SA Health

South Australian Medicines Formulary (Establishment and Maintenance)

Framework

Government of South Australia

SA Health

1. Contents

2. Definitions and Terminology

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

2.1 Generic equivalent medicine

Medicines are considered generic equivalents if they have the same quantitative composition of therapeutically active substances, same pharmaceutical form, produce the same therapeutic response and have the same safety and efficacy properties. Generic medicines must adhere to the strict quality standards set by the Therapeutic Goods Administration (TGA), including proof of bioequivalence.

2.2 Biosimilar Medicines

A biological medicine is biosimilar if they are able to demonstrate a degree of similarity to an already approved reference medicine. Biosimilar medicines must adhere to the strict quality standards set by the Therapeutic Goods Administration (TGA), including proof of bioequivalence.

2.3 Therapeutic Alternative

Medicines which differ chemically from each other but provide the same or similar clinical effect when administered to patients. Therapeutic alternatives produce a response through a similar pharmacological action, however as they are not chemically equivalent, clinical and pharmacokinetic effects may differ.

2.4 Therapeutic Class

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

2.5 High Cost Medicine

Those medicines for which the predicted expenditure is:

- ≥$10,000 per patient per treatment course or per year; or
- ≥$100,000 for an individual hospital per year; or
- ≥$300,000 within the SA public health system per year.

Exemptions:

- medicines to be used in a clinical trial that have been approved by the hospital's 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
- low cost medicines which represent a high cost due to high volumes of use (e.g. sodium chloride for injection).

2.6 Restriction

A condition of use for a medicine. Restrictions may be defined on

the basis of clinical indication, prescriber, or location of use.

2.7 Preferred Medicine

A medicine recommended for use in SA Health ahead of other similar medicines. Preferred medicines will be selected from and included in SA Health clinical guidelines where possible.

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

A list of medicines which are approved for 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, first-line medicines for the treatment of the majority of patients for specific indications. Restrictions may be placed on prescribing certain medicines and prescribing notes or clinical protocols on best practice may be linked to medicine listings.

3. Rationale

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

To achieve this goal, SA Health believes that a statewide approach to the availability of medicines will limit duplication of effort and resources, facilitate equity of access, and enable realisation of procurement efficiencies. This will be accomplished by the creation of the South Australian Formulary Committee (SAFC) to establish and maintain the South Australian Medicines Formulary available within SA Health. The SAMF will be based on considerations of efficacy, safety cost-effectiveness and acquisition costs. 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 will allow prescribers to seek approval from their local Drug and Therapeutics Committee (DTC) to access medicines not listed on the SAMF.

The SAMF will form the official formulary for all medicines and pharmaceutical preparations approved for use within South Australian public hospitals and health services. The Formulary will be regularly updated, accessible via electronic means and, over time, will be fully integrated with the Enterprise Patient Administration System (EPAS), prescribing and dispensing software.

4. Background

Quality use of medicines is fundamental to good health care. Appropriate use of medicines can improve the quality of life as well as prolong life. However over recent decades with advances in pharmaceutical science, the range of medicines, their indications for use and overall costs have increased. This has resulted in increased complexity of prescribing, dispensing and administration with associated increased medication related incident risk. In a climate of increasing budgetary pressure across the healthcare system, cost effective medicine purchasing needs to be optimised.

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.

A critical first step in maximizing the therapeutic benefit of public sector expenditure on drugs is rational selection of drug products to ensure that medicines used within the public sector are safe, efficacious, cost-effective and relevant to the needs of the patients being treated (Larmour et al 2011; Walker et al 2006).

The majority of South Australian public hospitals have had local medicines formularies in place for many years and generic prescribing and dispensing is used for most medicines. This practice assists in standardising prescribing within hospitals and increases procurement opportunities for these medicines; however there is considerable variation in formularies between sites.

