SA Health

South Australian Medicines Formulary

Framework

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Government of South Australia
SA Health

Contents

1. Definitions and Terminology

For the purposes of this framework, the following definitions apply:

Generic equivalent medicine
Medicines are considered generic equivalents if they have the same quantitative composition of therapeutically active substances and same pharmaceutical form. Generic equivalent medicines must have proof of bioequivalence, which means they have similar pharmacokinetic characteristics according to the strict quality standards set by the Therapeutic Goods Administration (TGA),

Biosimilar Medicines
A biosimilar medicine is a highly similar version of a reference biological medicine. The reference biological medicine is the first brand to market. Biosimilars and reference biological medicines are derived from living cells or organisms and are highly similar though not identical. Minor structural differences are due to inherent variability of biological systems used in the manufacturing process. Biosimilar medicines must adhere to the strict quality standards set by the TGA, including evidence of bioequivalence, and comparable efficacy and safety to the reference product.

Therapeutic Alternatives

Therapeutic alternatives are medicines that produce a similar clinical response, however, may have different pharmacological and pharmacokinetic effects.

Therapeutic Class

Group of pharmacologically similar medicines which produce a similar therapeutic response and may be used for the treatment of the same condition.

High-Cost Medicine

Those medicines for which the predicted expenditure is:

≥ $15,000 per patient per treatment course or per year; or

≥ $150,000 for an individual hospital per year; or

≥ $450,000 within the SA public health system per year.

Exemptions:

medicines to be used in a clinical trial that have been approved by the local health network's (LHN) Drug and Therapeutics Committee and Ethics Committee and paid for by the sponsor of the clinical trial; or

medicines funded by a pharmaceutical company as part of a Medicines Access Program for that medicine, which are covered under another SA Health policy; or

medicines listed under the Pharmaceutical Benefits Scheme (section 85 or section 100) used in accordance with the PBS criteria for subsidy; or

medicines funded under the Commonwealth's Life Saving Drugs Program; or

medicines accessed via the National Medical Stockpile (NMS); or

other free of charge (FOC) stock

Restriction
A condition of use for a medicine. Restrictions may be defined based on clinical indication, specialty, or location of use (where equity is not expected to be greatly compromised).

Preferred Medicine
A medicine recommended for use in SA Health ahead of other similar medicines. Preferred medicines have been selected from and included in SA Health clinical guidelines where possible. They may also be first-line medicines in clinical guidelines.

South Australian Medicines Formulary (SAMF) - also referred to as "the Formulary"

A list of medicines which are approved for initial prescribing within South Australian public hospitals and health services, which is constantly evolving in accordance with best evidence for appropriate and cost-effective prescribing. The list specifies preferred medicines for the treatment of most patients for specific indications. Restrictions may be placed on initiating certain medicines and prescribing notes or clinical protocols on best practice may be linked to medicine listings.

2. The South Australian Formulary Committee

The South Australian Formulary Committee (SAFC) is an established sub-committee of the South Australian Medicines Advisory Committee (SAMAC). The SAFC comprises members with expertise from a range of specialties, particularly those representing high medicine use. Members include SA Health medical, pharmacy, and nursing clinicians, as well as health economists/epidemiologists/experts in drug utilisation, and consumer advocates.

The Chairperson of SAFC is a practising clinician with expertise in quality use of medicines and/or medicines evaluation. The SAFC Executive Officer is a SA Pharmacy senior pharmacist and is responsible for assisting the work of SAFC in maintaining and updating the Formulary and Committee Secretary duties. The SA Pharmacy SAMF Portfolio Lead will have responsibility for facilitating the provision of medicines utilisation and costing data to SAFC and liaison with Procurement and Supply Chain Management (PSCM), SA Health.

Additional members may be invited to participate in individual meetings/evaluations on an *ad hoc* basis where additional expertise is required from specialities not represented on the group and to ensure due consideration of special patient group needs.

For more information, refer to *Terms of Reference: South Australian Formulary Committee*[1].

3. Rationale

SA Health is committed to the equitable, safe, cost-effective, and quality use of medicines to benefit South Australians and supports Australia's *National Medicines Policy* and Quality Use of Medicines principles.

To achieve this goal, a state-wide approach to the availability of medicines will limit duplication of effort and resources, facilitate equity of access, familiarity with available medicines and enable realisation of procurement efficiencies. This has been accomplished by the 2012 establishment of the South Australian Formulary Committee (SAFC) to maintain the South Australian Medicines Formulary (SAMF) within SA Health.

New medicines or proposed changes to a medicine listing will be subject to a robust evaluation process to determine if a medicine is suitable for listing on the Formulary. An Individual Patient Use (IPU) process allows prescribers to seek approval from their local Drug and Therapeutics Committee (DTC) to access medicines not listed on the SAMF. The Formulary is regularly updated, accessible via electronic means (SAMF website) and dispensing software (iPharmacy). Over time, it is intended to be integrated with electronic medical record (EMR) software (Sunrise) and chemotherapy prescribing software (iQemo) to support quality use of medicines.

4. Background

Quality use of medicines is fundamental to good health care. Appropriate use of medicines can improve quality of life as well as life expectancy. However, modern advances in pharmaceutical science and the range of medicines and their indications for use, have led to higher overall medicine costs. This has resulted in increased complexity of prescribing, dispensing and administration, with associated greater medication-related incident risk. In a climate of increasing budgetary pressure across the healthcare

system, cost-effective medicine purchasing needs to be optimised. The establishment of a statewide formulary is an evidence-based approach to managing these challenges[2-5].

Many medicines currently available are minor variations of a prototype medicine and offer little or no therapeutic advantage over other medicines already on the market, but with significant cost differentials. These are referred to as 'therapeutic alternatives'. Sometimes medicines show high toxicity relative to their therapeutic benefit or new agents may be released with insufficient information on efficacy or toxicity to determine the true benefit of the medicine. Conversely, a new medicine may provide significant dosing advantages for patients. These are part of several considerations made during new Formulary medicine evaluation.

South Australian LHN Drug and Therapeutics Committees (DTCs) work collaboratively with the SAFC to evaluate the safety, efficacy and cost-effectiveness of medicines proposed for use within SA Health to determine if they will be listed on the Formulary and any associated guidelines. Various other expert clinical groups also provide SAFC advice to assist in evaluation of new Formulary medicines. SAFC works closely with the South Australian Medicines Evaluation Panel (SAMEP) which evaluates high cost medicines proposed for use within SA Health, according to the *Statewide Formulary for High Cost Medicines*[6] or to provide advice on complex formulary requests that require the most comprehensive assessments. The South Australian Expert Advisory Group on Antimicrobial Resistance (SAAGAR) was established to consider issues relating to antimicrobial use and resistance in South Australia. The SA Health Cancer Drug Committee (SAHCDC) oversees the development, approval, and review of cancer chemotherapy protocols within SA Health Hospitals.

