**Please read this before completing the application form:**

All the notes in RED are for completion in full by Applicant. All sections in RED must be completed (and the red print deleted) before submitting the form

All the notes in BLUE are for your guidance on completing the form. Please remove / delete all the notes in BLUE before submitting the form.

**Guidance on completing the form**

* Section 1 and 2 will be completed by the relevant Principal Pharmacist or Principal Pharmacist to MK PAG; this will normally be carried out once Section 3 has been completed and any issues discussed with the applicant.
* Section 3 will be completed by the applicant
* Your submission should be comprehensive and indicate which, if any, information has been supplied by a pharmaceutical company.
* **The application must reflect consensus from your directorate / CSU / specialty / area.**
* **Each submission must be countersigned by a professional with accountability for clinical and budget management in your organisation. These are:**

|  |  |
| --- | --- |
| **Clinical Management** | **Budget Management** |
| **MKHFT - Clinical Director of the relevant CSU or** | **Finance Business Partner of the relevant** **CSU / Trust** |
| **MKCCG – Chief Pharmacist or** |
| **CNWL-MK - Medical Director** |

**Applications from Milton Keynes Hospital NHS Foundation Trust**

* Send a signed hard copy to Principal Pharmacist, MKPAG at MKUHFT
* Send electronic copy to michelle.mccarthy@mkuh.nhs.uk

**Applications from MKCCG**

* Send hard copy to Chief Pharmacist MKCCG
* Send electronic copy to janet.corbett@nhs.net

**Applications from CNWL – Central and North West London NHS Foundation Trust, MK**

* Send a signed hard copy to Chief Pharmacist CNWL-MK
* Send electronic copy to anne.tyrrell@nhs.net

**Notes**

MKUHFT and MKCCG and CNWL-MK will inform each other immediately, via chief pharmacists, where drug use or the effect on patient pathways of an application is relevant to their organisation.

**Submission to MKPAG**

* MKPAG Meetings are scheduled for the last Wednesday of every odd number month. i.e. May, July, September, November, January, March.
* Applications should normally be submitted at least one month before the meeting, whenever possible.
* The MKPAG Principal Pharmacist will notify you of the date of the meeting when the application will be considered, subject to the receipt of all necessary information including that relating to sources of funding.
* You will be invited to attend to put forward the case for inclusion and answer any questions the group may have. If you are unable to attend you may send a representative on your behalf or request to defer to a later meeting date. Submissions will be considered, at the discretion of the MKPAG Chairman, in the absence of the applicant if appropriate information is available at the time when the agenda and papers are prepared.
* Applicants will not be present when the MKPAG discusses its recommendation.

We suggest that you contact your organisation’s pharmacy/medicines management service before you complete this form, so that we can help you with the process and advise on relevant issues.

**SECTION 1**

**Date of Meeting: To be completed by pharmacy Agenda Item to be completed by MKPAG secretariat**

|  |  |  |
| --- | --- | --- |
| **What is the item?**  | **Generic name:****To be completed by applicant** | **Brand name:****To be completed by applicant** |
| **Manufacturer: To be completed by applicant** |

|  |  |
| --- | --- |
| **Who is bringing this to the MKPAG?** **To be completed by pharmacy** | **Designation:****To be completed by pharmacy** |
| **Supporting Pharmacist:** In hospital, this will be the Principal Pharmacist for your CSU**To be completed by pharmacy** | **Designation:****To be completed by pharmacy** |

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| **Why is this being brought to the MKPAG?** **To be completed by pharmacy** |

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| **What is the MKPAG being asked to discuss?** **To be completed by pharmacy** |

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| **What are the options available? To be completed by pharmacy****Option 1:** **Option 2:** **Option 3:**  |

|  |
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| **Recommendations, Evidence level and summary key points for consideration:** **To be completed by pharmacy** |