Currently, most South Australian public hospital Drug and Therapeutics Committees (DTCs) evaluate the safety, efficacy and cost-effectiveness of medicines proposed for use within that hospital to determine if they will be listed on the hospital formulary and any associated guidelines. The South Australian Medicines Evaluation Panel (SAMEP) established in 2011 to evaluate and High Cost Medicines proposed for use within SA Health, according to the policy, 'Statewide Formulary for High Cost Medicines'. Similarly, the South Australian expert Advisory Group on Antimicrobial Resistance (SAAGAR) was established to consider issues relating to antimicrobial resistance in South Australia and is the expert group which advises on how antimicrobials should be used in this state.

Variable decision making by individual hospitals can result in different medicines being used in different hospitals for the treatment of the same conditions and local decision making results in duplication of efforts.

Additionally, a number of South Australian public hospital formularies currently list multiple therapeutic alternative medicines. The development and implementation of a list of medicines from each therapeutic class which may be prescribed within a hospital/health service has shown to result in significant savings (Larmour et al, 2011).

The expanding range and number of medications are associated with increased costs associated with additional stock lines, risk of wastage through expiry and increased error risk in the areas of purchasing and supply. Patient care is known to be compromised by look-alike sound alike selection and administration errors.

Finally, medicines which are known to be safe and effective may not always be prescribed optimally within the public healthcare setting. This may be due to difficulties in accessing unbiased drug information and the high number of medicines which prescribers must familiarise themselves with when working across SA Health sites. Traditionally, many hospitals provided a printed copy

of their hospital formulary to prescribers; however most sites now provide their formulary on the hospital intranet to facilitate easy update and reduce costs of producing the printed formulary book. It was also anticipated that an online resource would facilitate access by prescribers, however many sites report difficulties in intranet access at the time of prescribing and there are also issues relating to the search functionality to retrieve associated guidelines.

The provision of current, unbiased, drug information is essential in any health system that wishes to ensure that drugs are prescribed, distributed, and used appropriately.

5. Aims

5.1 To ensure equity of access to medicines across the South Australian public health system

5.2 To ensure that medicines used within SA Health are safe and clinically-effective.

5.3 To ensure that cost-effective medicines are used within SA Health.

5.4 To provide a standard list of medicines with any restrictions to be used across SA Health.

5.5 To be integrated into EPAS for the implementation of preferred medicines and restrictions.

5.6 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 (eg storage, labelling requirements, etc).

5.7 To optimise the Quality Use of Medicines (QUM) by supporting prescribers to make appropriate, evidenced-based medicines choices

5.8 To avoid frequent changes to listed preferred medicines, optimising purchasing power and reducing change for prescribers (eg medical practitioners, nurse practitioners, etc), pharmacists, nurses, midwives and patients.

5.9 To facilitate 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'.*

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 (Walker et al, 2006). Delays in the

decision making process for evaluating new medicines may result in a high number of Individual Patient Use requests. 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
- Implementing an effective Individual Patient Use (IPU) process for timely access to non-formulary 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.
- Implementation of a communication strategy to ensure engagement and education of all key stakeholders including consumers and community practitioners.

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

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

- Implementing this framework.

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

- Ensuring local hospital formularies reflect 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.

8.3 SAFC is responsible for:

- Determining processes for the evaluation and assessment of medicines to determine formulary listings (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.

8.4 SAMAC is responsible for:

- Establishing SAFC and the implementation of this framework
- Overseeing the operations of SAFC
- Approving decisions of SAFC

8.5 SA Pharmacy is 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 Legislation

- *Controlled Substances Act 1984* (SA) - This act regulates the access of medicines and other controlled substances.
- *State Procurement Act 2004* (SA) - This act regulates the procurement operations of public authorities.
- *Therapeutics Goods Act 1989* (Cth) – This act relates to therapeutic goods within Australia.

10. Relevant SA Health policies, procedures and guidelines

- Complementary and Alternative Medicines (Directive)
- Interaction between SA Health and the Therapeutic Goods Industry (Directive)
- Medicines Access Programs - Product Familiarisation Programs and Expanded Access Programs (Directive)
- Patient's Own Medications (Directive & Guideline)
- Preventing Adverse Drug Events - Documenting, monitoring and Communicating Adverse drug reactions and allergies (Directive & Guideline)
- Procurement policies
- Samples - Product Starter Packs (Directive)
- Statewide Formulary for High Cost Medicines (Directive)

11. Framework Overview

The process for establishment and maintenance of the South Australian Medicines Formulary is summarised in **Figure 1**.

