Milton Keynes Clinical Commissioning Group

Prescribing and Medicines Management Strategy

We welcome feedback on this policy and the way it operates. We are interested to know of any possible or actual adverse impact that this policy/procedure may have on any groups in respect of gender or marital status, race, disability, sexual orientation, religion or belief, age or other characteristics.

Version	Date originally approved	Last review	Review date	Equality impact assessment	Author/ contact person
2.3	March 2009	September 2019	September 2022	E.I. assessed	Janet Corbett

For use in (area)	All Clinical areas including General Practice
For use by (staff group/s)	All healthcare staff
For use for (staff/patients/public)	Staff / Patients / public
Document owner (Director)	Janet Corbett, Head of Prescribing and Medicines Management
Document status (draft/approved)	Approved

Version	Date	Author	Reason
1.0	March 2009	Janet Corbett	Review due
2.0	March 2012	Janet Corbett	Review due
2.1	May 2013	Janet Corbett	Updated with CCG logo
2.2	March 2014	Janet Corbett	Review due
2.3	March 2018	Janet Corbett	Review due
2.4	September 2019	Janet Corbett	Review prior to approval at CCG Prescribing Group 4th September 2019

Contents

1.0 Introduction

1.1 Policy statement and aim

NHS Milton Keynes CCG has a responsibility to ensure that all resources utilised for health care are used in the most effective and efficient way – this includes prescribing.

This strategy details the aims and objectives, problems to implementation, potential for change and the continuing activity necessary to ensure high quality, cost-effective prescribing and medicines management for patients in Milton Keynes.

Activity is guided and assisted by local and national initiatives to promote effective and reduce ineffective or excessive prescribing. These principles are applied to the prescribing arena by the Pharmaceutical Advisers. Examples include encouraging increased use of inhaled steroids in asthma, increased use of ACE inhibitors in heart failure, use of aspirin in suspected myocardial infarction or stroke, reducing inappropriate antibiotic prescribing, and discouraging the use of ineffective drugs such as appetite suppressants or vasodilators.

1.2 Objectives

The residents of Milton Keynes will receive all necessary medication chosen by well-informed prescribers based on the principles of efficacy, safety, acceptability and cost-effectiveness.

High level objectives include

- **Promote cost effective and clinically appropriate prescribing to support corporate objectives**
  Improving health and reducing inequalities
  Improve quality and assure safety of services
  Achieving financial balance and strategic use of resources
  Create an effective organisation
  Improve public and partners' confidence in local NHS
- **Contribute to the improved health of Milton Keynes' residents though effective use of medicines**
  Clinical guidance on medicines prescribing and usage to improve health
  Medicines usage monitoring and reporting through ePACT2 data
  Financial frameworks and budgetary advice
  Cost saving agenda
  Support medicines management in the Provider organisation
- **Develop interface relationships with other agencies to improve local medicines management**
- **Minimise risks associated with medicines across the CCG**
  Development of Patient Group Directions
  Involvement in training for Independent and Supplementary Prescribing
  Therapeutics updates for staff
  Provision of clinical pharmacy services
- **Support QIPP delivery**

2.0 Scope of document

This strategy applies to all healthcare professional working within Milton Keynes Clinical Commissioning Group and the CCG's associated independent contractors. It should be considered by commissioners when commissioning new services. It does not include staff employed in provider Trusts but provides a framework for discussions with those organisations.

3.0 Roles and responsibilities

The Head of Prescribing and Medicines Management is responsible for all aspects of the safe use of medicines. The Accountable Officer has overall responsibility for the safe use of medicines. The Director of Programme Delivery is the Board member with responsibility for the safe use of medicines. The Chief Finance Officer has responsibility for the financial risk associated with prescribing.

4.0 Prescribing and Medicines Management Strategy

4.1 Executive Summary

The prescribing and medicines management strategy of Milton Keynes Clinical Commissioning Group (NHSMK CCG) details the aims and objectives, problems to implementation, potential for change and the continuing activity necessary to ensure high quality prescribing and medicines management for patients in Milton Keynes.

