

INFORMATION PACK

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MODUS OPERANDI OF THE WA DRUG EVALUATION PANEL

The Western Australian Drug Evaluation Panel (WADEP) is a Sub-Committee of the Western Australian Therapeutic Advisory Group (WATAG). Its current membership is listed in the attached Appendix. These members are appointed for their expertise, rather than as representatives of their organisations.

WADEP undertakes to provide independent advice to WATAG as to the clinical and cost effectiveness of drugs being proposed for use in Western Australian public hospitals. Submissions to the panel should be forwarded by Drug and Therapeutics Committees, or their surrogates. Drugs to be considered by the Panel will include high cost and / or high volume drugs, highly specialised drugs or drugs to which there is significant variation in access across sites. WADEP will only consider unregistered drugs in very exceptional circumstances, where their use has implications for clinical outcomes and cost-effective drug use in Western Australia.

The following categories of recommendation are made by the WADEP:

1. Recommended for general inclusion in the hospital formulary
2. Recommended for inclusion in the hospital formulary with restrictions (to be specified)
3. Not recommended for use at present as further evidence of clinical effectiveness and/or acceptable cost effectiveness is required.
4. Not recommended (reason then given).

All submissions should be made to the local Drug and Therapeutics Committee (DTC) in the first instance. The DTC will then check and sign the submission and return it to the applicant for submission to WADEP. **Five (5) printed copies** (including the signed original) of the Common Submission Form and all supporting documents should be forwarded by posted to

Executive Officer (WATAG)
Royal Perth Hospital
PO Box X2213
PERTH WA 6847

PLUS, an **electronic copy** of the completed Common Submission Form (and any other electronic documents) should be sent via email to:

RPH.WATAG@health.wa.gov.au

WADEP meetings are held in private and are normally scheduled bi-monthly. The lead clinician (or deputy) making a submission may be invited to make a brief supporting presentation at the commencement of the meeting where an application is to be considered. The Panel may also ask questions related to the application. Presenters will be required to declare any conflicts of interest.

Collegiate submissions or those supported by more than one health service will be considered more favourably. Consultation with other prescribers is encouraged, including colleagues internal and external to your institution, and from professional specialty groups.

After evaluation of a submission, WADEP makes its recommendations to WATAG where these are reviewed and a final recommendation prepared. The principle applicant of a drug submission will also receive an evaluation report of the interim WADEP recommendations made to WATAG. The evaluation report will summarise the quality of evidence provided in support of the submission; judgements as to the efficacy, clinical effectiveness, toxicity and cost-effectiveness of the drug considered for use in

the intended population in Western Australia; and comments on the feasibility and scientific rigour of any local protocol or audit methodology proposed by the applicant.

Applicants may wish to seek further clarification concerning the WADEP interim recommendations, and will have an opportunity to express alternative views. The Panel will consider correspondence of this kind, but this does not constitute an appeal and WADEP is not required to respond.

A final recommendation is made by WATAG. Positive recommendations are referred to the State Health Executive Forum (SHEF) Operations Review Committee (ORC) to ensure affordability and corporate oversight of the recommended high-cost drug listing. A positive recommendation must be approved by ORC for a high-cost drug to be listed at any public hospital for the specified indication. **Approval by ORC does not constitute an offer of additional funding for any institution. Health services and applicants should access internal mechanisms to resolve resource implications of a newly approved and listed drug.**

In the case of a negative recommendation from WATAG, the applicant and the ORC are advised of the outcome. Outcomes (positive and negative) of this process are open to appeal by the original applicant. An applicant who wishes to appeal against an outcome should direct their appeal to the WATAG and appeals should be on the basis of procedural unfairness or substantial new evidence. Reapplication for the listing of a drug for the same or similar indication will be considered at the discretion of WADEP on a case by case basis.