5. Aims

The aims of implementing the SA Medicines Formulary are:

- to ensure equity of access to medicines across the South Australian public health system;
- to ensure that medicines used within SA Health are safe and clinically effective;
- to ensure that cost-effective medicines are used within SA Health;
- to provide a standard list of medicines with any restrictions to be used across SA Health;
- to be integrated into electronic medical record (EMR) for the implementation of preferred medicines and restrictions;
- to reduce duplication of effort in assessing medicines for use across SA Health hospitals and health services;
- to reduce the number of therapeutically equivalent medicines purchased to maximise resource utilisation and reduce overhead costs (e.g., storage, labelling requirements, etc);
- to optimise the Quality Use of Medicines (QUM) by supporting prescribers to make appropriate and evidenced-based medicine choices;
- to avoid frequent changes to listed preferred medicines to thereby, optimise purchasing power and increase familiarity for prescribers (e.g., medical practitioners, nurse practitioners), pharmacists, nurses, midwives and patients;
- to align with the implementation of SA therapeutic guidelines.

6. Scope

All medicines in use and proposed for use within SA Health are in scope of this framework. Note that medicines that meet the criteria for a 'High Cost Medicine' require additional assessment as defined in the policy *Statewide Formulary for High Cost Medicines* and are reviewed by SAMEP.

Items out of scope:

- radiological contrast agents
- dialysis fluids and dialysis agents
- enteral feeds (including infant formulas)
- test strips and reagents
- equipment used for medicine administration i.e., inhalation aids, syringes, filters
- raw materials used within manufacturing
- dressings
- agents used for testing purposes i.e., glucose for glucose tolerance tests
- blood products
- bulk fluids
- medicinal gases
- administration devices
- medicines funded by a pharmaceutical company as part of a Medicines Access Program for that medicine, which are covered under another SA Health policy
- other items as deemed by the South Australian Formulary Committee and/or South Australian Medicines Advisory Committee.

7. Risks

Formularies can be perceived as a mechanism to restrict and delay access to new, innovative therapeutic developments, reduce clinical freedom, and exclude stakeholders such as the patient and the pharmaceutical Industry from the decision-making process[7,8]. Delays in the decision-making process for evaluating new medicines may result in a high number of Individual Patient Use requests (IPU). Furthermore, unfavourable decisions not to list certain medicines on the Formulary may result in perceived inequities for patients wanting to access these medicines.

These risks will be mitigated by:

> ensuring a timely, transparent and robust evaluation process involving consultation with key stakeholders;

> access to an effective IPU process for timely access to non-formulary medicines which can be augmented with streamlined processes for more frequently requested medicines;

> performing horizon scanning for new medicines likely to be used within South Australian public hospitals to optimise timely decision making and pro-actively add medicines to the Formulary;

> undertaking regular review of medicines listed on the formulary with clinical experts;

> implementation of a communication strategy to ensure engagement and education of all key stakeholders including consumers and community healthcare providers.

Furthermore, there is the risk that the full level of savings may not be realised in the short-term due to continuation of patients on a non-preferred medicine who present to hospital on this medicine and/or were initiated on the medicine at the hospital, prior to implementation of the formulary.

8. Responsibilities

The Chief Executive of SA Health, Chief Executive Officers (CEOs) of LHNs, and Executive Directors (EDs) of South Australian public hospitals and health services or SA Health Divisions are responsible for:

> implementing and maintaining this framework.

Drug and Therapeutics Committees (DTCs) (and equivalent committees) are responsible for:

- ensuring local medicine use reflects SAMF decisions within a therapeutic group, as they are developed;
- facilitating the communication of Formulary decisions and access to the Formulary;
- monitoring medicines usage within their institutions;
- assessing applications for individual patient use (IPU) of non-formulary medicines/indications.

SAFC is responsible for:

- determining processes for the evaluation and assessment of medicines to determine formulary listings in a time-sensitive manner (including development of relevant documentation and application forms and processes for regular review);
- developing and implementing a consistent, statewide process for consideration of non-formulary IPU requests (including development of relevant documentation);
- facilitating the communication of formulary decisions and access to formulary listings.

SAMEP is responsible for:

- the evaluation and assessment of high cost medicines to determine formulary listings;
- providing advice to SAFC on complex formulary requests (e.g. relating to cost-benefit or benefit-risk).

SAMAC is responsible for:

- the implementation of this framework;
- overseeing the operations of SAFC;
- approving decisions of SAFC.

LHNs and all health clinicians are responsible for:

- facilitating adoption of SAMF decisions within SA Health and compliance with the framework through ensuring medicines are available and procured in accordance with the Formulary;
- reporting any patient care issues that arise from the framework.

9. Relevant SA Health Policies, Procedures and Guidelines

Complementary and Alternative Medicines Policy Guideline

Interaction between SA Health and the Therapeutic Goods Industry Policy Directive

Medicines Access Programs Policy Directive

Patients' Own Medications Policy

Preventing Adverse Drug Events Policy

Responsibility Matrix for SA Health Procurements

Statewide Formulary for High Cost Medicines Policy

10. Formulary Review Principles

Determination and Evaluation of Therapeutic Alternatives

A list of therapeutically alternative medicines from each therapeutic class on the Formulary is considered based on current usage, product information, other published evidence as well as expert clinical opinion.

Any medicines which meet the criteria for a High Cost Medicine, as defined in the *Statewide Formulary for High Cost Medicines* or require a high level of evaluation will be referred to SAMEP for consideration. Similarly, the SAFC will liaise with relevant statewide medicine committees where needed e.g., all antimicrobial medicines will be referred to SAAGAR and all chemotherapy medicines will be referred to SAHCDC for advice.

SAFC will then evaluate and compare medicines within each therapeutically alternative group to determine the 'preferred medicine(s)' from each group. Therapeutic alternatives will be compared according to criteria including the following:

- **PBS listing -** Selecting medicines which are listed on the PBS improves continuity of medication management when patients are transferred back into the community, improves cost-recovery for SA Health and ensures medicines have been considered safe and cost-effective by the Pharmaceutical Benefits Advisory Committee (PBAC).
- **TGA registration** – Medicines on the Australian Register of Therapeutic Goods (ARTG) should be recommended over unregistered medicines where possible. Unregistered medicines may be considered over registered products when there is a clear clinical advantage of using the unregistered product or where there is no viable registered medicine. It is noted patient consent must be obtained for use of all unregistered products. The Council of Australian Therapeutic Advisory Groups (CATAG) guiding principles for the quality use of off-label medicines need to be considered for medicines used in ways other than specified in the TGA-approved product information[9].
- **Comparative evidence for safety and effectiveness** - This is determined from published evidence, experience of medicines within SA Health and expert clinical opinion.
- **Range of relevant formulations** - Expert clinical advice with consideration of special patient groups will be sought to determine which available formulations would be beneficial for the treatment of SA Health patients.
- **Patient acceptability**- Consideration will be given to dosing and administration convenience, on-going patient costs and continuity of supply.
- **Cost of medicine and other associated costs** – SA Pharmacy will with work with Procurement and Supply Chain Management (PSCM) to access the most cost-effective price for Formulary medicines. The medicine with the lowest therapeutic daily treatment cost will be given preference in the consideration of the preferred medicine for the therapeutic group if clinically appropriate.
- **Safety and Quality considerations** – review quality of product packaging and naming (e.g., look alike sound alike considerations).
- **Confidence in Continuity of Supply –** The SAFC Portfolio Lead and Directors of Pharmacy will be consulted to determine the reliability of continuous supply by various manufacturers to minimise any impact of stock shortages.
- **Applicably of medicine to SA Health patients** - Medicines which may be used to treat a range of indications relevant to SA Health patients may be favoured above those which may not be used for the same range of indications.
- **Statewide Clinical Guidelines** – medications within a current or pending SA Health clinical guideline will ideally align with the Formulary and efforts will be made to achieve this.
- **Current usage** - Data obtained from iPharmacy and Sunrise will be used to determine the current usage of different therapeutic alternatives. If all other factors are equal, the medicine which is used the most would be favoured as it would result in the least impact on current clinical practice.

