

Application to use a New Medical Device Containing Medicine(s)

Use this form to apply for:

- approval to purchase and use a new medical device which contains medication(s)
- approval to use a medicine(s)-containing medical device for a new indication (i.e. for indication not previously approved)
- approval for use of a medicine-containing device under other circumstances (e.g. Device Access Program or similar)

It is intended that a multidisciplinary, collaborative approach is used to complete this form. Some submissions may not require all sections of the form to be completed. Prior to submitting the completed form to the Drug and Therapeutics Committee, it is recommended that advice from a member of the Drug and Therapeutics Committee/hospital pharmacy department is sought. Local clinical governance processes should determine the means by which communication and collaboration with the Hospital/District Device Committee (or similar) occurs.

1. Product profile

Australian Approved Device Name	
Manufacturer/Supplier	
Medicine(s)	
Pharmacological class and action of medicine(s) [Summary]	

NOTE: If this medication is an antimicrobial, sign-off is required by Infectious Diseases prior to DTC consideration. (See page 7)

2. Indication(s) for use

Category of medical device (please tick):

- Bone cements containing antimicrobials
- Dressings containing medications (e.g. silver sulfadiazine, antimicrobials)
- Drug-eluting devices such as stents, prostheses, cardiovascular devices, beads
- Supportive devices such as meshes, patches and tissue adhesives
- Implantable devices, including insulin pumps and analgesic elastomeric pumps
- Other

What are the proposed indication(s) for use of the device in the hospital?

Is the medical device registered by the Therapeutic Goods Administration for these indication(s)?

YES / **NO**

If NO, under what circumstances is the medical device being supplied?

Is this device already in use in the hospital for other indications?

YES / **NO**

Please provide details:

Is this device to be used as part of a device access program?

YES / **NO**

If YES, please provide details:

Proposed dose/concentration to be administered to individual patients		As per product registration? YES <input type="checkbox"/> / NO <input type="checkbox"/> Provide further details if NO
Proposed duration of use in individual patients		As per product registration? YES <input type="checkbox"/> / NO <input type="checkbox"/> Provide further details if NO
How will device use be documented in the medical record		

Are there other devices available in the hospital for the same purpose and indication? **YES** / **NO**

If yes then provide details:

Provide justification for why a new medical device or use for a new indication is requested:

Is the device in use in other NSW public or private hospitals? If yes provide details:

<p>Is usage limited to a defined group of specialists?</p> <p>Is accreditation/training required?</p> <p>If yes then who will provide this accreditation/training?</p>	<p>Detail:</p>
<p>Proposed place in therapy:</p> <p>Describe parameters for patient selection.</p> <p>Which patient groups are most likely to benefit?</p> <p>Will this device be used as first-, second- or third-line therapy?</p>	

Attach relevant supporting documentation (e.g. usage protocols, consensus guidelines, approval by overseas agencies, published data, clinical trial data, etc.)

3. Comparative Safety and Efficacy

- When submissions are for TGA-approved indications the product information documentation may provide some of the information required below

Comparative safety:

- Include names of comparators. If necessary attach additional information as a separate document.
- If there is no therapy currently available for this indication then please reference other appropriate comparators.

Significant adverse effects*	Device under consideration:	Current therapy available:
Common <i>(i.e. incidence of 1% or more)</i>		
Infrequent or Rare <i>(i.e. incidence of 1% or less)</i>		

Main benefit in safety*	Device under consideration:	Current therapy available:
Incidence of main adverse event expressed as a percentage: <i>Specify (e.g. stroke, mortality, allergic reaction, etc.).</i>	%	%

Main benefit in effectiveness*	Device under consideration:	Current therapy available:
Incidence of main effectiveness outcome measure expressed as a percentage: <i>Specify outcome measure (e.g. cure rate, relapse rate) and whether measure represents a surrogate marker or an actual health outcome.</i>	%	%

Additional benefits*	Device under consideration:	Current therapy available:
<i>Specify (e.g. surgery or procedure averted, admission averted, reduced length of stay, etc.).</i>		

*Reference the sources used for above data.

