Royal National Orthopaedic Hospital NHS Trust
Drugs and Therapeutics Committee

Terms of Reference

Overall Purpose

The RNOH Drugs & Therapeutics Committee (DTC) aims to provide multidisciplinary leadership on the following key areas:

- To support the North Central London (NCL) Joint Formulary Committee (JFC) in the review of a new medicine application. Critical review of such applications should be conducted by the JFC but may be conducted by the DTC on the advice of the JFC. New medicine applications may comprise of licensed and unlicensed medicines, advanced therapy medicinal products, and medical devices which are used as a pharmaceutical.

- To ensure that new medicinal products (hereafter referred to as medicines) are introduced into the RNOH Formulary in accordance with best published clinical evidence and to promote their safe and effective use in a cost-effective manner.

- To ensure that the RNOH Formulary is continuously reviewed to ensure that medicines listed are not in conflict with best published clinical evidence.

- To review and approve drug-related policies and guidelines, patient group directions, and shared-care protocols. To ensure such documents are re-reviewed at regular intervals.

- To receive recommendations on appropriate areas of work from other Committees and the Clinical Governance Board.

1. Application Process

1.1. Medicines not reviewed by NICE

1.1.1. All members of staff at RNOH with prescribing authority are required to comply with the RNOH Formulary. This includes Medical and Non-Medical prescribers.

1.1.2. New medicine applications will be considered by the JFC (or the DTC on the instruction of the DTC) following completion of the appropriate application form by the requesting physician. A signature either confirming or denying support from the Divisional Head of Operations (budget holder) is essential on the form. Electronic signatures are acceptable. All signatories must be RNOH staff. If the form is incomplete it will be returned to the applicant before it will be considered.

1.1.3. Non-Medical prescribers are not authorised to lead on a new medicine application and must therefore liaise with a consultant to take one forward.

1.1.4. Applications must specify whether the new medicine is included in the locally approved PbR (payment by results; out of tariff) list or not.

1.1.5. Applications will be evidence based and will specify the likely number of patients involved and estimated costs of introducing the new therapy (in both secondary and primary care) per annum.

1.1.6. Where the JFC have instructed the DTC to review a new medicine application, the application will be presented by a member of the DTC. A summary of the evidence base supporting the application, written by the RNOH Formulary Pharmacist, will be available to members of the DTC. The written summary will also be sent to the applicant in advance of the meeting.

1.1.6.1. The applicant will be invited to attend the meeting to facilitate discussion of the new medicine application. Applications may be considered without the applicant being present if agreed by the applicant ahead of the meeting or at the Chair's discretion.

1.1.6.2. Review of a new medicines application by the DTC is driven by an evidence based approach. The DTC should endorse the availability of a new medicinal product if it offers significant advantage over existing products on the RNOH Formulary. An advantage may be conferred by advantages in the following domains:

- Efficacy
- Safety / tolerability
- Patient / staff convenience
- Cost / cost-effectiveness

1.2. Medicines reviewed and recommended within a NICE Technology Appraisal

1.2.1. The DTC will follow the recommendations of the Department of Health (DoH) as detailed in the document "Innovation, Health and Wealth: Accelerating adoption and diffusion in the NHS" and the Secretary of State direction with regards to implementation and funding of NICE recommended therapies within its *Technology Appraisal (TA)* work programme.

1.2.2. The DTC will not seek to duplicate NICE assessments or challenge an appraisal recommendation. The DTC will not act as a barrier to the uptake of NICE approved medicines.

1.2.3. The DTC will work closely with the Clinical Governance Committee with regards to facilitating the implementation of therapies recommended within a TA (as detailed in the NICE Guidance Policy).

1.2.4. The DTC will ensure that implementation of any recommendations is conducted in a manner that supports safe and clinically appropriate practice.

1.2.5. A tracking report of RNOH compliance with published NICE Technology Appraisals will be continuously updated by the RNOH Formulary Pharmacist and submitted to the RNOH Clinical Governance Committee and the JFC on a monthly basis. The report will also be uploaded on to the Trust internet page from April 2013 as instructed by the Chief Pharmaceutical Officer (Dr Keith Ridge)

1.3. ***Communication of decisions***

1.3.1. Formal notification of the DTC decision will be made in writing within 2 to 3 weeks of the meeting. Categories include: approved, approved under category of evaluation, deferred, or not approved.

1.3.2. Any approved medicines will be for a specific indication as specified within the application. It will not be assumed that if a drug is added to the RNOH Formulary for an

approved indication that it may be prescribed for other indications or for unlicensed (off-label) use.

1.3.3. For any medicines which are a decision of not approved was reached, applicants may submit an appeal provided that new data are submitted as part of the appeal.

1.3.4. All decisions will be published within the minutes of the meeting and posted on the Pharmacy section of the RNOH website.

1.3.5. Any approvals under the Category of Evaluation will specify a duration of data collection after which point the applicant will be contacted reminding them to submit such data to the DTC for consideration. Failure to submit requested data after two reminders, one month apart, will lead to the medicine being withdrawn from the RNOH Formulary.