11. Formulary Maintenance

11.1 Consideration of Medicines within Therapeutic Groups

Medicines are considered in therapeutic groups (e.g., Cardiology, Immunomodulators, Anti-infectives) according to therapeutic usage of medicines in individual classes (e.g., anti-anginal drugs, anti-tumour drugs, antihypertensive drugs, antibiotics, etc). A list of therapeutic classes used in the Australian Medicines Handbook (AMH) is provided in **Appendix 1**.

The Formulary is maintained by reviewing therapeutic groups and associated classes. As each class is reviewed, more medicines will be added or deleted from the statewide formulary according to appropriate current practice and evidence-based guidelines. This review process will improve patient care through discontinuation of use of drug products that are less safe and/or effective and provide the basis for economic improvements for hospitals' medicines budgets.

11.2 Prioritisation of Therapeutic Groups

Consideration of therapeutic groups will be prioritised based on areas where greatest benefit can be achieved within SA health sites using the statewide formulary.

Factors that will be considered when prioritising medicines for evaluation are:

- significant changes to clinical practice or national/international guidelines;
- multiple therapeutically alternative medicines in the class;
- medicines with greatest potential for savings (greatest price difference amongst therapeutic alternatives or potential to negotiate a lower cost);
- medicines which may be used for the treatment of the most prevalent diseases and patient characteristics within SA Health;
- medicines that have been known to be problematic in the past (e.g., high risk of medication errors);
- key clinical stakeholder support.

SAFC formulates and maintains recommendations regarding which therapeutically alternative medicine(s) should be listed on the Formulary as preferred therapy for the treatment of a particular indication(s). SAFC will also provide recommendations regarding whether the medicine should be restricted to certain types of prescribers (e.g., only to be prescribed by infectious diseases clinicians; only to be initiated by pain specialists, etc), or certain patient groups (e.g., adults, children, outpatients, etc).

There may be situations where a particular medicine is suitable for most of the patient population but may not be suitable for a particular patient due to potential interactions with other medicines the patient is taking, co-morbidities or other factors, such as genetic markers. If there are multiple therapeutically alternative medicines with slightly differing clinical profiles, then more than one medicine may be recommended for listing on the Formulary in order of preference. If a prescriber wishes to prescribe a medicine which is not preferred therapy, they must demonstrate clinical need to use this medicine (i.e., already trialled preferred therapy or patient characteristics/contraindications preclude treatment with the recommended preferred therapy).

In some cases, SAFC may not consider there to be a justifiable need for any medicine from a particular therapeutically alternative medicine within the hospital. This may be particularly the case for newer medicines, where the risks of harm and/or costs associated with the medicine outweigh any clinical benefits.

11.3 Therapeutic Group Reviews

SAFC routinely updates therapeutic groups to ensure that the Formulary reflects current practice, is evidence-based, cost-effective and equitable. A working group of a small number of specialist clinicians will undertake initial maintenance review of all medicines in the therapeutic group to suggest changes

to the listings. Consultation will then be undertaken with key clinical stakeholders (e.g., DTCs, Statewide Clinical Networks, heads of clinical units and key specialists) to evaluate the acceptability of recommended changes to Formulary medicines. Stakeholders will be requested to consider the proposed Formulary changes in the context of any relevant clinical practice guidelines to ensure consistency between recommended medicines and guidelines. Stakeholders will be provided with the recommended Formulary changes, highlighting medicines that were considered to be 'therapeutically alternative' and the rationale for or against the inclusion of specific medicines on the Formulary.

SAFC will review feedback after the consultation period and then seek SAMAC endorsement of the new therapeutic group recommendations. Once endorsed by SAMAC, Health Executive endorsement is sought in accordance with the cost and risk thresholds (section 12.9) before the new changes are implemented.

Communications will be sent to DTCs, Statewide Clinical Networks and key stakeholders advising of the updated Formulary changes for that therapeutic group so that all prescribers are aware of which medicines can now be prescribed. Clinical networks and other groups involved in the development and implementation of clinical practice guidelines will be requested to ensure that any medicines recommended in their guidelines are consistent with Formulary decisions. Clinical pharmacists will play an educational support role for the therapeutic equivalence concept with health professionals, patients, and carers. Sites can stock formulary medicines and related products or strengths depending on level of local use without compromising availability and accessibility.

12. Submissions to Add or Change Medicines on the Formulary

A prescriber wanting to add a new medicine to the Formulary or seeking a change to an existing listing should direct their request to the local health network (LHN) Drug and Therapeutics Committee (DTC), or equivalent committee. The submissions must be made electronically on the *SA Health Medicines Formulary Request* form and then emailed to the relevant DTC or equivalent to screen for completeness and relevance to SAFC (i.e., the request is within SAFC scope). If suitable for SAFC consideration, the DTC Executive Officer (or equivalent) would refer submissions to SAFC (via SAFC Executive Officer) for consideration. Medicines meeting the definition of a High Cost Medicine or need complex cost-benefit or benefit-risk assessment will be referred to SAMEP. Any potential conflicts of interests must be declared by the applicant, stakeholders, and decision makers.

Suitable applications will proceed through the *Formulary Request Process* as per Appendix 2. Individual Drug and Therapeutic Committees (DTC) have a greater understanding of their health services' requirements and consultation will be requested for the formulary process, along with key stakeholders and expert advisory groups. SAFC will review feedback after the consultation period. Once the application is given a recommendation (positive or negative) by SAFC, SAMAC is notified or asked to endorse applications according to this process. Health Executive review and endorsement is required in situations of very significant financial implication (section 12.9) or for high risk applications.

Formulary updates will be regularly sent to DTCs, Statewide Clinical Networks and key stakeholders at the conclusion of the new formulary request process. The SAMF website will also be updated concurrently.

A summary of the types of pathways for new formulary requests and variations are outlined below. Deviations from the recommended pathways below will be at the SAFC Chair's discretion on a case-by-case basis due to urgency or complexity of the application.