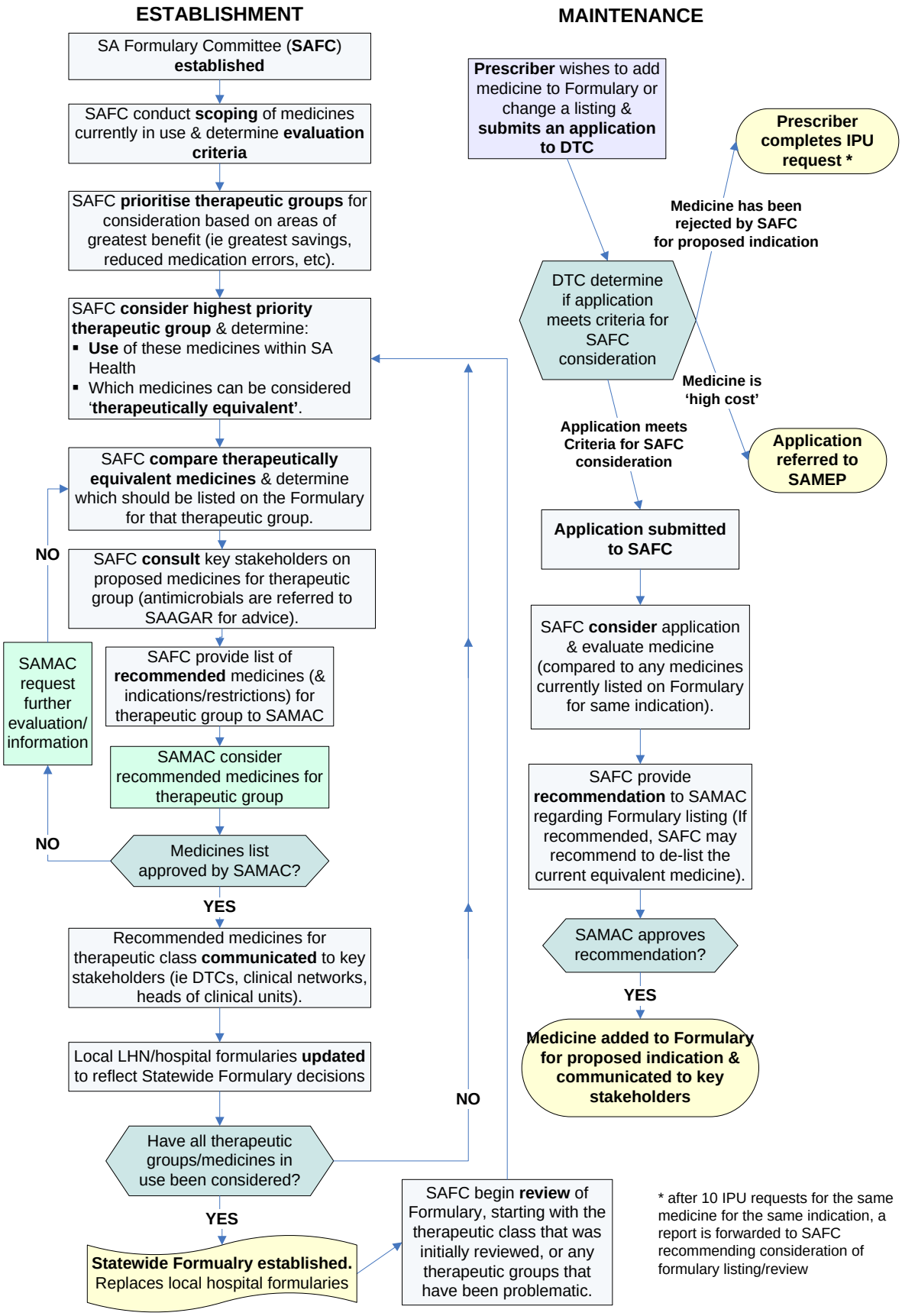

***Figure** 1: Process for the Establishment and Maintenance of a Statewide Formulary within SA Health*

12. Establishment of a SA Formulary Committee (SAFC)

A South Australian Formulary Committee (SAFC) will be established as a sub-committee of the South Australian Medicines Advisory Committee (SAMAC). SAFC will develop and implement policies on medicines selection, evaluation, procurement, safe use, and drug information within SA Health. SAFC may also assist in the formulation of decision support tools relating to medicines to be integrated into the Enterprise Patient Administration System (EPAS).

SAFC will include medical, pharmacy, nursing, economic/epidemiological and procurement expertise as well as consumer advocate(s). Medical representation will be included across a range of specialities, particularly those representing high medicine use.

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.

13. Compilation of Initial South Australian Medicines Formulary(SAMF)

13.1 Consideration of Medicines within Therapeutic Classes

Medicines will be considered in groups according to therapeutic usage (eg 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 SAMF will be developed by reviewing therapeutic classes. As each class is review, its medicines will be added to the Formulary or removed from local formularies.

The Formulary will be developed by reviewing one therapeutic class at a time. As each class is reviewed, more medicines will be added to the Formulary or removed from local formularies. 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 budget.

13.2 Prioritisation of Therapeutic groups

Consideration of therapeutic groups will be prioritised based on areas which greatest benefit can be achieved until eventually all medicines in use within SA Health have been considered and either added to the Formulary or removed from any local hospital formularies where they were listed.

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

- 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 (eg high risk of medication errors).

- Key clinical stakeholder support.

13.3 Determination and Evaluation of 'Therapeutic Alternatives'

A list of 'therapeutically alternative' medicine groups from each therapeutic class will be developed by SAFC, based on current usage, product information and other published evidence as well as expert clinical opinion.