4. Comparative costs of therapy:

<i>Include names of comparators</i>	Under consideration	Alternative (1)	Alternative (2)
a. Average cost per device			
b. Average number of devices used per treatment			
c. Cost per treatment (a x b)	\$	\$	\$
d. Additional costs per patient per treatment <i>(e.g. monitoring requirements, additional equipment/drugs, etc.)</i>	\$	\$	\$
e. Total cost per treatment (c + d)	\$	\$	\$
f. Expected number of treatments per year/patient <i>(Include the basis for this estimate)</i>	\$	\$	\$
g. Annual cost per patient (e + f)	\$	\$	\$
h. Estimated number of patients/year			
i. Total annual cost (g x h)	\$	\$	\$
j. Annual Difference (new – current cost)		\$	\$
k. Cost offsets if new device introduced:			
l. Proposed funding source:			

5. Issues regarding safe use

Product packaging and labelling

E.g. is product nomenclature likely to lead to confusion in selection? Is packaging clearly labelled? Is each device labelled in such a way to allow identification up to the point of use? Does packaging facilitate clear and practical storage? Are appropriate instructions for use available?

Education

E.g. will hospital staff require training regarding prescribing, handling or administration? Are there any WHS issues?

6. Contributors to this submission

Name	Profession/Affiliation (e.g. Medical, Nursing, Drug Company/Industry, Pharmacy)

7. Conflicts of Interest of applicants

If the applicant has received funds, or may receive future benefit from companies or other institutions, there may be a real or perceived conflict of interest from your application. This could include, but is not limited to:

- (a) Shareholdings (does not include mutual fund ownership) and/or board membership
- (b) Paid employment, including consultancy, commissioned fee-paid work, paid speaker, paid expert advisor
- (c)
- (d) Fellowship, research grant, education grant
- (e) Travel grant or conference fees or other hospitality or gift
- (f) Any other direct or indirect pecuniary interest

Declaration of potential or actual conflict of interest which may be relevant to this application:

- Gifts
- Industry paid food/refreshments
- Travel expenses
- Honoraria
- Samples
- Research support
- Other _____
- Nil conflict of interest

Details:

Please Note: This declaration of conflict of interest must be completed for all relevant applicants.

8. APPROVAL PROCESS

The following must be completed prior to submitting application to the DTC

Infectious Diseases implications:

If the device contains an antimicrobial then approval must be provided by Infectious Diseases:

Name of Director Infectious Diseases			
Signature		Date	

Details of Applicant:

Name of Applicant			
Position / Appointment			
Signature		Date	

Endorsed by:

Name of Manager of Department			
Signature		Date	

Executive sign-off

The Executive is aware of the financial implications of addition of this product and accepts these as reasonable:

Name of Executive			
Signature		Date	

Now complete checklist ►

- All sections of form completed (including endorsement)
- Supporting data attached (relevant papers, consensus guidelines, etc.)
- Prescribing criteria/protocol/guideline attached

✦ Forward completed form to Pharmacy with supporting data and relevant protocol/guideline.

Pharmacy may be contacted on

(phone)

or

(email)

for questions or discussions regarding this application.

FOR DRUG AND THERAPEUTICS COMMITTEE USE ONLY

Comparative Approvals:

Has this device been considered for approval by other DTCs in NSW public hospitals? **YES / NO**

If **YES**, list relevant DTCs and their decisions. (NB: Information available via NSW TAG)

Outcome of application process:

Process	Date/Detail/Notes
Application received (Date)	
Application considered (DTC meeting date)	
Outcome: <input type="checkbox"/> Approved <input type="checkbox"/> Rejected <input type="checkbox"/> Deferred	
Conditions of approval (specify)	
Review requested <input type="checkbox"/> Yes <input type="checkbox"/> No Detail review date and audit specifications:	
Applicant advised of outcome (Date)	

Signed on behalf of DTC: _____
 (Chairperson)

Date: _____

Acknowledgment: NSW TAG wishes to acknowledge the work of the JHH QUM Committee in the development of this application form.