PBAC Executive to improve the capacity, efficiency, flexibility and operations of the Committee through triaging and considering certain applications. The PBAC Executive has already commenced and comprises of the Chair (and will comprise also the Deputy Chair of the PBAC, once appointed), the Chairs of both the Drug Utilisation Subcommittee and the Economic Subcommittee and a Consumer Representative. The PBAC Executive considers items that are less complex and makes recommendations to the full committee for ratification, as outlined in Appendix 1.

PBAC members who are also members of the PBAC Executive have an increased workload compared to non-executive members. The Chairs of the Drug Utilisation Subcommittee and the Economic Subcommittee already have responsibilities to attend their respective subcommittee meetings three times per year, plus additional their technical work to provide required advice to the PBAC.

The PBAC Executive generally meets nine times per year to consider items prior to PBAC meetings. Preparation time for each meeting is expected to be approximately one day with each meeting up to two hours in duration. This equates to around 12 days (approximately three meeting days plus nine days of preparation) per annum work that is additional to other part-time members. An additional remuneration provision for the members is proposed based on this additional work load.

Members of the PBAC meet three times per year for three days per meeting, and three separate single day meetings (approximately 12 meeting days per annum) as well as ad hoc
meetings as required. In addition, each meeting requires considerable preparation time. It is estimated that at the present time each PBAC member is required to commit around 50 days per year to preparing for PBAC meetings and other expert committee work. This equates to a total of around 60 days (50 days plus 12 meeting days) each year.

Based on the above calculations it is considered reasonable to consider that members of the PBAC Executive will have an additional work load of around 20 per cent when compared to non-executive PBAC members. To account for this increase work load an additional remuneration sub-clause at a rate of 1/5 of the member remuneration is requested for those part-time members who are also members of the PBAC Executive. This equates to \$10,656 per annum ($53,280 ÷ 5) on top of the requested base salary increase request in part c) above. Please note that the additional remuneration for members of the PBAC executive do not apply to the PBAC Chair or the Deputy Chairperson, where these positions are occupied on a full-time basis.

(e) Summary of proposed remuneration arrangements
The table below summarises the remuneration arrangements proposed in this submission.

Table 4: Remuneration arrangements proposed in this submission

<table>
<thead>
<tr>
<th>Office</th>
<th>Basis</th>
<th>Base salary (and total remuneration) per annum</th>
<th>Travel tier</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBAC Chair</td>
<td>Full-time</td>
<td>$292,460 ($417,800 total package)</td>
<td>1</td>
</tr>
<tr>
<td>PBAC Deputy Chair</td>
<td>Full-time</td>
<td>$219,345 ($313,350 total package)</td>
<td>1</td>
</tr>
<tr>
<td>PBAC member</td>
<td>Part-time</td>
<td>$53,280</td>
<td>1</td>
</tr>
<tr>
<td>PBAC Executive member</td>
<td>Part-time</td>
<td>Additional remuneration: $10,656</td>
<td>1</td>
</tr>
</tbody>
</table>

Date of establishment of the office of Deputy Chair:
Establishment of the office of Deputy Chair by July 2017 would allow the new arrangements to be in place for the next PBAC cycle.

Contact details:
Pharmaceutical Evaluation Branch
Department of Health
This appendix provides further detail about the background of the Pharmaceutical Benefits Advisory Committee (PBAC), the role and expertise required of the Deputy Chair, the PBAC Executive and a comparison of related office within the Department of Health.

Background of the PBAC
Further information about the PBAC is provided below to address the Guidelines for Making a Submission to the Remuneration Tribunal.

The PBAC is established under the National Health Act 1953 (the Act). Under the Act, the roles of the PBAC include:
- Recommends medicines and medicinal preparations to the Minister for Health for funding under the Pharmaceutical Benefits Scheme (PBS).
- Recommends vaccines for funding under the National Immunisation Program (since 2006).
- Advises the minister about the clinical effectiveness and cost-effectiveness (‘value for money’) of medicines for PBS listing.
- Advises the minister on particular matters related to exempt items, combination items and therapeutic groups.
- Recommends maximum quantities and repeats on the basis of community use, and any restrictions on the indications where PBS subsidy is available.
- Regularly reviews the list of PBS items.
- Advises the minister about any other matters relating to the PBS.

The PBAC meets three times a year, usually in March, July and November. Meetings are generally for three days. There are also:
- extra-ordinary or ‘special’ meetings (generally one day, three times per year);
- stakeholder meetings, which are becoming increasingly regular; and
- out-of-session considerations (eg. to determine alternative arrangements when an essential medicine becomes unavailable).