12.1 Full review pathway

This pathway is for formulary requests that are not registered on ARTG or have non-TGA licenced and/or non-PBS indications. These medications will require the most robust formulary process that involves review of the clinical evidence and cost analysis as there are potentially significant cost implications. Two DTCs will be asked to undertake the clinical review on behalf of the SAFC and help

inform SAFC's recommendation for the Formulary prior to the DTC and stakeholder consultation period. Requests for PBS-approved indications with therapeutic alternatives will go through the full review pathway but may exclude DTC review if deemed appropriate by SAFC. If a medicine is on a DTC-approved or statewide protocol, this will also increase the efficiency of the process. Delays may occur depending on need for additional information from applicant or conflicting DTC consultation feedback.

12.2 Fast-track pathway

This pathway is for formulary requests with PBS-approved indications and no SAMF alternatives. The clinical evidence for these medications will have already been assessed by PBAC and will not be required by SAFC. They are also less likely to incur a financial burden to SA Health. Hence, these applications will be 'fast-tracked' for formulary inclusion and DTCs, stakeholders and SAMAC will be notified of the outcome.

12.3 Niche medicines

Niche medicines are specialised medicines that are prescribed to small patient populations for specialised conditions or diseases. Depending on the PBS status, these medications may be processed via the full or fast-track pathways. The full review pathway initiates with DTC review from the DTC the application originated from.

12.4 Minor Formulary changes

Minor Formulary changes including expansion of restrictions, additional strengths, brand, or presentation where necessary will be managed internally by the SAFC.

12.5 Requests for additional strengths

If a medicine is available in multiple strengths, these will be considered for the formulary. They may be listed if there is a positive recommendation for the active ingredient and there are no concerns (e.g., financial or safety) with listing all strengths. Individual sites may choose to stock these strengths based on local usage.

12.6 Chemotherapy agents

Chemotherapy agents must be in a SA Health approved cancer chemotherapy protocol or be reviewed for inclusion such a protocol concurrently with any new formulary requests. This will help to increase efficiency of the formulary request process as it ensures that the agent has been reviewed by the expert group SAHCDC. The Efficient Funding of Chemotherapy (EFC) Program allows PBS-listed chemotherapy medicines to be supplied cost-effectively and if EFC medicines are recommended for formulary listing, all strengths will be listed.

12.7 Medicines under consideration by PBAC for listing on PBS

Clinicians may submit formulary applications for medications pending PBS approval by the PBAC. These may not necessarily be approved before the PBS approval is granted but will be assessed by the SAFC under the Full Review pathway (see 13.1) and Formulary outcomes will be dependent on PBAC decision.

12.8 Requests for further information

If further information is requested from the applicant by SAFC for a new formulary request, it is expected that a response is provided in a timely manner. Generally, a two-week window with a further two-week reminder should be given to the applicant before the appropriate head of unit is contacted to request follow up. If this is unsuccessful the application will be cancelled, and the applicant and the local DTC will be informed.

12.9 Financial delegation

SAFC can endorse for low-moderate estimated cost requests below $25 000 statewide per annum. SAMAC can endorse for moderate-high estimated cost requests between $25 000 to $75 000 statewide per annum. Health Executive endorse requests of significant financial implications, when expenditure

is estimated to be greater than $75 000 statewide per annum (includes SAMEP applications) or for high risk requests. Recommendations are provided to the Chief Pharmacist to action or facilitate Health Executive review. Six monthly reports of approved and rejected requests will be provided to LHN Chief Executives (or their delegate).

13. Evaluation of New Medicines for Formulary Inclusion

Medicines proposed for formulary inclusion require a written evaluation comparing the newly requested drug with current formulary drugs used for the same indications. Criteria for comparison are as per section 12 above on *Formulary Review Principles*.

When reviewing drugs for formulary decisions the following questions shall be considered:

- Is the medicine registered in Australia?
- What is the current usage in SA Health public hospitals?
- Is there a justified need for the medicine as demonstrated by published clinical trials?
- If there is already another medicine on the Formulary which meets this need, then does the new medicine provide any clinical advantage (i.e., safer, easier to use, improved patient acceptability, more efficacious and/or more cost-effective)? If so, can the other medicine be delisted from the Formulary?
- Does the use of the new medicine justify its expense and associated costs?
- Is the medicine readily and reliably available from suppliers?
- Is this medicine subsidised by other funding mechanisms (e.g., the PBS)?
- Is it equitable to make this medicine available on the statewide formulary?
- Other considerations as appropriate

If the new medicine is found to be superior to an existing drug on the Formulary, it will be added to the formulary. Existing medicine(s) on the Formulary found to be inferior, and not needed for use for other indications, will be deleted from the Formulary.

If the medicine is considered to be unique and there are no suitable alternative medicines listed on the Formulary, it will be recommended for listing on the Formulary providing there is sufficient evidence for safety, clinical effectiveness, and cost-effectiveness to justify its routine use.

14. Formulary Listing of Off-Label or Unregistered Medicines

Registered medicines should be considered and utilised first, in accordance with its approval by the TGA, over unregistered medicines. Recommendations need to be considered in the context of priority by triaging aspects such as impact on patient care, timeline of treatment and differences in cost.

All medicines considered for off-label or unregistered use on the Formulary must undergo the full review pathway (see 13.1). The evaluation of individual patient circumstances, obtaining written informed consent and reporting of adverse events is the responsibility of the prescriber.

14.1 Off-label use of medicines

The use of medicines off-label, in ways other than specified by the TGA-approved product information, may be clinically appropriate in some circumstances. The CATAG guiding principles for the quality use of off-label medicines should be used to support decision making by the Formulary in their evaluation and recommendation for medicines used off-label[9,10].

14.2 Unregistered medicines

The use of a therapeutic good(s) that is not registered on the ARTG, such as those available via the Special Access Scheme (SAS), may be necessary in some situations[10]*. This may include medicine

shortages and when the approved use of a registered medicine does not meet the clinical requirement of the patient(s) and the unregistered medicine is clinically justified[11,12].

If an unregistered medicine is considered for the Formulary, an evaluation should be undertaken including the following principles:

- Efficacy and safety - The evaluation of evidence and medication safety of the unregistered medicine for the requested indication includes assessment of the quality level of evidence supporting the use of the medicine and comparative evidence for safety and effectiveness.
- Product quality - The overseas registration status from comparable overseas regulators (e.g. European Medicines Agency (EMA), United States Food and Drug Administration (FDA))[13] for the requested indication, manufacturer country of origin and registered reputable supplier will guide evaluation of product quality.
- Confidence in continuity of supply – The ability for the SAS supplier to continue provision of stock and supply on an ongoing basis.
- Supplier reliability - Supply chain and ongoing logistics.
- Language of label – The label of the product should be in English or the SAS supplier to provide English translation.
- Cost-effectiveness – If the use of an unregistered medicine is clinically justified, consideration may be given for cost-efficacy of the formulary listing.

A risk-benefit assessment of these factors is to be considered on a case-by-case basis, to guide whether there is overall sufficient justification to recommend an unregistered medicine for the Formulary.