**SECTION 2**

|  |
| --- |
| **Introduction and description of new medicine for review or new use for a medicine already on the formulary at** [**www.formularymk.nhs.uk**](http://www.formularymk.nhs.uk)***This box will expand*** |
| **BNF Category: To be completed by pharmacy** |

**SECTION 3 – To be completed by applicant**

|  |  |  |
| --- | --- | --- |
|  | **Medicine (Generic and Brand name)** | **To be completed by applicant** |
|  | **Strength and formulation** | **To be completed by applicant**  |
|  | **Licensed indication** | **To be completed by applicant**  |
|  | **Dosage and administration** | **To be completed by applicant**  |
|  | **Intended indication and dose (if different from above)** | **To be completed by applicant**  |
|  | **Course length** | **To be completed by applicant**  |
|  | **Place in therapy relative to alternative treatments** | **To be completed by applicant**  |
|  | **Does this medicine replace one already on the formulary?** **If so, which one(s)?** | **To be completed by applicant**  |
|  | **List any potential additional benefits of the new medicine**  e.g. route of administration, side effects, reduced need for community input | **To be completed by applicant**  |
|  | **Patient Safety - adverse effects****Link to SPC (eMC)** | **To be completed by applicant**  |
|  | **Impact on Patient Choice and/or Equity of access** e.g. effect patient pathway; differential responses by age or ethnicity | **To be completed by applicant**  |
|  | **Clinical effectiveness / Evidence for use** Information to include Numbers Needed to Treat (NNT),and Numbers Needed to Harm (NNH) from relevant, good quality clinical trials.**Please supply references** | **To be completed by applicant**  |
|  | **Please provide a brief summary of the condition being treated, including morbidity, quality of life and mortality estimates** | **To be completed by applicant**  |
|  | **Proposed sector of prescribing;** Primary Care or Secondary Care or Both | **To be completed by applicant** |
|  | **If added to the formulary would GPs be asked to initiate treatment?** | **To be completed by applicant**  |
|  | **Will the GP be asked to continue treatment started in secondary care?** If yes, MKPAG may request you produce a written “shared care” protocol | **To be completed by applicant**  |
|  | **Has the support of the Milton Keynes CCG Prescribing Group been obtained for prescribing in primary care?**If you answered “YES” to question 15 or 16, MKPAG secretariat will confirm the response from the Milton Keynes CCG Prescribing Group via Janet Corbett janet.corbett@nhs.netYou may expect a response within a week, including whether this will need to discussed at the full GP prescribing group meeting. | **To be completed by Pharmacy** |
|  | **Is this drug for this indication excluded from the PbR Tariff and what information do you have on whether it funded by commissioners?**  | **To be completed by applicant**  |
|  | **Medicine Cost** (Specify: Prices from MIMS, BNF, hospital pharmacy and whether VAT is included) | **To be completed by applicant**  |
|  | **What monitoring is required? Are there any other costs associated with prescribing this medicine?** e.g. blood tests | **To be completed by applicant**  |
|  | **Cost effectiveness or resource impact and cost comparison data if available.****MKHFT Business case requirements*** **If the drug requested is to be used within the hospital, either for treatment initiation for hospital out-patients, or for prescribing for in-patients or as part of hospital-only procedures, and any additional costs will be incurred, then a business case may need to be completed for the Division.**
* **Information on these requirements can be obtained through pharmacy or from your Divisional managers.**
 | **To be completed by applicant** |
|  | **Potential number of patients in MK. Please state either** * + - Estimated number of patients likely to be treated annually in Milton Keynes (and specify whether this relates to CCG or hospital)
		- Impact per 100,000 population
 | **To be completed by applicant**  |
|  | **Disinvestment** * + - How will this medicine help to address local health priorities?
		- By using this medicine, what disinvestment in other medicines, interventions and services would be possible?
		- How much would this save?
		- Affordability considerations.
		- Will this medicine help to address local health priorities?
 | **To be completed by applicant**  |
|  | Decisions from national bodies and policy drivers | **To be completed by applicant** What are the decisions from the following national bodies about this drug / device?Please give details, where available.1. **National Institute of Health and Care Excellence (NICE)**
2. **Scottish Medicines Consortium (SMC)**
3. **All Wales Medicines Strategy Group (AWMSG)**
4. **Professional guidelines e.g. Royal College of ……**
 |
|  | Stakeholder views (Complete all boxes with details; boxes will expand) | **To be completed by applicant**