Any medicines which meet the criteria for a High Cost Medicine, as defined in the framework 'A Statewide Formulary for High Cost Medicines' will be referred to the South Australian Medicines Evaluation Panel (SAMEP) for consideration. Similarly, all antimicrobial medicines will be referred to SAAGAR for advice, as antimicrobial resistance is a key consideration in the decision regarding how antimicrobials should be used across SA Health.

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 PBAC
- **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 and on-going patient costs and continuity of supply.
- **Cost of medicine and other associated costs** - Procurement and Supply Chain Management (PSCM) will be involved to determine the lowest price which may be negotiated for a particular medicine if it is chosen as the first-line therapy on the Formulary. The medicine with the lowest therapeutic daily treatment cost will be given high preference in the consideration of the preferred medicine for the therapeutic group.
- **Safety and Quality considerations** – review quality of product packaging and naming (eg look alike sound alike considerations)
- **Confidence in Continuity of Supply –** Public hospital Directors of Pharmacy and PSCM 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.
- **Current usage** - Data obtained from iPharmacy 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.

13.4 Compilation of recommended medicines list for therapeutic group

SAFC will then formulate recommendations regarding which 'therapeutically alternative' medicine(s) should be listed on the Formulary as first-line 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 (eg only to be prescribed by infectious diseases clinicians; only to be initiated by pain specialists, etc), or certain patient groups (eg adults, children, outpatients, etc).

There are sometimes situations where a particular medicine is suitable for the majority 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 genetics. 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 (first-line therapy, second-line therapy, etc). If a prescriber wishes to prescribe a medicine which is not first-line therapy they must demonstrate clinical need to use this medicine (ie already trialled first-line therapy or patient characteristics/contraindications preclude treatment with the recommended first-line therapy).

In some cases, SAFC may not consider there to be a justifiable need for any medicine from a particular 'therapeutically alternative' medicine group 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.