NHSMK CCG aims to promote high quality, rational, cost-effective, evidence based prescribing by all its general practitioners and other authorised prescribers, whilst also ensuring that patients receive the treatment they need.

Prescribing and medicines management advice is available at three levels: -

- Strategic - strategic advice to ensure dissemination of good prescribing practice, managed introduction of new drugs, performance management etc.
- Facilitative - advice available to individual practices and provider services, dissemination of strategies and protocols, education and training for healthcare professionals
- Implementation - working within the provider services and practices to implement agreed changes and support staff; offering solutions to individual patients with medication-related problems

Prescribing and medicines management advice will be tailored to reflect local and national agendas and are founded on the overriding principle of clinical effectiveness. Key factors that the strategy addresses include: -

- Measures to ensure good housekeeping in prescribing, including reducing overprescribing of certain drugs such as antibiotics, benzodiazepines, drugs of limited therapeutic value, premium priced drugs, therapeutic substitution, generic substitution, dose optimisation and management of repeat prescribing systems.

- A commitment to work through the CCG Prescribing Group and Milton Keynes Prescribing Advisory Group to ensure that the clinical and cost-effectiveness of new chemical entities / new clinical applications are considered (in consultation with local specialists).

- Ensuring that there is a consistent approach at the $1^0/2^0$ Care Interface and that prescribing decisions in secondary care are based on evidence of effectiveness.

- Supporting the development of non-medical prescribing.

- Assuring the quality of prescribing by identifying and managing risks associated with the handling and storage of medicines.

The above has to be set in the context of on-going service reconfiguration and organizational change.

4.2 Background

4.2.1 NHSMK CCG is a commissioning agency purchasing health care for all residents of Milton Keynes.

4.2.2 The CCG has the following key functions:

- To improve the health of the community and tackle inequalities in health
- To support the development of primary, community, mental health, learning disability and children's services
- To commission hospital services
- To commission general medical services
- To support the integration of health and social care

4.2.3 Prescribing and Medicines Management are integral parts of all these functions.

4.2.4 NHSMK CCG has a part time Head of Prescribing and Medicines Management and four part time Practice Pharmacists, a Care Home Pharmacist, two Medicines Management Technicians and a full time Senior Medicines Management Technician.

4.2.5 Milton Keynes CCG covers a population of around 285,000 (2018) registered with GPs, with a rapidly expanding population. The number of people aged 50 years and over is expected to rise by three times the national rate in the same period. This will bring challenges to the prescribing agenda as it is recognised that the need for medication increases with age.

There are significant areas of deprivation in parts of the town. Additionally there is variation in access to health services within populations and this is marked between the most affluent and least affluent wards in Milton Keynes Council. The key health issues relate to:

- Higher birth rates than the England and Wales average; Higher mortality rates for lung cancer, pneumonia and COPD
- Three electoral wards have significantly higher prevalence of people with mental health problems than the national average

Tackling these issues has implications for prescribing and medicines management.

4.2.6 Residents of Milton Keynes come from a range of cultural and ethnic backgrounds. Prescribing has to be sensitive to these differences which may lead to raised demand, compliance issues and misunderstandings where English is not the first language.

4.2.7 There are 27 GP practices in Milton Keynes.

4.2.8 Unweighted data shows that the CCG has fewer GPs per 100,000 population than the national average.

4.2.9 The principal providers of acute and specialist services are Milton Keynes Hospital Foundation Trust and Buckinghamshire Hospital Foundation Trust with some cancer services provided by Northampton General Hospital Trust. A significant level of service is also provided from outside the county by, in particular, Oxford John Radcliffe and several of the London Hospitals.

4.2.10 Milton Keynes has 44 Community Pharmacies, who are contracted by NHS England to meet the pharmaceutical needs of the population. There is potential for increased participation in patient care. This requires a greater degree of co-operation between the Pharmacists and GPs, which the Pharmaceutical Advisers are actively seeking to foster. Community pharmacy services are covered in a separate strategy document.

4.2.11 The prescribing budget forms part of a unified budget managed by the Clinical Commissioning Group and represents a considerable financial risk. There is a high degree of clinical risk associated with medicines.