(*Clinical trials have a separate approval pathway and are outside the Formulary scope)

15. Deletion of Discontinued Formulary Medicines

Due to global or local medication shortages or obsolescence, medicines are often discontinued. DTCs and the relevant Statewide Clinical Networks shall be notified whenever a formulary drug is under consideration for deletion to contribute to the decision-making process and provide any evidence for retention.

15.1 Processes for Deletion of Discontinued Items

> For items with no or low usage with a formulary alternative, deletion may occur after SAFC consultation. Notification about deletion will be included in Formulary update to DTCs, Statewide Clinical Networks, key stakeholders and SAMAC. Within the SAMF update, clinicians are welcome to propose an alternative product with rationale for requirement i.e., an abridged formulary request.

> For items with high usage and an alternative cost-effective SAS product(s) is available, then SAFC to automatically switchover and notify clinicians as per ‘items with little or no usage’ above.

> For items with high usage and an alternative SAS product(s) incurs a significant expenditure or there is no formulary alternative, then consultation and endorsement involving DTCs, Statewide Clinical Networks and key stakeholders is required. SAMAC will be notified of the deletion.

16. Endorsement of SAFC Recommendations

SAFC will provide a summary of formulary medicine evaluations to SAMAC, which includes recommendations for or against Formulary listing including any restrictions on prescribing. SAFC will seek endorsement of agents depending on estimated financial expenditure (see 12.9) and/or safety and

risk. After considering the recommendations from SAFC, SAMAC may seek further information or consideration by SAFC, if appropriate.

When a positive recommendation for a medicine has been endorsed (Appendix 2), it will be available on the Formulary for use within SA public hospitals and health services.

A negative recommendation must be endorsed by SAMAC for medicines not recommended for listing on the Formulary. When a decision has been made against a Formulary listing, the applicant will be informed and is permitted to submit a letter of appeal to SAMAC within 15 business days of receipt of the notification of the SAMAC recommendation.

Streamline non-formulary approval (SNoFA) requests (often incorrectly referred to as Streamlined IPU but does not consider individual circumstances of patients) may be recommended for a medicine that has clinical utility within SA Health, however, needs justification of its usage, safety, and efficacy. SNoFA requests should be audited by SAFC at regular intervals (6-18 months) and inform formulary recommendation.

The approvals for patient use of medicines not formulary listed fall outside the role of SAMAC and fall within local DTC governance. Patients being treated chronically with a medicine only provided by the hospital, which has been removed from the Formulary, must be considered for switching to the new preferred medicine. If a negative recommendation has been made, SAFC will provide guidance to DTCs as to when IPUs for that medicine would not be appropriate. The local DTC will decide if there are sufficient individual clinical grounds to approve IPUs to continue or initiate non-formulary medications.

17. Formulary Listings

Medicines will be listed on the Formulary according to therapeutic class as this classification system is useful for prescribers as well as nurses, pharmacists, and other clinical staff involved. Medicines will be generally added to the Formulary under their active ingredient name which is classified by International Non-proprietary Names (INN)[14]. The use of active ingredient names (generic names) serves to support purchasing and prescribing by generic name.

Brands are considered for formulary inclusion for biologics e.g., monoclonal antibodies as there can be significant medicine cost savings of biosimilars compared to the reference product. Clinicians should refer to the Governance of biologics in SA Health facilities Clinical Guideline for more information about prescribing biologics. Brands are also considered on a case-by-case basis where SAFC determine that the bioavailability and bioequivalence of drug products manufactured under different brand names vary so significantly that they can alter the desired therapeutic effect or there are potential safety concerns if the wrong brand is selected e.g., clozapine and warfarin. SAFC may also recommend specific volumes or pack sizes where there is large cost-differential between them.

Preferred Formulary listings will have no restrictions as it is assumed that the prescribing of these drugs will follow ARTG-registered indications or use according to CATAG guiding principles for the quality use of off-label medicines[9]. Restricted Formulary listings will include the indication(s) for prescribing as well as any restrictions and associated treatment guidelines (e.g., restrictions to only certain prescriber types). The Statewide Clinical Networks (or equivalent clinical groups) will be consulted to ensure that clinical practice guidelines are consistent with formulary listings, and are electronically linked to the formulary listing, where appropriate.

The formulary is externally accessible via the SA Formulary website on desktop, laptop, and mobile devices such as iPhone/iPad/Android devices.

18. Communication Strategy

An effective communication strategy to ensure stakeholder engagement is critical to the success of the Formulary. Ensuring the prescribers have the opportunity to comment in relation to medicines under

consideration by SAFC will further promote clinician engagement in the process.

18.1 Communication from SAFC

It is important to describe to prescribers the rationale and benefits of prescribing preferred therapeutic alternatives recommended on the formulary to ensure that prescribers support the formulary concept and are comfortable to prescribe recommended medicines in the majority of patients. This may be facilitated through education of interns and medical students, academic detailing of prescribers by clinical pharmacists and/or development of promotional material such as leaflets, lanyards, etc.

It will be equally important to ensure that all prescribers are informed of formulary decisions and have ready access to formulary listings. This is best achieved where communications are sent to prescribers via a number of different media (e.g., email, printed letters, intranet site, iPhone/Android application, EMR, direct verbal communications, seminars, academic detailing, etc) and via a number of different pathways (e.g., directly from SAFC/SAMAC or via DTCs, Heads of Clinical Units, Statewide Clinical Networks, clinical pharmacists, etc).

19. Accessing Medicines Listed on the Formulary

19.1 Prescribing Medicines

The Formulary will include recommendations regarding the preferred medicine to be used for the treatment of a particular condition. Prescribers are expected to use the recommended preferred therapy before using other restricted therapies listed on the formulary unless there is a strong clinical reason not to use the preferred therapy. If a particular medicine is not listed on the Formulary, a prescriber may submit a request for Individual Patient Use (IPU) of the medicine to their local DTC.

19.2 Integration of Formulary into EMR (Sunrise)

Integration of the statewide Formulary into Sunrise is an important process. The Formulary and associated treatment guidelines should be loaded into Sunrise which will assist in assessing compliance with the formulary at the point of prescribing/charting. The manner of integration will be in consultation with DTCs to create the best workflows.

20. Individual Patient Approvals for Use of Non-Formulary Medicines

Where a prescriber wishes to use a medicine which is not listed on the Formulary there will be the ability for the Chair of the relevant regional/hospital Drug and Therapeutics Committee, or their delegate, to consider use of the medicine where there is a justifiable clinical need over the medicine(s) listed on the Formulary. Applications will be made on the standard *Individual Patient Use (IPU) Medicine Request Form*. Requests should be forwarded to the applicant's local DTC.

Regular reports of IPUs considered by DTCs should be available for SAFC information. Each local DTC will consider whether the medicines provided by means of IPU should be listed on the statewide Formulary and/or if any previous formulary decision in relation to this medicine should be reviewed. Site specific formularies cannot be implemented through IPU approvals.