GUIDANCE NOTES FOR COMPLETION OF THE COMMON DRUG SUBMISSION FORM

BEFORE YOU START:

Please ensure that you are using the most up-to-date version of the Common Drug Submission Form as these documents are periodically updated. If you are in any doubt, please contact the Executive Officer of the WATAG to check that you have the current version: Tel: 08 9224 2819; Fax: 08 9224 3797, email: RPH.WATAG@health.wa.gov.au (the form is dated in the bottom right hand corner).

Please read the information regarding the WADEP, its structure, its decision-making processes and how it conveys its decisions. Please note that the WADEP will not, in general, consider unregistered drugs, but in practice may consider such drugs if this has implications for clinical outcomes and/or cost-effectiveness in Western Australia.

COMPLETING THE DOCUMENTATION

The 'Common Drug Submission Form' is to be used for all WADEP and Non-WADEP applications. Submissions to WADEP require completion of sections A and C only. Section B is for local drug submissions for Non-WADEP drugs. In order for the submission to be considered by WADEP, all relevant parts of the form are to be completed. If a section cannot be completed, justification for this, and any additional information, should be given in a covering letter. The submission should be completed by a clinician and a clinical pharmacist. The pharmacist should contact the Executive Officer of the WATAG as soon as possible to register that the drug is being submitted. This will facilitate collaboration and ensure that no one else has already done the work.

Please note that the boxes in the form expand with the text. The submission form has been designed to be completed electronically and may be "locked" to allow <Tab> movement from one text field to the next. When completing the submission, please ensure that your response appears in a different font than the questions.

SECTION A

PART A 1 GENERAL INFORMATION

A 1.1 Applicant details

Please provide all requested details and provide names and a contact e-mail address for each listed applicant.

A 1.2 Brief description of drug, indication and rationale

Please provide all requested details. When responding regarding rationale for the proposed drug please:

- use the approved drug name throughout, not the brand name
- state the precise indication(s) for which approval is sought
- present reasons why this drug should be prescribed at your hospital
- indicate whether it is intended for first, second or third line treatment

A 1.3 Target population

Please indicate the target population by checking one of the boxes provided. If you are recommending restrictions, please detail these including restrictions to prescribing according to medical speciality and special clinics, for example.

PART A 2 DRUG INFORMATION & STATUS

A 2.1 Published Information

All WADEP applications - Please attach the manufacturer's approved Product Information.

A 2.2 TGA registration

Please provide details on regulatory status using the exact wording from the appropriate registration.

A 2.3 Pharmaceutical Benefits Scheme (PBS) availability

Please indicate if the drug is listed under the PBS and if so, provide exact wording of each indication listed. If not PBS listed, check 'No'.

If the drug is intended for use with outpatients, please explain why the hospital should provide a PBS listed drug in this instance.

A 2.4 Availability in other jurisdictions

If the drug is currently available in other states of Australia or overseas countries please provide details that may assist the evaluation of the current submission, including regulatory status in these other jurisdictions, where appropriate.

PART A 3 CURRENT THERAPIES & PLACE OF NEW DRUG

Questions A 3.1 to A 3.3

In the areas indicated, please identify current practice and how this will be changed by the introduction of the new drug under consideration. Please specify what current treatments, if any, can be used as the comparator (treatment currently used for this indication). In some cases, surgical treatment may be the only valid comparator. Outline the proposed status of this new treatment within existing practice and provide details of therapies that could be replaced if this request is approved.

A 3.4 Clinical guidelines and protocols

As indicated please provide details of prescribing criteria appropriate to use of the drug and attach any prescribing guidelines or protocols.

A 3.5 Similar new products

Please list any new products under development and indicate if they are likely to reach the Australian market in the next 12 months.

PART A 4 BENEFITS RELATIVE TO EXISTING TREATMENTS

A 4.1 to A4.4 Existing Treatments and Comparator Drugs

Please identify the comparator drug/treatment used in pivotal trials to assess benefit. This is the closest pharmacological analogue and will usually be indicated in the manufacturer's documentation.