4.2.12 The Pharmaceutical Advisers have been developing and refining the prescribing budget setting methodology, and continue to do so. It is important that there is a fair and robust mechanism for setting prescribing budgets that takes into consideration many factors that can affect an individual practice's prescribing requirements (such as age-sex breakdown, deprivation, patients living in nursing and residential homes and high cost drug prescribing – see Appendix 3 for more details.)

4.3 Drivers for change

The prescribing agenda must respond to the CCG corporate objectives and a number of local and national drivers and priorities. The direction of work will take account of:

4.3.1 National Aspirations

- To improve medicines optimization

4.3.2 Milton Keynes CCG Strategic Aims

The high level aims are to:

- Improve health and well being
- Reduce inequalities and social exclusion
- Secure fair, fast access to a comprehensive range of services
- Improve the quality and safety of services
- Increase choice and convenience
- Improve users' experience of services.

The key therapeutic areas are cardiovascular disease, respiratory disease, cancer, infections and mental health. Medicines play a significant role in all these conditions.

Key principles include:

- **Putting people more in control** – for example, by supporting people in deprived areas assess and tackle their lifestyle risks
- **Improving access to primary care** – for example, through incentives to GP practices to offer responsive opening times
- **Improving access to community services** – for example, by piloting individual budgets that bring together several income streams and put people more in control of their care packages
- **Focusing support on the whole needs of individuals, especially those with long-term conditions and greatest need** – for example, through integrated care plans
- **Shifting care closer to where people live** – for example, through a new generation of community hospitals with strong ties to social care, and a shift in spending away from hospitals to more local settings

It is important that the mechanisms for prescribing and medicines management reflect these changes.

4.3.4 The NHS Constitution

The NHS Constitution aims to address variations in the availability of medicines and treatments resulting from inconsistency in local decision-making processes, whilst accepting natural variation will exist, and is appropriate, in order to meet the differing health care needs of local populations. The CCG therefore needs to work to a set of guiding principles in order that patients *"have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you (the patient) and your doctor feel would be right for you, they will explain that decision to you." (Ref NHS Constitution)*

4.3.5 National Institute for Health and Clinical Excellence

The role of the National Institute for Health and Clinical Excellence is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current "best practice". The guidance covers both individual health technologies (including medicines, medical devices, diagnostic techniques, and procedures) and the clinical management of specific conditions.

The CCG is expected to implement the guidance within three months of publication. The Pharmaceutical Advisers provide information to the CCG Prescribing Group on all sets of NICE Guidance that involve drug therapy and, disseminate information to primary care and provider prescribers.

4.3.6 nGMS Quality and Outcomes Framework (QoF)

The 2004 GP Contract provides a framework designed to support and systematise care. It sets targets for a wide range of indicators such as blood pressure control, cholesterol levels, diabetes management etc.

The QoF also sets out a number of medicines management targets which provide the Pharmaceutical Advisers with additional opportunities to influence the practice prescribing agenda.

4.3.7 Public Health
There are a number of areas where the prescribing and public health agendas overlap. These include smoking cessation, obesity management, substance misuse, prevention of coronary heart disease and diabetes, teenage pregnancy, sexually transmitted disease and others. The CCG will ensure appropriate use of medicines to support patients and encourage community pharmacists to promote healthy living.

4.3.8 Admission avoidance
Better management of medication and prescribing can have a significant impact on admission avoidance. The Pharmaceutical Advisers will explore innovative ways of contributing to this agenda.

4.3.9Public Engagement
It is widely recognised that adherence to prescribed medicines is poor. Therefore the Pharmaceutical Advisers will seek opportunities to provide information to patients in a readily accessible form. A member of Healthwatch sits on the CCG Prescribing Group.

4.4 Measures to ensure good housekeeping in prescribing
The Audit Commission in 1994 identified several problem areas in prescribing that afforded opportunities for many practices to improve their prescribing. These still remain relevant today. NHSMK CCG supports work to improve the cost-effectiveness of prescribing by targeting the following areas: -

Overprescribing of certain drugs such as antibiotics and benzodiazepines.
Excessive antibiotic prescribing has been highlighted as a cause of antimicrobial resistance. Over-use of benzodiazepines may impair the quality of life of patients and current thinking suggests that efforts should be made to wean patients off long-term treatment where-ever possible. There are explicit links to the Control of Infection agenda in relation to antibiotic prescribing.