Under the *National Health Reform Agreement*, SA public hospitals are only permitted to charge Medicare eligible patients (public or private) for pharmaceuticals upon discharge or for outpatients[15]. Under exceptional circumstances where a patient wishes to self-fund the cost of their own medicine, a LHN DTC may consider the administration of a medicine to a patient for whom an IPU request has not been granted provided due processes have been followed to ensure that it is safe and appropriate to do so.

21. Switching of Patients Currently Taking a Non-Formulary Medicine

There will be situations where patients are already taking medicines that are not listed on the Formulary,

or not listed for the relevant indication. Patients already taking a medicine not listed on the Formulary will not automatically be switched to the preferred medicine listed on the Formulary (product substitution). However, if such a change was clinically appropriate, this should occur. Processes would differ depending on the circumstances:

21.1 Patient is admitted to hospital already stable on a non-formulary medication

If patients are already stable on a non-formulary medication their medication should not be changed unless there is a clear clinical reason to do so. This will help to improve continuity of medication management.

Some hospitals may decide to administer patients' own medications (POMs) brought into hospital by the patient, with the patient's consent, where it is safe and clinically appropriate to do so, in accordance with the *SA Health Policy Directive: Patients Own Medications*[16].

If patients are in hospital for an extended duration (long stay inpatients), their non-formulary medication from prior to admission should be reviewed and clinically assessed to consider switching to a formulary listed medication where appropriate.

21.2 Patients receiving medicines on a chronic basis from the hospital

In these cases, if the preferred therapeutically equivalent medicines change then consideration should be given to switching the patient. It will be up to individual hospitals and health services to determine whether these patients would be continued on the same medicine or switched to the alternative medicine listed on the Formulary.

Continuation of patients on the same medicine that they have already been taking holds the advantage that the patient is already familiar with that medicine and the therapeutic response is likely to be known and dosage stabilised. However, switching patients to the preferred medicine listed on the Formulary may result in improved safety and savings due to use of a potentially lower cost medicine.

When predicting the savings that could be realised through the selection of a particular preferred medicine, the number of patients who are likely to be continued on a non-preferred medicine must be considered. A decision to switch all patients to a preferred medicine would also mean that hospitals would not need to stock a full range of medicines and there would be less potential for medication error due to the use of several different medicines used to treat the same indication. A significant reduction in look-alike, sound alike equivalents is anticipated.

22. SA Medicines Formulary Website

The SA Medicines Formulary website will contain a link to the database of each medication listed on the South Australian Medicines Formulary as well as information about the statewide formulary and SAFC. This website is accessible via local intranets and publicly on electronic devices (laptop, PC, iPhone, Android). SAFC will be responsible for the administration of SAMF webpages. The SAMF database is alphabetically searchable with clear guidance on restrictions and indications. The website also provides links to necessary Individual Patient Use forms as well as streamlined non-formulary request forms.

23. Monitoring Outcomes

23.1 Patient outcomes and safety

Adverse drug events associated with the use of medicines listed on the Formulary will be monitored according to the *SA Health Preventing Adverse Drug Events Policy Directive* and associated *Preventing Adverse Drug Events Policy Guideline*.

Any increases in drug related adverse events following Formulary changes will be carefully monitored and a decision may be made to review the preferred medicine for a particular group, if it is associated with a significant number of adverse events.

23.2 Drug use evaluation and audits

The use of medicines within SA Health will be monitored using electronic records in software such as iPharmacy and Sunrise. This will provide data on which medicines are being used within SA Health, however, at present, the indication for the prescription is not captured by iPharmacy data and thus must be cross referenced with Sunrise. Where medicines have been used that are not on the Formulary, a corresponding IPU approval should be documented in the hospital's IPU database.

23.3 Savings

Savings generated by the implementation of the statewide formulary will be determined on a regular and cumulative basis. Changes in market dynamics, the status of individual medicines and the inclusion of new target therapeutic classes may change the availability and comparative benefits of medicines listed on the Formulary. Therefore, medicines listed on the Formulary for a therapeutic class will be reviewed on a rotating basis. After the initial Formulary has been compiled, the first therapeutic class that was considered for the initial Formulary will be reviewed. Significant changes in clinical evidence or market conditions within an existing therapeutic class may warrant an immediate Formulary review.

23.4 SAFC Framework

This framework and its operations will be reviewed at regular intervals.

24. Relevant Legislation

Controlled Substances Act 1984 (SA) - This act regulates the access of medicines and other controlled substances.

Therapeutics Goods Act 1989 (Cth) – This act relates to therapeutic goods within Australia.

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Appendix 1: Therapeutic Classes of Medicines (AMH)

1. **Allergy and anaphylaxis**
    - Sympathomimetics (anaphylaxis)
    - Antihistamines
        - Sedating antihistamines
        - Less sedating antihistamines
2. **Anaesthetics**
    - General anaesthetics
        - IV general anaesthetics
        - Inhaled anaesthetics
    - Neuromuscular blockers
        - Non-depolarising neuromuscular blockers
        - Depolarising neuromuscular blockers
    - Other agents used in anaesthesia
        - Alpha2 and imidazoline agonists
        - Opioids (anaesthesia)
        - Anticholinergics (anaesthesia)
        - Drugs for reversing neuromuscular blockade
    - Drugs for local anaesthesia
        - Local anaesthetics
3. **Analgesics**
    - Drugs for pain relief
        - Non-opioid analgesics
        - Opioid analgesics
4. **Antidotes and antivenoms**
    - Gastrointestinal decontaminants
    - Antidotes
    - Antivenoms
        - Snake antivenoms
        - Other antivenoms
5. **Anti-infectives**
    - Antibacterials
        - Aminoglycosides
        - Carbapenems
        - Cephalosporins
        - Glycopeptides
        - Lincosamides
        - Macrolides
        - Penicillins
        - Quinolones
        - Rifamycins
        - Tetracyclines
        - Antimycobacterials
        - Other antibacterials
    - Antifungals
        - Azoles
        - Echinocandins
        - Other antifungals
    - Antivirals
        - Guanine analogues
        - Neuraminidase inhibitors
        - Antivirals for viral hepatitis

        - Other antivirals
    - Antiretrovirals
        - Nucleoside reverse transcriptase inhibitors
        - Non-nucleoside reverse transcriptase inhibitors
        - HIV-Protease inhibitors
        - Integrase inhibitors
        - Other antiretrovirals
    - Antiprotozoals
        - Antimalarials
        - Other antiprotozoals
    - Anthelmintics
        - Benzimidazoles
        - Other anthelmintics