13.5 Consultation on Proposed Medicines List for a Therapeutic Class

When SAFC has considered all medicines within a Therapeutic Class a proposed Formulary will be developed for that Therapeutic Class. Consultation will then be undertaken with key clinical stakeholders (eg DTCs, statewide clinical networks, heads of clinical units and key specialists) to evaluate the acceptability of medicines recommended for inclusion on the Formulary for that Therapeutic Class and the appropriateness of any restrictions. Stakeholders, in particular, the statewide clinical networks will be requested to consider the proposed Formulary listings 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 as well as the total list of medicines considered within that Therapeutic Class, highlighting medicines that were considered to be 'therapeutically alternative' and the rationale for or against the inclusion of specific medicines on the Formulary.

13.6 Communication of new Medicines List for a Therapeutic Class

After reviewing a class of medicines, the Formulary will contain only the medicine(s) selected for that class and restricted prescribing may be immediately implemented only for the medicines in that Therapeutic Class.

It will be critical at this stage to ensure clinician buy-in by communicating listed medicines to all prescribers, outlining the benefits of prescribing the

preferred therapeutic alternatives. Communications will be sent to hospital DTCs advising them to ensure that the medicines listed on their local formulary from within that Therapeutic Class are in accordance with the new Formulary. The medicines list for each therapeutic class will be uploaded onto the SA Health intranet, as the list for each therapeutic class is completed. The medicines will also be loaded into EPAS, along with any restrictions and guidelines, when this system is implemented. Consideration will also be given to the development of an iPhone/iPad/Android application which will provide the list of approved medicines from each therapeutic class, as soon as it is completed. This would facilitate access by prescribers and would be easily updated.

Communications will also be sent to key stakeholders such as heads of clinical units and to statewide clinical networks regarding the new Formulary for that Therapeutic Class 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. These guidelines would eventually be linked to Formulary listings.

In addition, clinical pharmacists will play an educational support role for the therapeutic equivalence concept with health professionals, patients and carers.

13.7 Timeframe

It is anticipated that the compilation of an initial Formulary will take approximately one - two years to complete as it will involve the consideration of over a thousand medicines.

14. 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, pharmacy technicians, and procurement staff involved.

Medicines will be generally admitted to the Formulary under their ‘International Non-proprietary Name’ (INN), or ‘generic’ name, as is the current practice within SA public hospitals. The use of generic names serves to promote purchasing and prescribing by generic name. Exceptions may be made 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 (eg warfarin).

The Formulary listings will include the indication(s) for prescribing as well as any restrictions and associated treatment guidelines (eg restrictions to only certain prescriber types). The Statewide Clinical Networks 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 and associated treatment guidelines will be placed on the SA Health intranet and will also be loaded into the Enterprise Patient Administration System (EPAS), when EPAS becomes available.

In the interim, the Formulary and associated treatment guidelines will be

placed on the SA Health intranet and will also be available in PDF, iPhone/iPad and Android format for ready access by prescribers. As a Formulary is developed for each therapeutic group, preferred medicines from a Therapeutic Group will be listed on the local hospital formulary and medicines from that Therapeutic Group not listed on the Formulary will be removed from the local hospital formulary. Eventually, when all Therapeutic Groups have been considered and evaluated, local formularies will be replaced by the statewide Formulary.

15. Communication Strategy

The development and implementation of an effective communication strategy to ensure stakeholder access and buy-in will be critical to the success of the Formulary.

Ensuring the prescribers have the opportunity to comment in relation to medicines up for consideration by SAFC will further promote clinician engagement in the process.

It will also be 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 would be best achieved using a multi-pronged approach, where communications are sent to prescribers via a number of different media (eg email, printed letters, intranet site, iPhone/Android application, EPAS, direct verbal communications, seminars, academic detailing, etc) and via a number of different pathways (eg directly from SAFC/SAMAC or via DTCs, Heads of Clinical Units, Statewide Clinical Networks, clinical pharmacists, etc).

16. Accessing Medicines listed on the Formulary

16.1 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 trial the recommended first-line therapy before using other non-first-line therapies listed on the formulary, unless there is a strong clinical reason not to use the recommended 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 (see section 17).