Using this comparator and the new drug compare the effectiveness, toxicity and other benefits or disadvantages of each and provide the details where indicated. Please be

as specific as possible and provide supporting evidence such as the sources of information and any methods of estimation.

PART A 5 DRUG COSTS

Using the same comparator described in part A 4, please complete the required cells in the tables for intermittent A 5.1(a) or continuous A 5.1(b) treatment regimens, respectively. Please provide as much detail as possible.

The estimated total cost per patient, per year must be provided.

PART A 6 CLINICAL TRIAL EVIDENCE

A 6.1 Pivotal Studies

Full copies of references should be submitted for each of the pivotal randomised controlled trials (RCTs) cited.

A 6.2 Other References

References supporting the submission but not considered pivotal studies, should be cited under "Other References". You are strongly encouraged only to submit evidence that has been peer-reviewed. However, other evidence will be considered if referenced. Up-to-date evidence should be submitted where possible. The search strategy/methodology should be stated.

It is the applicant's responsibility to include all the relevant literature and provide the WADEP with an unbiased, balanced report of the available evidence. Selective quoting of evidence in support of the submission would not be appropriate.

SECTION B: TO BE COMPLETED FOR LOCAL (NON-WADEP) SUBMISSIONS ONLY

SECTION C: TO BE COMPLETED FOR ALL WADEP SUBMISSIONS

PART C 1 DISEASE INCIDENCE AND PREVELANCE

Please provide estimates as indicated of proposed use in WA to reflect the level of anticipated use.

All estimates and projections must be justified and supported by providing the sources of information and methods of estimation. Approval of any drug will be strictly limited to the criteria in this proposal. If approved, actual use of any drug will be subject to clinical audit by comparison against approved criteria.

PART C 2 COST-EFFECTIVENESS ANALYSIS

C 2.1 Analysis based on intermediate outcomes (symptoms)

Complete all fields giving the incremental annual cost per patient from table A 5.1 and the estimated quantitative incremental change in symptoms per patient per year. Then calculate the cost-effectiveness of the proposed therapy using the figures from A + B.

C 2.2 Analysis based on survival benefit, if any.

Complete all fields where possible or provide an alternative means of economic analysis with justification. Non-drug incremental treatment costs and significant cost offsets may be important and these should be provided where possible.

C 2.3 Supplementary

Please provide details of supporting information or calculations used in the survival benefit analysis.

PART C 3 INPUT FROM OTHERS

C 3.1 Stakeholder consultation

As described, please provide details of any consultation with relevant clinical colleagues in support of this application. In particular please state if this application is supported by professional colleagues at other institutions.

One of the objectives of WADEP is to provide uniform listing of high-cost drugs at health services in WA. Consultation with stakeholders is encouraged and collegiate submissions or those supported by more than one health service will be considered more favourably. Summarise any consultation with your colleagues both internal and external to your institution, including interstate, and indicate current usage at institutions other than your own.

C 3.2 Other Involvement

Please provide details of any assistance given during completion of the submission. If a pharmaceutical company was involved in providing information or preparing the submission, you must check the box provided.

PART C 4 SUPPORTING SIGNATURES FOR WADEP SUBMISSION

The submission must be signed by the Chairman of your hospital Drug & Therapeutics Committee.

POTENTIAL CONFLICT OF INTEREST

It is essential that you answer this question by ticking yes or no as indicated. If any potential conflict of interest exists please check the "YES" box and indicate the nature of the potential conflict by marking boxes 1 to 6 as appropriate, AND provide details of potential conflicts in the space provided. If no potential conflict of interest exists, please check the "NO" box.

Note: A potential conflict of interest will NOT usually exclude a submission but is important for WADEP to make a fully informed decision.

Please make sure you read the information regarding the WA Drug Evaluation Panel, its structure, its decision-making processes and how it conveys its decisions.

New drug meeting WADEP criteria for high-cost

- more than \$300,000 annually within the WA health system, or
- more than \$100,000 annually for an individual health service, or
- more than \$10,000 annually for an individual patient