6. **Cardiovascular drugs**
    - Drugs for heart failure
        - Aldosterone antagonists
        - Loop diuretics
        - Sympathomimetics (cardiovascular)
        - Other drugs for heart failure
    - Drugs for angina and acute coronary syndromes
        - Nitrates
        - Other antianginal drugs
    - Antihypertensives
        - Thiazide and related diuretics
        - Other diuretics
        - ACE inhibitors
        - Sartans
        - Calcium channel blockers
        - Beta-blockers
        - Other antihypertensives
    - Drugs for arrhythmias
        - Antiarrhythmics
    - Drugs for dyslipidaemia
        - Statins
        - Fibrates
        - PCSK9 Inhibitors
        - Other drugs for dyslipidaemia
    - Drugs for pulmonary hypertension
        - Prostacyclin’s
        - Endothelin antagonists
        - Phosphodiesterase 5 inhibitors (cardiovascular)
        - Other drugs for pulmonary hypertension
    - Drugs for other cardiovascular disorders
        - Drugs for peripheral vascular disease
        - Drugs for orthostatic hypotension
7. **Blood and electrolytes**
    - Anticoagulants
        - Heparins
        - Vitamin K antagonists
        - Direct thrombin inhibitors
        - Factor Xa inhibitors
    - Antiplatelet drugs

        - Glycoprotein IIb/IIIa inhibitors
        - Thienopyridines
        - Other antiplatelet drugs
    - Thrombolytics
    - Other drugs affecting haemostasis
    - Drugs for reversing anticoagulation
    - Drugs for anaemias
        - Erythropoietin agonists
        - Other drugs for anaemias
    - Drugs for anaemias
    - Drugs that chelate iron
    - Drugs for electrolyte imbalance
        - Drugs for potassium imbalance
        - Phosphate binders
        - Other drugs for electrolyte imbalance

8. **Dermatological drugs**
    - Drugs for eczema
        - Corticosteroids (skin)
        - Tars
        - Other drugs for eczema
    - Drugs for psoriasis
        - Immunosuppressants (psoriasis)
        - Other drugs for psoriasis
    - Drugs for acne
        - Retinoids (skin)
        - Retinoids (oral)
        - Other drugs for acne
    - Drugs for skin infections
        - Azoles (skin)
        - Other antifungals (skin)
        - Antibacterials (skin)
        - Antivirals (skin)
    - Scabicides and pediculicides
    - Drugs for warts
    - Drugs for actinic keratoses
    - Drugs for alopecia
    - Other dermatological drugs
9. **Ear, nose and throat drugs**
    - Drugs for ear infections
        - Antibacterials (ear)
        - Corticosteroids with anti-infectives (ear)
        - Antiseptics (ear)
    - Drugs for ear wax
        - Cerumenolytics
    - Drugs for vestibular disorders
    - Drugs for rhinitis and sinusitis
        - Oral decongestants
    - Intranasal decongestants
        - Corticosteroids (intranasal)
        - Antihistamines (intranasal)
        - Other drugs for rhinitis and sinusitis
    - Drugs for other nasal conditions

- Drugs for mouth and throat conditions

10. Endocrine drugs

- Drugs for diabetes
  - Sulfonylureas
  - Dipeptidyl peptidase-4 inhibitor
  - Glucagon-like peptide-1 analogues
  - Sodium-glucose co-transporter 2 inhibitors
  - Other drugs for diabetes
- Drugs for hypoglycaemia
- Drugs for thyroid disorders
  - Thyroid hormones
  - Antithyroid drugs
  - Other drugs for thyroid disorders
- Drugs affecting bone
  - Bisphosphonates
  - Vitamin D
  - Other drugs affecting bone
- Drugs for adrenal insufficiency
  - Corticosteroids
- Drugs for infertility
  - Gonadotrophin-releasing hormone agonists
  - Other drugs for infertility
- Drugs for other endocrine disorders
  - Androgens
  - Antidiuretic hormone agonists and antagonists
  - Growth hormone
  - Nonselective alpha-blockers
  - Somatostatin analogues

11. Eye drugs

- Drugs for eye infections
  - Aminoglycosides (eye)
  - Quinolones (eye)
  - Other antibacterials (eye)
  - Antivirals (eye)
- Drugs for glaucoma
  - Beta-blockers (eye)
  - Prostaglandin analogues (eye)
  - Alpha2 agonists
  - Carbonic anhydrase inhibitors
  - Other drugs for glaucoma
- Drugs for allergic and inflammatory eye conditions
  - Vasoconstrictors (eye)
  - Antihistamines (eye)
  - Mast cell stabilisers
  - NSAIDs (eye)
  - Corticosteroids (eye)
- Other drugs for allergic eye conditions
- Drugs for dry eyes
- Drugs for eye examinations and procedures
  - Anticholinergics (eye)
  - Other drugs for mydriasis
  - Local anaesthetics (eye)

12. **Gastrointestinal drugs**
    - Drugs for dyspepsia, reflux and peptic ulcers
        - Antacids
        - H2 antagonists
        - Proton pump inhibitors
        - Other drugs for ulcers
    - Drugs affecting gastrointestinal motility
    - Antiemetics
        - Dopamine antagonists (antiemetic)
        - 5HT3 antagonists
        - Substance P antagonists
        - Other drugs for nausea and vomiting
    - Laxatives
        - Stool softeners
        - Stimulant laxatives
        - Osmotic laxatives
        - Other laxatives
    - Antidiarrheals
        - Opioid Antidiarrheals
        - Other drugs for diarrhoea
    - Drugs for inflammatory bowel diseases
        - Corticosteroids (gastrointestinal)
        - 5-Aminosalicylates
        - Other drugs for inflammatory bowel disease
    - Drugs for perianal disorders
    - Other gastrointestinal drugs
13. **Genitourinary drugs**
    - Drugs for urinary tract disorders
        - Anticholinergics (genitourinary)
        - Other drugs for urinary incontinence
    - Drugs for benign prostatic hyperplasia and prostatitis
        - Selective alpha-blockers (genitourinary)
        - 5-Alpha-reductase inhibitors
    - Drugs for sexual dysfunction
        - Phosphodiesterase 5 inhibitors
        - Other drugs for sexual dysfunction
    - Urinary alkalinisers and acidifiers
    - Drugs for kidney stones
    - Bladder instillations
14. **Immunomodulators and antineoplastics**
    - Cytotoxic antineoplastics
        - Alkylating agents
        - Anthracyclines
        - Antimetabolites
        - Platinum compounds
        - Taxanes
        - Topoisomerase I inhibitors
        - Vinca alkaloids
        - Other cytotoxic antineoplastics
    - Non-cytotoxic antineoplastics
        - Antineoplastic antibodies
        - Kinase inhibitors

        - Thalidomide analogues
        - Other non-cytotoxic antineoplastics
    - Hormonal antineoplastic drugs
        - Anti-androgens
        - Aromatase inhibitors
        - Gonadotrophin-releasing hormone agonists (oncology)
        - Selective oestrogen receptor modulators
        - Other hormonal antineoplastics
    - Drugs used with antineoplastics
        - Colony stimulating factors
        - Other drugs used with antineoplastics
        - Immunosuppressants
        - Calcineurin inhibitors
        - Corticosteroids
        - Immunosuppressant antibodies
        - mTOR inhibitors
        - Other immunosuppressants
    - Interferons