|  |  |
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| **Please specify whether any of the following have been consulted** | **Yes or NO** |
| Specialist doctors and / or specialist nurse prescribers, MK specialists |  |
| Patients / Public |  |
| Manufacturers |  |
| Specialist group(s) |  |

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| **APPLICANTS DETAILS**  |
| **Name of applicant** | **To be completed by applicant** Specify whether you are a Hospital Consultant, GP, Pharmacist, Independent Prescriber |
| **Department/Specialty:**  | **To be completed by applicant** |
| **Signature:** | **To be completed by applicant** |
| **Date:** | **To be completed by applicant** |

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| **COUNTERSIGNATORY – CLINICAL LEAD** |
| **Name:**  | **To be completed by the person with overall clinical responsibility.** Specify whether you are the MKUHFT Clinical Director Or MKCCG Chief Pharmacist Or CNWL-MK Medical Director |
| **Signature:** | **To be completed by person named above**  |
| **Date:** | **To be completed by person named above** |

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| **COUNTERSIGNATORY - FINANCIAL****Note that drugs cannot be added to the formulary until confirmation has been received by pharmacy MKHFT that budgetary impact of any changes is known and has been agreed.****The countersignature required here should indicate that appropriate steps have been taken and agreement on the source of the budget is in place. (See Section 3 boxes 17 and 21.)** |
| **Name:**  | **To be completed by relevant Finance Business Partner** Specify your designation |
| **Signature:** | **To be completed by person named above** |
| **Date:** | **To be completed by person named above** |

**The applicant is required to complete a declaration of interest form. This is a separate document and can be found in appendix 1 below.**

**Statement on Competing Interests (‘Potential Conflict of Interest’)**

**Appendix 1**

## PLEASE COMPLETE THE DECLARATION AFTER READING THESE NOTES

This applies to both medical and non-medical personnel.

Members, reviewers and all those who provide comments on medicines selection, use or promotion, e.g. in the Formulary, Pathways or other document(s) setting out information of a similar nature, are asked to declare to the Chairman of Milton Keynes Prescribing Advisory Group (MKPAG) any potentially competing interests relating to any item to be discussed, or on which they are making comment, by signing a ‘Declaration of Potential Conflict of Interest’ form in the format agreed by the Clinical Director of Pharmacy and Medical Director.

Members are requested to declare any and all potential conflicts of interest arising from their contacts with grant-awarding bodies, the pharmaceutical industry or other commercial organisations.

Only the existence of a potentially competing interest, the individual and/or organisation concerned and the nature of the interest need be recorded. The amount of any fees, grants etc. need not be disclosed.

This is consistent with the principles set out for medical journals e.g. BMJ <http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/declaration-competing-interests>

At the beginning of the financial year, members need to register their financial and other interests. If any assistance is required in order to complete this form, then the member or employee should contact the Principal Pharmacist, MKPAG or the Clinical Director for Pharmacy via

Michelle.McCarthy@mkuh.nhs.uk

Any changes to interest declared must also be registered within 28 days of the relevant event by completing and submitting a new declaration form.

A record shall be kept by MKPAG Secretariat of declarations of potentially competing interests relating to medicines use, and the related action taken by the MKPAG Chair. This will then be used to help meet NHS standards on probity and on the declarations of interests.