Therapeutic substitution is where an equally effective but less expensive drug of the same group is substituted. Examples include drug choices within the classes of proton pump inhibitors, ACE Inhibitors, statins etc.

Generic substitution.
Once a drug is no longer under patent, it is usually cheaper to prescribe it by its drug or generic name rather than as a brand name. A high generic prescribing rate is a marker of economical prescribing.

Therapeutic substitution and increased generic prescribing will help the CCG deliver cost-effective use of medicines.

Biosimilars
The CCG supports and encourages the introduction and use of biosimilars as they become available.

Drugs of limited therapeutic value, such as cough suppressants and cerebral and peripheral vasodilators may not benefit those patients taking them and may cause unwanted effects. Their usage should be reviewed and stopped where possible.

Premium priced drugs, including combination drugs and long-acting drugs.
Some drugs are marketed in both a standard form and a more expensive form that is claimed to improve compliance but the research is not generally convincing. These are known as premium priced products. The Audit Commission Reports on Primary Care Prescribing have highlighted this drug group as being poor value for money.

Dose optimisation
For a number of drugs, it is cheaper to prescribe one high strength tablet than two lower strength ones. The CCG encourages and supports practices in auditing their repeat prescribing systems in order to capitalise on savings in this way.

Management of Repeat Prescribing Systems
The Department of Health has defined repeat prescribing as a prescription issued by a GP without seeing the patient. Currently in excess of 70% of prescribing is repeat prescribing according to this definition. Such prescriptions are usually for chronic conditions where treatment is continued for many years. There is a tendency for GPs to prescribe for longer periods for such patients but this can be wasteful, as has been demonstrated by several studies. It can also lead to inadequate supervision of the patient's condition. NHSMK CCG supports a normal repeat duration of 28 or 56 days.

Research has shown that items on prescriptions are often written for differing periods of time / quantities. This increases waste as patients may re-order whenever the first item runs out, thereby stockpiling other items. This should be discouraged. Repeat Dispensing that is being rolled out as part of the Pharmaceutical Services contract should provide better management of repeat prescriptions although, to date, practices have been slow to adopt the process.

The CCG is hosting three workshops for GP practice staff to share good practice in repeat prescribing and will periodically remind patients about sensible re-ordering of repeat prescriptions in order to reduce waste.

4.5 Managing the Introduction of new drugs

The CCG is committed to improving the cost-effectiveness of prescribing in primary and secondary care.

It is widely recognised that the introduction of new drugs causes cost pressures within prescribing in both primary and secondary care. Furthermore, the choice of medicine in secondary care is an important influence on prescribing in primary care.

Usually a number of drugs will be introduced each year. These should be evaluated for evidence of efficacy, safety and cost-effectiveness in order to determine their place in therapy. These new innovations may then be classified into four categories: -

- A real therapeutic advance and expected to establish a place in therapy either as an innovative product, new indication or replacement for an existing, less effective therapy
- Offers advantage but unlikely to have much therapeutic impact in the area concerned
- Possibly helpful with little additional therapeutic value and should not change prescribing except in rare circumstances
- Nothing new – no advantage over other drugs eg "me toos"

Additionally, drugs may have
- High cost and widespread usage
- High cost and little usage
- Low cost and widespread usage
- Low cost and little usage

Although attention is often focused on high cost drugs (both low and high volume), equally damaging to the budget are those that are relatively low cost but very high volume (eg proton pump inhibitors, statins)

The CCG will work through the CCG Prescribing Group and Milton Keynes Prescribing Advisory Group to ensure that the clinical and cost-effectiveness of new chemical entities / new clinical applications are considered (in consultation with local specialists). Guidance is available to all prescribers within the Milton Keynes health economy. The MKPAG has agreed a process to support the introduction of new drugs onto the Joint Trusts Formulary. (see appendix 6)

Rarely prescribed and very expensive drugs for an individual patient will be considered by the Priorities Committee.