Product substitution will not occur at the pharmacy level. If the pharmacist determines that a non-preferred medicine has been prescribed without any reason provided, this matter will be followed-up with the prescriber, rather than automatic substitution.

16.2 Integration of Formulary into EPAS

Integration of the Statewide Formulary into EPAS will be critical to its success. The potential for EPAS to support the Formulary process should be

fully explored.

The Formulary and associated treatment guidelines will be loaded into EPAS when this system becomes available. When EPAS is implemented, compliance with the formulary will be facilitated at the point of prescribing.

The integration of the Formulary into EPAS will include prompts regarding the preferred medicine for the treatment of a particular indication. Further prompts would appear if a prescriber chooses to not to prescribe the recommended first-line therapy, if the system does not indicate that this medicine has already been trialled.

16.3 Formulary Access Prior to EPAS Integration

Until the formulary has been integrated into EPAS, prescribers will access medicines using existing formulary processes and compliance will be facilitated at the point of dispensing. A copy of non-formulary request should be retained in the case notes articulating clear reasons for considered best practice not being appropriate under the special circumstances for that patient. Clinical pharmacists may query where a second-line medicine has been prescribed before the recommended first-line medicine has been trialled.

Access to medicines will be monitored using iPharmacy. Where medicines which are not on the Formulary have been prescribed, the hospital pharmacy will require an associated IPU approval before the medicine may be dispensed.

17. Individual Patient Approvals for Use of Non-listed 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. Applications will be made on the standard Request for Individual Patient Use (IPU) Medicines Form. Requests should be forwarded via the usual local practice.

If the IPU request is for the use of a medicine which has been considered by SAFC and not recommended for listing on the Formulary, then the prescriber must demonstrate to the DTC why there is a specific clinical need for the medicine, over the medicine(s) listed on the Formulary.

If the IPU request is for the use of a medicine which has not yet been considered by SAFC, then the DTC will consider the clinical need for the new medicine for the proposed treatment of the particular patient and the prescriber will be encouraged to complete an application for addition to the Formulary. Regular reports of IPUs considered by DTCs will be forwarded to SAFC for information. When there are 10 IPU approvals for the use of a particular medication for the treatment of the same condition this will trigger SAFC to consider whether the medicine should be listed on the statewide Formulary and/or if any previous formulary decision in relation to this medicine should be reviewed.

Under the *National Healthcare Agreement Rules*, SA public hospitals are only permitted to charge Medicare eligible patients (public or private) for pharmaceuticals upon discharge or for outpatients. Under exceptional

circumstances where a patient wishes to self-fund the cost of their own medicine, a hospital 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.

18. Switching of patients currently taking a medicine not listed on the Statewide Formulary

There will be situations where patients are already taking medicines that are not listed on the Statewide 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 could occur. Processes would differ depending on the circumstances:

18.1 Patient is admitted to hospital who is 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.*

18.2 Patients receiving medicines on a chronic basis from the hospital.

In these cases if the preferred therapeutically equivalent medicines changes 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 first-line 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 taken into account. 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 a number of different medicines used to treat the same indication. A significant reduction in look-alike sound alike equivalents is anticipated.

19. Evaluation of new medicines for inclusion on the Formulary

Once the formulary is established medicines proposed for inclusion to formulary will required a written evaluation comparing the newly requested

drug with current formulary drugs used for the same indications. Criteria for comparison are efficacy, safety and cost.
When reviewing drugs for formulary decisions the following criteria shall be considered:

- 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 (ie safer, easier to use, improved patient acceptability, more efficacious and/or more cost-effective)?
- 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 (eg the PBS)?

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 any evidence for retention.

20. Submissions to Add or Change Medicines on the Statewide Formulary

When the initial Formulary has been established, a prescriber wanting to add a new medicine to the Formulary or seeking a change to an existing listing would direct their request to the hospital Drug and Therapeutics Committee (DTC), or equivalent committee. The DTC (or equivalent) would refer submissions for to SAFC for consideration. Medicines meeting the definition of a High Cost Medicine as defined by the policy '*Statewide Formulary for High Cost Medicines'* will be referred to the South Australian Medicines Evaluation Panel (SAMEP).