15. Neurological drugs

- Antiepileptics
    - Barbiturates
    - Benzodiazepines (neurology)
    - Other antiepileptics
- Drugs for parkinsonism
    - Dopamine agonists (parkinsonism)
    - Anticholinergics
    - Monoamine oxidase type B inhibitors
    - Other drugs for Parkinson's disease
- Drugs for migraine
    - Triptans
    - Calcitonin gene-related peptide antagonists
    - Other drugs to prevent migraine
- Drugs for Alzheimer's disease
    - Anticholinesterases in Alzheimer's disease
    - Other drugs for Alzheimer's disease
- Drugs for multiple sclerosis
- Drugs for myasthenia gravis
    - Anticholinesterases in myasthenia gravis
- Drugs for other neurological conditions

16. Obstetric and gynaecological drugs

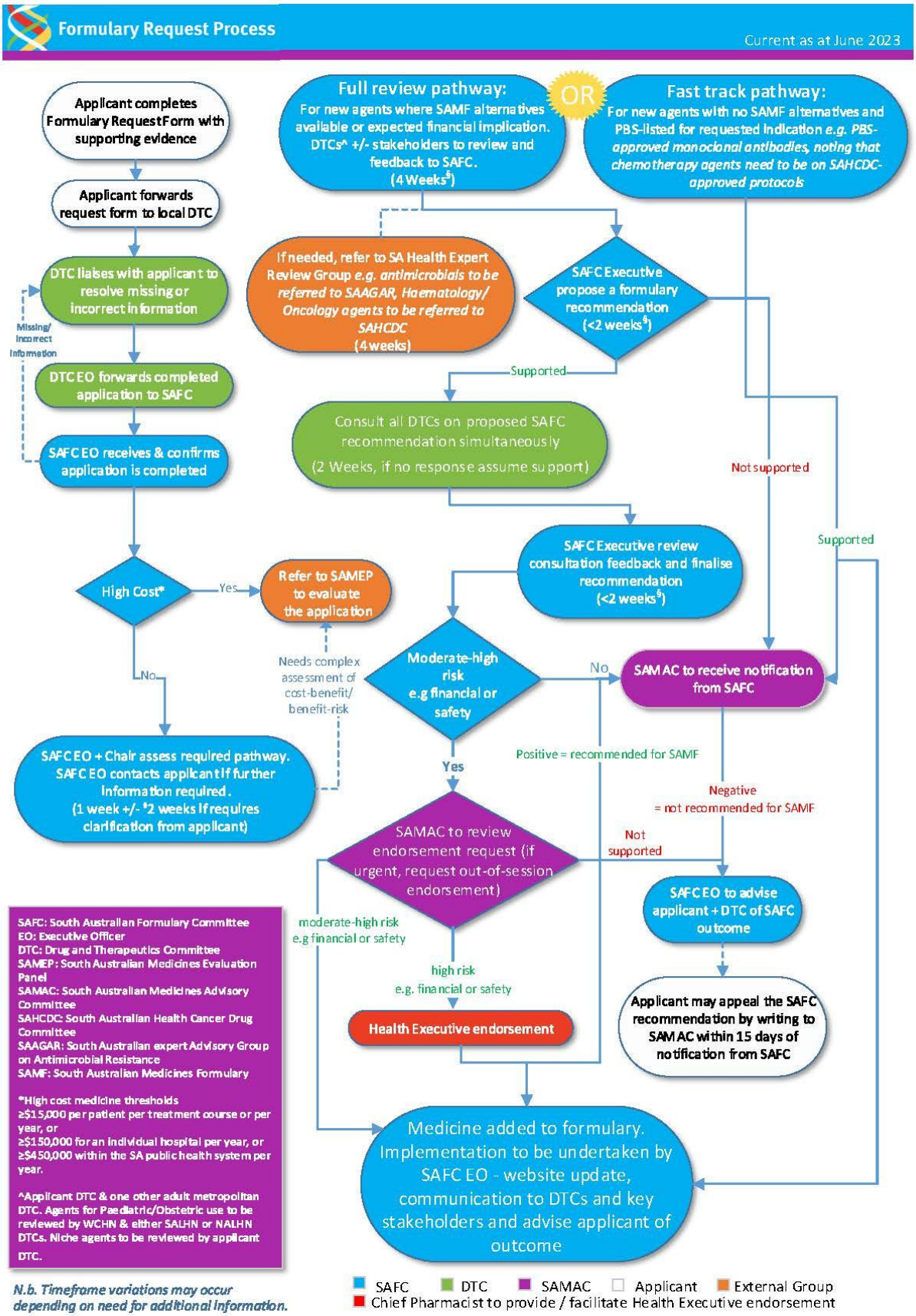
- Drugs for contraception
    - Combined oral contraceptives
    - Progestogens
    - Other combined contraceptives
    - Intrauterine devices
- Drugs for menopausal symptoms
    - Hormone replacement therapy
- Drugs for heavy menstrual bleeding
- Drugs for endometriosis
- Drugs for preterm labour
- Drugs in pre-eclampsia and eclampsia
- Drugs in labour

        - Oxytocic drugs
        - Prostaglandins
        - Other drugs used in obstetrics
    - Drugs affecting lactation
    - Drugs for vaginal infections
        - Azoles (vaginal)
        - Other vaginal anti-infectives
    - Drugs for menstrual symptoms

17. **Psychotropic drugs**
    - Antidepressants
        - Monoamine oxidase inhibitors
        - Selective serotonin reuptake inhibitors
        - Tricyclic antidepressants
        - Serotonin and noradrenaline reuptake inhibitors
        - Other antidepressants
    - Antipsychotics
    - Drugs for bipolar disorder
    - Drugs for anxiety and sleep disorders
        - Benzodiazepines
        - Non-amphetamine psychostimulants
        - Orexin receptor antagonists
        - Other drugs for anxiety and sleep disorders
    - Drugs for attention deficit hyperactivity disorder
        - Psychostimulants
        - Other drugs for attention deficit hyperactivity disorder
    - Drugs for alcohol dependence
    - Drugs for nicotine dependence
    - Drugs for opioid dependence
    - Other psychotropic drugs
18. **Respiratory drugs**
    - Drugs for asthma and chronic obstructive pulmonary disease
        - Beta2 agonists
        - Anticholinergics (inhaled)
        - Theophyllines
        - Corticosteroids (inhaled)
        - Other drugs for asthma
    - Drugs for cough
        - Opioid cough suppressants
        - Mucolytics
    - Drugs used in cystic fibrosis
    - Pulmonary surfactants
    - Other respiratory drugs
19. **Rheumatological drugs**
    - Immunomodulating drugs
        - TNF-alpha antagonists
        - Immunosuppressants (rheumatology)
        - Other immunomodulating drugs
    - Drugs for gout
        - Xanthine oxidase inhibitors
        - Other drugs for gout
    - Drugs for other musculoskeletal conditions
        - NSAIDs

20. **Vaccines**
    - Vaccines
21. **Miscellaneous drugs and late additions**
    - Specialised drugs
    - Blood products
    - Immunoglobulins

Appendix 2: Formulary Request Process



For more information

South Australian Formulary Committee
Medicines and Technology Policy and Programs
SA Health
Health.SAFC@sa.gov.au
www.sahealth.sa.gov.au/SAFC