The Pharmaceutical Industry spends an average of £15,000 per year per GP to market its products. This contrasts with the small sum the CCG spends on prescribing advice, which is considerably less than 10% of

this figure. The Pharmaceutical Advisers have developed a strategy for working with the pharmaceutical industry (see Appendix 4). Guidance notes have been distributed to General Practices and Trust Staff.

4.6 Prescribing across the Primary/Secondary Care Interface

There has been a tendency in the past for hospitals to shift the cost of prescribing to the GP, particularly in the case of high-cost drugs. This also shifts the clinical responsibility to the GP because it is the prescriber who is responsible for any adverse effects of a drug. Often the GP has insufficient knowledge in such specialised areas to take on this responsibility. A Primary/Secondary Care Interface Prescribing Policy seeks to address this issue. (Appendix 1).

Medicines Reconciliation (MR) is defined as the process of ensuring that medicines prescribed on admission to hospital correspond to those that the patient was taking before admission. Admission to hospital is a high-risk time for medicines errors to occur. Literature reviews suggest medicines errors affect 30-70% of patients admitted to hospital.

4.7 Prescribing and Commissioning

The Pharmaceutical Advisers support Commissioners by providing advice on high cost or rarely used medicines and exclusions to the national tariff.

4.8 Clinical Trials

Prescribing and supply of clinical trial medication is the responsibility of the initiator Trust and the local research & ethics committee will need to assure itself that arrangements for any on-going treatment are in place before medication is commenced. Standard out-patient or in-patient treatment costs will be met for patients on a trial as required by HSG (97) 32; this will not include the cost of the trial drugs as a separate item either during or after the trial. In order to respond appropriately to any suspected adverse events that occur outside hospital, the GP should be informed in writing within a given time period that a patient is participating in a clinical trial.

All studies must have been subject to local research & ethics committee scrutiny, when the arrangements for consulting and informing GPs should be considered. Where drug therapy may have a significant financial impact this should be discussed with the CCG Pharmaceutical Advisers before commencement of the trial. Patients participating in a clinical trial must be made aware that there is no guarantee that the drug will be continued at the end of the trial, irrespective of the results. There must be discussion between the Acute Trust and CCG in time for mechanisms to be put in place for supply at the completion of the trial, where individual patient benefits indicate such a requirement.

4.9 Non-medical prescribing

Changes to legislation have enabled nurses, allied health professionals and pharmacists to become independent and/or supplementary prescribers. The CCG supports these developments as a means to make best use of the workforce and move workload away from general practitioners. A non-medical prescribing strategy has been approved. The non-medical prescribing steering group reports to the CCG Prescribing Group.

NHSMK CCG will encourage the use of Patient Group Directions as a further means of extending non-medical prescribing. These are covered in detail in the Care and Control of Medicines Policy.

4.10 Controls Assurance

The CCG needs to ensure that all risks associated with the handling and storage of medicines are identified and managed effectively. The CCG also needs to ensure that it has effective systems in place for the reporting of adverse events involving medicinal products and a pro-active approach to investigating any incidents locally.

4.11 Out of hours and urgent care availability of medicines

The development of a more responsive out of hours pharmaceutical service is seen by the government as a priority in its plans to modernise the NHS. Improving OOH pharmacy services was mentioned in the *NHS Plan* and expanded in *Pharmacy in the Future.*

- Information for patients on the opening hours of local pharmacies is more reliable and more readily available
- Wherever possible, patients who need to start taking common medicines out of hours are able to obtain them at the same time as the consultation
- Arrangements for dispensing other drugs urgently out of hours are well co-ordinated and reliable, and readily accessible by those who need them.

Additional insight into the government's plans for OOH services can be found in:

1. *Raising standards for patients: New partnerships in out of hours care*
2. *Department of Health response to the independent review of GP out of hours services in England report: Raising standards for patients. New partnerships in out of hours care.*
3. *Securing proper access to medicines in the out of hours period 2004*

An independent review of GP out of hours services published in 2000 noted that the supply of appropriate medicines outside of normal working hours was often problematic. The report therefore recommended that, other than in exceptional circumstances, patients should be able to receive the medication they need at the same time and in the same place as the out of hours consultation. The CCG has reviewed arrangements and taken steps to make sure that the patient experience is positive in this respect.