The submissions must be made on the standard Submission Form and submitted either electronically, or in hard format to the SAFC Executive Officer.

SAFC Executive Officer will review the application for completeness and to determine if the medicine is suitable for SAFC consideration (ie the medicine does not meet the criteria for a high cost medicine and it has not been previously considered for the same indication by SAFC).

Suitable applications will be reviewed by SAFC. 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.

21. Providing Recommendations to SAMAC

SAFC will provide a report of medicine evaluations to SAMAC, which includes recommendations for or against Formulary listing with a protocol for use of the medicines, including any restrictions on prescribing.

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

A positive recommendation must be approved by SAMAC for a medicine to be listed at any public hospital for the specified indication. SAMAC will issue an instruction to the hospitals indicating whether or not the medicine can be used and any relevant restrictions and/or conditions for its use and this information will be published on the SA Health intranet. When a medicine has been approved for listing by SAMAC, it will be available for use within SA public hospitals and health services. If a decision has been made not to list a medicine on the Formulary, prescribers must submit an IPU request if they wish to initiate that medicine.

Patients being treated chronically with a medicine only provided by the hospital, which has been removed from the Statewide Formulary, must be considered for switching to the new preferred medicine. If there are sufficient clinical grounds for continuation an IPU request will need to be approved by the local DTC.

22. Formulary Intranet Pages

The list of preferred medicines for each therapeutic class SA Health intranet along with any associated approved treatment guidelines. SAFC will be responsible for the administration of the intranet pages.

The intranet pages will also contain information on whether classes of medicines which have been considered and which specific medicines have been considered within that class.

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 Policy Directive and associated Guideline on 'Preventing Adverse Drug Events (Documenting, monitoring and Communicating Adverse drug reactions and allergies).*

Currently, patient outcomes due to treatment are not recorded electronically, so analysis of this data will not be practical until the implementation of EPAS.

While it is anticipated that medication safety will be improved following the implementation of the Formulary, any increases in drug related adverse events following Formulary implementation 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 Audit

The use of medicines within SA Health will be monitored using iPharmacy. 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. Where medicines have been used that are not on the Formulary, a corresponding IPU approval should be found in the hospital's IPU database.

When the Electronic Patient Administration System (EPAS) is implemented

over the next few years, prescribers will only be able to select medicines listed on the Formulary for approved indications unless an IPU approval has been granted and this information will be captured electronically.

23.3 Savings

Savings generated by the implementation of the Statewide Formulary will be calculated 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, approximately every two years. After the initial Formulary has been compiled, the first therapeutic class that was considered for the initial Formulary will be reviewed. A major market change within an existing therapeutic class may warrant an immediate Formulary review.

This framework and its operations will be reviewed after the compilation of an initial Formulary (one to two years).

24. References

Larmour, I., Pignataro, S., Barned, K.L., Mantas, S. and Korman, M.G., 2011, 'A therapeutic equivalence program: evidence-based promotion of more efficient use of medicines', MJA 2011; 194 (12): 631-634

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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
        - Carbapenems
        - Cephalosporins
        - Glycopeptides
        - Lincosamides
        - Macrolides
        - Nitroimidazoles
        - 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
        - Protease 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
        - Potassium-sparing diuretics
        - ACE inhibitors
        - Sartans
        - Calcium channel blockers
        - Beta-blockers
        - Selective alpha-blockers (cardiovascular)
        - Other antihypertensives
    - Drugs for arrhythmias
        - Antiarrhythmics
    - Drugs for dyslipidaemia
        - Statins
        - Bile acid binding resins
        - Fibrates
        - Other drugs for dyslipidaemia
    - Drugs for pulmonary hypertension
        - Prostacyclins
        - Endothelin antagonists
        - Phosphodiesterase 5 inhibitors (cardiovascular)
    - 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 anaemias
        - Erythropoietin agonists
        - Other drugs for anaemias
    - 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)