2. Responsibilities of the DTC

2.1. Management of the RNOH Formulary

2.1.1. To provide a consistently robust, transparent and evidence-based system for evaluation of new medicines for consideration for addition to the Formulary.

2.1.2. To ensure that the most efficacious, safe, convenient and cost-effective medicines are available for prescription on the NHS within RNOH including licensed and unlicensed medicines as well as Advanced Therapy Medicinal Products (ATMP).

2.1.3. To provide a clinical governance forum for the safe prescribing, supply and administration of medicines via multidisciplinary membership.

2.1.4. To promote the cost-effective use of medicines and good prescribing practice through Formulary and education.

2.1.5. To ensure that systems are in place (via approval of policies and protocols) to maintain high standards of safe and effective use of medicines Trust-wide.

2.1.6. To evaluate requests for unlicensed medicines requests, including risk assessments if considered clinically appropriate for use.

2.1.7. To provide a governance forum for the evaluation of non-Formulary drug usage.

2.1.8. For medicines that will be prescribed for private patients, evidence for effectiveness and safety will be considered.

2.1.9. To develop and maintain an online Formulary

2.1.10. To ensure that any medicines that offer no clinical advantage, carry undue potential harm or provide poor cost-benefit are excluded from the Formulary.

2.1.11. To ensure that systems are in place (via approval of policies and protocols) to maintain high standards of safe and effective use of medicines Trust-wide.

2.1.12. To monitor publications of drug-related Technology Appraisals which relate to practice at RNOH and liaise with senior clinicians where appropriate to arrange for submission of the relevant application form.

2.1.13. To ensure the implementation and monitoring of prescribing policies comply with national and local guidelines and RNOH Trust contracts.

2.2. Safety of Medicines and its appropriate use

2.2.1. To provide a clinical governance forum for the safe prescribing, supply and administration of medicines via a multidisciplinary membership.

2.2.2. Improving quality of prescribing through education of doctors, pharmacists and nurses.

2.2.3. Risk assessment of drug errors.

2.2.4. Develop and support audits.

2.2.5. Promotion of national guidance from NICE and NPSA.

2.2.6. Review and ratification of policies relating to use of medicines and prescribing, including Patient Group Directions and Clinical Guidelines.

2.2.7. To promote the cost-effective use of medicines and good prescribing practice through Formulary and education.

2.2.8. To monitor and control the use of unlicensed and non-formulary drugs in accordance with the non-formulary prescribing policy.

2.3. Chairman's Action

2.3.1. To actively communicate with colleagues that prescribing at RNOH should be in line with the RNOH Formulary.

2.3.2. To review any non-Formulary requests in the following manner:

2.3.2.1. Authorisation of a non-Formulary request for *continuation* of therapy is delegated to the Formulary Pharmacist or the Chief Pharmacist [on two occasions per medicine, per consultant] if they consider the request to be appropriate (i.e. if a Formulary alternative is not available or suitable). Any further requests should be referred to the DTC Chair.

2.3.2.2. For all *initiations* of a non-urgent non-Formulary medicine, the request should be submitted to the Formulary Pharmacist to take to the next DTC meeting for consideration. Should the situation become urgent prior to the meeting, the request will be forwarded to the DTC Chair for consideration outside of the meeting.

2.3.2.3. For all *initiations* of a non-Formulary medicine for use within an urgent situation (e.g. serious / life-threatening condition) and delaying a discussion on the appropriateness of the non-Formulary medicine would cause exceptional hardship to the patient, the DTC Chair may consider the request outside of the meeting. Approval may be granted if considered appropriate for supply on a named patient basis. Note, Chairman's action will not be used to introduce new medicines for a group of patients, as this is the remit of the DTC via the new medicines application process.

2.3.3. To review any Individual Funding Requests (IFR) in the following manner:

2.3.3.1. As the frequency of DTC meetings is once every 2 months, it is agreed that in order to prevent delays in access to medicines via the IFR route that such forms may be considered outside of the scheduled meetings.

2.3.3.2. Authorisation of IFR forms is delegated to the DTC Secretary (i.e. Chief / Deputy Chief Pharmacist) if considered appropriate. In the event that the proposed indication for the medicine specified within the IFR is considered experimental, review of the IFR form should be escalated to the DTC Chair.

2.3.4. The Formulary Pharmacist will compile a list of all medicines supplied under Chairman's action at the following DTC meeting to allow the Committee to comment on their appropriateness. A maximum of TWO approvals for a non-Formulary medicine may be authorised via the Chairman's action route, after which the DTC will request a new medicine application. The above process applies to all licensed medicines (for use within and outside of their Marketing Authorisation) and all unlicensed medicines.

2.3.5. Chairman's Action will not be available for any medicine that has been reviewed and not-approved by the JFC or DTC (unless the medicine is required for use in a life-threatening condition).

2.4. Finance relating to Medicines

2.4.1. To monitor and influence drug expenditure and advise on clinical and / or economical parameters where appropriate.