To provide context as to the complexity of the Committee’s work, many Committee documents are publicly available through http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings, including agendas, outcome statements and public summary documents.

Further details of the Committee, including membership, are available at: http://www.pbs.gov.au/info/industry/listing/participants/pbac

The PBAC works to a 17 week meeting cycle, from the cut-off date for major submissions to the time of Committee consideration of the submission. Further details are available in the PBAC Guidelines, available at: http://www.pbac.pbs.gov.au/information/role-of-pbac.html

Sub-Committee structure
Under the Act, PBAC may also establish subcommittees to help it perform its functions. There are currently two subcommittees:
Drug Utilisation Sub-Committee (DUSC) — which monitors the patterns and trends of medicine use and makes such data available publicly. DUSC evaluates use and financial forecasts of selected major submissions to PBAC.

DUSC was formed by PBAC in 1988. The members have a broad range of relevant expertise and mainly come from organisations interested in the evaluation of medicine use.

Economics Sub-Committee (ESC) — which advises on cost-effectiveness policies and evaluates cost-effectiveness aspects of major submissions to PBAC by reviewing and interpreting economic analyses and assessing their quality, validity and relevance. After a preliminary period as a working party, ESC was formed by PBAC at the beginning of 1994. The members include clinicians, clinical epidemiologists, health economists, biostatisticians and clinical pharmacologists. As part of its terms of reference, ESC is also responsible for revisions of the guidelines.

Nutritional Products Working Party (NPWP) — which advises the PBAC on clinical and financial matters in submissions on any matters relating to nutritional products (medicinal foods) referred to them by the PBAC. The NPWP may also consider issues from submissions for nutritional products deferred or not recommended by the PBAC. The members include individuals with expertise in paediatrics, general practice, dietetics, the pharmaceutical industry and consumer interests. One member of the NPWP is a member of the PBAC.

Role of the Deputy Chair
This new position will strengthen the PBAC’s capacity and capability to manage the increasing volume and complexity of submissions, and will allow for increased consumer and industry engagement in the PBAC process. The creation of the position will also enable the creation of a PBAC Executive for triaging and considering certain applications.

The PBAC Executive meets nine times per year and will help triage and consider certain submissions (cost-effectiveness/cost-minimisation). This will help to streamline and expedite assessment of certain submissions. Further, the Deputy Chair will have central role in leading the consideration of assessing submissions proposing Managed Access Programs. This is a mechanism that will enable the PBS listing of products, under special circumstances of high unmet clinical need, on terms that allow for the resolution of otherwise unacceptable clinical or economic uncertainty. This will involve consultations with affected parties (the pharmaceutical manufacturer, clinicians and patient groups), identification of the sources of the otherwise unacceptable uncertainty, consideration of the data that would be required to address this and how this could be made available, assisting the Department to negotiate deeds of agreement that include terms for that data collection, outlining the potential consequences of the evidence outcomes, et cetera.

Further, the creation of a Deputy Chair position will enable the flexibility to appoint the Chair on a part-time basis if required. Should the Chair of the PBAC be appointed on a part-time basis, this would increase the workload of the Deputy Chair. The Deputy Chair would be expected to step in for the Chair.

In addition, the Deputy Chair will be required to:
- read through and appraise all submissions received (several volumes of variable length). For 35 major submissions, at 1.5 days to read and appraise each submission, this alone would take over 10 full weeks of a 17 week submission cycle. In addition
the committee generally receives around 25 minor submissions, many of which also require technical evaluation;
- ratify minutes and other communications of the PBAC and its Subcommittees including the Public Summary Documents. Further, the Deputy Chair may be required upon to assist in negotiating the content of these documents with the relevant sponsor (e.g. what information can be made publicly available as part of a Public Summary Document);
- participate at the two of the Subcommittees of the PBAC: the ESC and the DUSC, which provide information and advice to the parent Committee at each of its meetings. The ESC meets for two or three days, three times per year and the DUSC meets for one or two days, three times per year.
- participate at ‘special PBAC meetings’, which tend to be held for one day, three times per year.
- participate at stakeholder meetings when issues arise over a particular drug or treatment of a particular disease. An increasing number of sponsors and patient groups are requesting stakeholder meetings;
- meet with expert professional bodies and pharmaceutical industry representatives, answer media enquiries (as a PBAC spokesperson), and represent the PBAC at conferences and other fora. For example, the Chair of the PBAC and two PBAC members appeared before the ‘Senate Inquiry on the availability of new, innovative and specialised cancer drugs in Australia’. Further, the former Chair of the PBAC and a PBAC member also appeared on the SBS Insight program.
- other PBAC-related matters. The Deputy Chair would be required to play an active role, including providing technical expertise, participating in working group meetings and broader stakeholder meetings.

