Organization of Eastern Caribbean States/Pharmaceutical Procurement Service (OECS/PPS)
Guidelines on Essential Medicines List (EML)/Formulary Management

OECS Pharmaceutical Procurement Service's regional formulary represents an essential medicines list which is developed to meet the majority of patients' primary healthcare needs. This document describes the criteria for adding and deleting medicines, and the procedure for submissions to the OECS Technical Advisory Committee (TAC).

An EML consists of those medicines intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price that the individual and community can afford.

The medicines on the list are categorized according to Pharmacologic Therapeutic Classifications and bear numerical indications that can be directly referenced to the American Hospital Formulary Service (AHFS) of the American Society of Health-System Pharmacists.

In general, it is our goal that drugs within a given drug class will be included in the formulary based on their efficacy, safety, pharmacodynamics, pharmacokinetics, sites of action and side effect profiles.

Pharmaceuticals sourced through the OECS/PPS are selected from the EML based on economies of scale and availability.

Criteria for selection

The following factors should be considered when specific drugs or drug classes are reviewed for Formulary inclusion

1. **The disease burden:** Consider factors such as local demography and pattern of diseases; treatment facilities; training and experience of the available personnel; local availability of individual pharmaceutical products; financial resources; and environmental factors.

2. **Sound and adequate data on the efficacy, safety:** The medicine's efficacy and safety is the most important consideration in determining whether it can be added to the formulary. The assessment of efficacy and safety is based on an objective evaluation of published data and the experience of clinical staff. This includes information from the following areas:
   • Pharmacodynamic and pharmacokinetic data such as drug absorption, metabolism, excretion, Cytochrome P450 System, and half-life.
   • Risks such as potential to cause a sentinel event, abuse, medication error, “look alike / sound alike” errors.
   • Pharmacoeconomic data such as cost effectiveness in comparison to similar and readily available products.
   • Stability in tropical conditions
   • Dosing interval and side-effect profile
   • The need for special diagnostic or treatment facilities and
   • Pharmacokinetic properties, if appropriate.

When adequate scientific evidence is not available on current treatment of a priority disease, the Committee may either defer the issue until more evidence becomes available, or choose to make recommendations based on expert opinion and experience.

3. **Comparative cost-effectiveness of available treatments:** The impact of cost on a drug's inclusion in the formulary is an important consideration. This factor is of particular importance when comparing several drugs within the same therapeutic class. The cost of total treatment rather than the unit cost of the medicine is considered. Although cost is an important issue, providing high quality patient care remains the highest priority and will not be compromised by cost considerations.

4. **Availability of alternative drugs:** Any drug added to the Formulary must have advantages in efficacy and safety, dosing interval and side-effect profile, or cost. An alternative drug can often be deleted when a more effective drug is added.

5. **Single vs. combination products:** Most essential medicines should be formulated as single compounds, and fixed-ratio combination products are selected only when the combination has proven therapeutic, safety or compliance- advantage over single compounds administered separately.

The Committee shall solicit the advice and recommendations of clinical consultants, if needed, on the usefulness of specific drugs. The principal role of these experts is to assist Committee members to understand the clinical circumstances in which a drug may be useful, and to address the relevant literature. Decisions are based primarily on objective evaluation of published data, rather than the anecdotal experiences of individual physicians.

Any physician, pharmacist and or nurse may request a drug or preparation be added to, or deleted from the Regional Formulary.

Requests for additions, deletions or changes to the Formulary, using the addition/deletions (AD) form, should be submitted through the Central Medical Stores (CMS) Managers, to the OECS/PPS, at least 1 month prior to Technical Advisory Committee (TAC) meeting, for initial review and evaluation.

OECS/ PPS is responsible for editing and maintaining the EML, and the CMS Manager will be responsible for initially notifying the requesting personnel of the OECS Therapeutics Committee decision(s).