        - TNF-alpha antagonists (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
        - Insulins
        - Sulfonylureas
        - Thiazolidinediones
        - Dipeptidyl peptidase-4 inhibitor
        - 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
        - Dopamine agonists
        - 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)
        - 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
- Antidiarrhoeals
    - Opioid antidiarrhoeals
    - Other drugs for diarrhoea
- Drugs for inflammatory bowel diseases
    - Corticosteroids (gastrointestinal)
    - 5-Aminosalicylates
    - TNF-alpha antagonists (gastrointestinal)
- Drugs for obesity
- Drugs for perianal disorders
- Other gastrointestinal drugs

13. Genitourinary drugs

- Drugs for urinary tract disorders
    - Anticholinergics (genitourinary)
- Drugs for nocturnal enuresis
- Drugs for benign prostatic hyperplasia and prostatitis
    - Selective alpha-blockers (genitourinary)
    - 5-Alpha-reductase inhibitors
- Drugs for erectile dysfunction
    - Phosphodiesterase 5 inhibitors
    - Other drugs for erectile dysfunction
- Urinary alkalinisers and acidifiers
- Drugs for kidney stones
- Bladder instillations

14. **Immunomodulators and antineoplastics**
    - Cytotoxic antineoplastics
        - Alkylating agents
        - Anthracyclines
        - Antimetabolites
        - Platinum compounds
        - Podophyllotoxins
        - Taxanes
        - Topoisomerase I inhibitors
        - Vinca alkaloids
        - Other cytotoxic antineoplastics
    - Non-cytotoxic antineoplastics
        - Antineoplastic antibodies
        - Tyrosine kinase inhibitors
        - 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
        - Sirolimus derivatives
        - Other immunosuppressants
    - Interferons
15. **Musculoskeletal drugs**
    - Drugs for osteoarthritis
        - NSAIDs
    - Drugs for rheumatoid arthritis
        - TNF-alpha antagonists (rheumatoid arthritis)
        - Immunosuppressants (rheumatoid arthritis)
        - Gold salts
        - Other antirheumatics
    - Drugs for gout
    - Drugs for other musculoskeletal conditions
        - Other musculoskeletal drugs
16. **Neurological drugs**
    - Antiepileptics
        - Barbiturates
        - Benzodiazepines (epilepsy)
        - Other antiepileptics
    - Drugs for parkinsonism
        - Dopamine agonists (parkinsonism)
        - Anticholinergics
        - Other drugs for Parkinson's disease
    - Drugs for migraine
        - Ergot alkaloids
        - Triptans
        - 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

17. **Obstetric and gynaecological drugs**
    - Drugs for contraception
        - Combined oral contraceptives
        - Other combined contraceptives
        - Progestogens
        - 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
    - Drugs affecting lactation
    - Drugs for vaginal infections
        - Azoles (vaginal)
        - Other vaginal anti-infectives
    - Drugs for menstrual symptoms
18. **Psychotropic drugs**
    - Antidepressants
        - Monoamine oxidase inhibitors
        - Selective serotonin reuptake inhibitors
        - Tricyclic antidepressants
        - Other antidepressants
    - Antipsychotics
    - Drugs for bipolar disorder
    - Drugs for anxiety and sleep disorders
        - Benzodiazepines
        - Other drugs for anxiety and sleep disorders
    - Drugs for attention deficit hyperactivity disorder
    - Drugs for alcohol dependence
    - Drugs for nicotine dependence
    - Drugs for opioid dependence
19. **Respiratory drugs**
    - Drugs for asthma and chronic obstructive pulmonary disease
        - Beta2 agonists
        - Anticholinergics (inhaled)
        - Theophyllines
        - Corticosteroids (inhaled)
        - Cromones
    - Other drugs for reactive airways diseases
    - Drugs for cough
        - Opioid cough suppressants
        - Mucolytics
        - Pulmonary surfactants
    - Other respiratory drugs
20. **Vaccines**
    - Vaccines
21. **Miscellaneous drugs and late additions**
    - Specialised drugs
    - Blood products
    - Immunoglobulins

For more information

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