Expertise required of the Deputy Chair
The Deputy Chair of the PBAC will be a prominent and well-respected position. The Deputy Chair would need to be a person well-known and highly regarded by pharmaceutical industry, academia, the medical profession and patient groups. The specific expertise required for a Deputy Chair includes:

- Specialist clinical knowledge. The position would likely be filled by someone at the Professor or Associate Professor level, and/or
- Specialist skills in health technology assessment including clinical epidemiology, biostatistics and health economics. Such skills are scarce internationally, and/or
- Experience and expertise with stakeholder engagement in industry, academia, clinical practice, and consumers; the Government and the Department, and/or
- Extensive experience in other Government health advisory boards. For example, the appointee would be required to have a collaborative and pragmatic working relationship with: the Committee; stakeholders in industry, academia, clinical practice, and consumers; the Government and the Department. The appointee would also be required to have demonstrated strategic thinking skills, given:
  - the potential for litigation. Recent experience is that companies deploy legal challenges to the PBAC’s recommendations and PBS processes as part of their standard commercial conduct; and
  - pricing strategies of pharmaceutical companies given expenditure implications of the Committee’s recommendations, noting the PBS expenditure was over $10.8 billion in 2015-16.
Deputy Chair annual fee rather than daily fees

Should the Deputy Chair be appointed on a part-time basis, it is proposed that an annual fee be applied, rather than daily fees. The rationale for this is:
- it is consistent with the current remuneration arrangements of PBAC members, who are currently paid at an annual rate of $41,780;
- it is appropriate given the responsibilities of the office and the high level of skill required;
- the overall workload of the committee is consistently increasing (refer to ‘Role of the Deputy Chair’);
- it provides certainty of income to the office holder and the Department of Health (e.g. an annual stipend is likely to be more attractive to a potential Deputy Chair who may be required to balance a PBAC workload against university/hospital demands compared to a variable yearly income based on payment at a daily rate); and
- it is administratively straightforward.

Role of the PBAC Executive

The development of the PBAC Executive was announced as part of the PBAC Streamlining measures in the PBS Access and Sustainability Package in the May 2015 Budget. It made provisions for the establishment of a PBAC Executive to improve the capacity, efficiency, flexibility and operations of the Committee through triaging and considering certain applications.

The PBAC Executive has already commenced and is comprised of the following members:
- PBAC Chair
- ESC Chair
- DUSC Chair
- Consumer representative

When the PBAC Deputy Chair is appointed they will also form part of the PBAC Executive.

The PBAC Executive considers items that are less complex and make recommendations to the full committee for ratification. In general, all minor (less complex) submissions of a particular type (nutritional products, major resubmissions, secretariat, and regular minor submissions) are considered at a set Executive meeting within each PBAC cycle. The recommendations of the Executive will be considered and, if agreed, ratified through the full committee at their usual meetings in March, July and November.

Comparison to related offices in the Department of Health

<table>
<thead>
<tr>
<th>Committee</th>
<th>Authority</th>
<th>Chair</th>
<th>Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory Committee</td>
<td>Schedule A</td>
<td>Salary of $247,810. Total annual remuneration of $339,460.</td>
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<tr>
<td>Medical Services Advisory</td>
<td>Remuneration Tribunal Determination 2016/18:</td>
<td>Annual fee of $80,950. Daily sitting fee</td>
<td></td>
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<tr>
<td>Committee</td>
<td>Chair – Schedule A</td>
<td>of $784.</td>
<td></td>
</tr>
<tr>
<td>Members – Schedule B</td>
<td>Prostheses List Advisory Committee</td>
<td>Remuneration Tribunal Determination 2016/18 – Schedule C</td>
<td>Annual fee of $41,780 plus additional daily fee of $1,098.</td>
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</tr>
<tr>
<td>Therapeutic Goods Administration Advisory Committees</td>
<td></td>
<td>Remuneration Tribunal Determination 2016/18 – Schedule B</td>
<td>Daily fee of $1,098.</td>
</tr>
</tbody>
</table>

Advisory Committee for Biologicals, Advisory Committee on Chemicals Scheduling, Advisory Committee on Complementary Medicines, Advisory Committee on Medical Devices, Advisory Committee on Medicines, Advisory Committee on Medicines Scheduling and Advisory Committee on Vaccines.