The Register of Declarations of Interest will be reported to each meeting of MKPAG.

|  |
| --- |
| **Declarations should include existing interests and those arising** **over the past 12 months or planned for the next 12 months.** |

It shall be for the meeting Chairman to decide on the action to then be taken regarding participation in the discussion and subsequent decisions relating to that product or issue.

Members and employees completing this declaration form must provide sufficient detail of each interest so that a member of the public would be able to understand clearly the sort of financial or other interest the member or employee has and the circumstances in which a conflict of interest with MKPAG decisions might arise.

**Appendix 1**

**Competing interests exist when professional judgement concerning a primary interest may be influenced by a secondary interest. Competing Interests will be defined in the manner used by the British Medical Journal i.e.**

* “A competing interest exists when professional judgement concerning a primary interest (such as patients’ welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise when they have a financial or other interest that may influence – probably without their knowing – their interpretation of their decisions or those of others”.
* Conflict of interest is a state, not a behaviour and exists whether or not judgement is actually influenced by competing interests.

Milton Keynes University Hospital NHS Foundation Trust and Milton Keynes Prescribing Advisory Group asks that potentially competing interests are declared by: all persons who submit applications; MKPAG members; reviewers; and those who provide comments.

The types of interest that should be declared include, but are not limited to:

### Personal Interests

Personal interests in an organisation (e.g. a pharmaceutical company) that may in any way gain or lose financially from work undertaken on behalf of the meeting. Personal interests include consultancies, fee-paid work or directly managed shareholdings (but not shareholdings through unit trusts or similar).

### Non-Personal Interests

Non-personal interests in an organisation that may in any way gain or lose financially from work undertaken on behalf of the meeting. Non–personal interests are those that benefit a department for which the member is responsible, or in which they work, but not the member personally.

Examples of non-personal interests include fellowships, grants for the running of a unit or department, sponsorship of a post or member of staff, commissioned research or other work from staff in the unit and, sponsorship of attendance at scientific or similar meetings.

### Other Potential Conflicts

We would also ask reviewers and those who provide comments to declare other potential conflicts of interest. For example, former employment in an organisation that may in any way gain or lose from work undertaken on behalf of the hospital, political or religious convictions which might influence conclusions, or academic or personal links with somebody whose interests may be affected by decisions made and advice given to/by the meeting.

**Declaration of Potential Conflict of Interest**

|  |  |
| --- | --- |
| Name:**Appendix 1**(Please print) | **To be completed by applicant** |
| Organisation:(Circle) | MKUH NHS FT / MK CCG / CNWL-MK / Other (specify): |
| Position within organisation: | **To be completed by applicant** |
| **THIS INFORMATION WILL NOT BE DISCLOSED WITHOUT PERMISSION** |

As required in the Terms of Reference of the Milton Keynes Prescribing Advisory Group (MKPAG) on Declaration of Interest, I wish to declare the following Potential Conflicts of Interests which may have arisen **during the last 12 months or planned over the next 12 months**

**Declaration of Potentially Competing Interest(s):**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Item | Company or Organisation | Outline description/ Comments(Salary, Grants, Fees, etc) |
| 1. | Shareholding and/or Company Directorship |  |  |
| 2. | Paid consultancy work either direct or via an agency or other third party |  |  |
| 3. | Occasional payments for lecturing; please identify regularity |  |  |
| 4. | Sponsorship of posts in clinical or research team(s) |  |  |
| 5. | Sponsorship for conferences or other educational events  |  |  |
| 6. | Sponsorship of any other description (travel, materials to support practice, research) |  |  |
| 7. | Any other links (e.g. relatives)Or other potential areas of conflict |  |  |

|  |  |  |
| --- | --- | --- |
| or | I have nothing to declare |  |

|  |  |
| --- | --- |
| Signature: | Date: |

|  |
| --- |
| Action taken by ChairmanDate: |

## The completed form should be sent by email as a scanned signed form to MKPAG Secretariat at: Michelle.McCarthy@mkuh.nhs.uk