2.4.2. To maintain a review of departmental spend to identify cost pressures in year and report to the Divisional Manager and primary care colleagues where appropriate.

2.4.3. To identify the means to achieve cost-effectiveness in use of medicines.

2.4.4. To report on PbR excluded drugs usage and claim back expenditure from NCL Commissioners.

2.4.5. The Finance representative will:

2.4.5.1. Provide the DTC with monthly reports as requested including total year to date expenditure by month and detail of the top 20 drugs issued as well as all PbR exclusions and income claw backs.

2.4.5.2. Provide support in achieving cost-effectiveness in use of drugs.

2.4.5.3. Provide support in producing business cases to seek financial authorisation and funding for new drug applications.

2.4.5.4. Ensure that representation is present at every meeting.

2.5. Communication with Primary Care representatives

2.5.1. Maintaining good communication links and processes for medicines management across primary and secondary care organisations.

2.5.2. Resolution of issues of concern related to use of medicines

2.5.3. To ensure that shared-care policies across the primary/secondary interfaces are developed and approved by the Committee for consideration by NHS Barnet Medicines Management Committee for final approval where appropriate

2.6. Electronic Prescribing

2.6.1. To provide relevant input to IT with regards to implementation and governance of electronic prescribing.

2.6.2. To develop and support close working relationships where there is key representation of DTC members within the Electronic Prescribing Group.

2.7. Strategic Role

2.7.1. To provide information, support and strategic direction to the Trust to facilitate good practice in relation to medicines procurement, provision and use.

2.7.2. To take a leading role in the development of strategic changes for medicines management within RNOH

2.7.3. To identify, promote and commission appropriate drug-related audits.

2.7.4. To identify specific research areas relating to pharmacovigilence

2.7.5. To report a summary of meeting activities to the Trust Clinical Governance Board on an annual basis.

2.8. Additional Duties

2.8.1. To provide information, support and strategic direction to the Trust to facilitate good practice in relation to medicines procurement, provision and use.

2.9. Key Relationships

2.9.1. To oversee the activity of the following work streams:

- Non-Medical Prescribers Group
- Antimicrobial Stewardship Committee

2.9.2. To liaise with the following Committee as appropriate:

- General Operational Management Group
- Medical Staffing Committee
- Audit Committee
- Clinical Governance Committee
- Risk Management Committee
- Joint Academic Committee
- Research and Ethics Committee

3. Procedural Notes

- The Committee encourage the invitation of RNOH staff who submit applications

- The Committee welcome the attendance of other staff to attend meetings on an ad-hoc basis (depending on the agenda) provided the Chair is notified in advance

- The Committee support the establishment of sub-Committee working groups for the discussion of items which are not possible within the defined meetings

- The Committee will meet every two months

- Papers will be available two weeks prior to meetings

- The Committee will submit a summary of activity on an annual basis to the Trust Clinical Governance Committee

- The Committee will refer any items of concern/difficulties which have exhausted their normal review processes to the Trust Clinical Governance Committee for ratification

4. Process for Monitoring Effectiveness

The DTC reports to the Trust Clinical Governance Committee.

The Formulary Pharmacist will produce summary reports on a bi-monthly basis for the following Committees:

- Clinical Quality Committee
- General Operational Management Group
- Clinical Support Committee
- Clinical Governance Committee

- The Formulary Pharmacist will also produce an annual report for the Clinical Governance Committee detailing all DTC activity (review of new medicine applications, QIPP initiatives, guidelines, policies, procedures, audits etc.) including member attendance.

5. Review

The Terms of Reference will be reviewed every TWO years or sooner if necessary.

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GLOSSARY

Medicinal Products

These products meet the definition of a medicinal product (MP) [Directive 2001/83/EC, amended by 2004/27/EC] as:

a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

1. Licensed medicinal products

A licensed medicine is a chemical medicinal product which has received a Marketing Authorisation (MA) from either the European Medicines Agency (European regulatory body) or the Medicines and Healthcare products Regulatory Agency (UK regulatory body). The MA provides assurances that the product meets the standards of safety, quality and efficacy for its intended use before it can be prescribed, sold, or marketed.

2. Unlicensed Medicinal Products (UMPs)

An UMP is a chemical medicinal product which does not hold a Marketing Authorisation (MA) within the UK (as granted by the EMA or MHRA). Additional in-house regulations thus need to be followed to ensure their safe use

3. Advanced Therapy Medicinal Products (ATMP)

An ATMP must meet the definitions of an MP but are classified as a biological medicinal product [Directive 2001/83/EC, amended by 2003/63/EC annex 1, Part 1] that can be categorised as either one or a combination of the below:

a) Gene Therapy Medicinal Product (GTMP)

An active substance which contains or consists of a recombinant nucleic acid (not including vaccines against infectious diseases)

b) Somatic Cell Therapy Medicinal Product (CTMP)

An active substance which contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties have been altered.

c) Tissue Engineered Products (TEP)

An active substance which contains or consists of cells or tissues with a view to regenerating, repairing or replacing human tissue.