The national Out Of Hours Drug Formulary has been implemented by MKUCS and the Walk in Centre.

CCGs have responsibilities for the quality of service provided with Out Of Hours service providers and the Pharmaceutical Advisers will liaise with MKUCS with regard to care and control of medicines. The Pharmaceutical Advisers have provided advice to commissioners undertaking the review and retendering of urgent care services.

4.12 Continuing activity

4.12.1 CCG Prescribing Group

The purpose of the CCG Prescribing Group is to provide advice to the CCG, provider services and primary care health professionals on medicines related issues and to act as the body authorised to ratify medicines policy on behalf of the CCG. It also provides a link with other agencies and groups such as the hospital, prison and council to work towards coherent prescribing policies locally. The membership and Terms of Reference are set out in Appendix 7.

4.12.2 Continuing medical and non-medical Education.

Members of the Pharmaceutical Advisers are available to hold educational sessions for prescribers, nurses and other healthcare professionals in the provider services and GPs or Specialist Registrars taking part in the GP Registrar training scheme. The team will work with educational providers, work force development confederations, service leads and individual practitioners to develop appropriate educational input.

4.12.3 Practice visits.

The Head of Prescribing and Medicines Management visits all practices during each twelve month period to discuss a range of prescribing topics.

The Practice Pharmacists support practices to optimize prescribing and medicines management.

There are a number of "housekeeping" activities on the repeat prescribing systems that help to reduce errors and improve the cost-effectiveness of prescribing. These are undertaken by the Medicines Management team.

The practice pharmacists and technicians have established good working relationships with twenty six practices and are working on areas of prescribing that have been identified as priorities.

In addition to ensuring that prescribing is cost-effective, the practice pharmacists undertake medication reviews of complex patients. This helps to improve the quality of care for these patients.

4.12.4 Prescribing newsletters.
These are produced on a bi-monthly basis and are a continuing form of education and advice for all prescribers and pharmacists in Milton Keynes. They are also a means of disseminating information from the CCG Prescribing Group. The newsletters focus on the areas of prescribing that have been identified as worthy of attention, or where new information has been published that may mean a change of emphasis or behaviour on the part of prescribers.

4.12.5 In addition to the prescribing newsletters themed information is produced regularly that relates to particular aspects of prescribing. These include critiques of significant clinical trials.

4.12.6 Supporting service reconfiguration
The Pharmaceutical Advisers will work closely with Commissioners and Service Managers to ensure that appropriate medicines management processes are built in to any service developments.

4.12.7 Budget setting
Budget setting will continue to be refined to reflect the differences between GP practices that can lead to a differing requirement for prescribing funds for an apparently similar population. (Appendix 3)

4.12.8 Prescribing Incentive Scheme
The need for an Incentive Scheme will be kept under review but is regarded as a helpful tool to influence prescribing. Practices will be supported in their efforts to achieve the targets.

4.12.9 High Cost Drugs and Exclusions from National Tariff
The provision of accurate and timely details of high cost drug expenditure to all practices will be a priority. This will enable practices to assess the effect of secondary care influence on their prescribing expenditure. The impact of high cost drugs will be taken into consideration when assessing a practice's performance against budget. BlueTeq is used as the approval mechanism.

The Pharmaceutical Advisers will monitor and advise commissioners as necessary.

4.12.11 Quality Prescribing
There is a continuing need to monitor prescribing in GP practices. Prescribing indicators are used to monitor prescribing activity and are kept under constant review to reflect changes in prescribing practice. These will be a combination of financial and quality indicators. They will be used to monitor and encourage/improve the prescribing so that it remains of high quality for the benefit of the population but at the same time is cost-efficient.

Appendix 1

Contracting for services and drug use across the primary care/secondary care interface

Summary

The Clinical Commissioning Group is looking for: -

- A consistent approach at the $1^0/2^0$ Care Interface
- Prescribing decisions to be based on evidence of effectiveness
- Information to be shared with the GP where an unfamiliar treatment is being requested to make it both safe and effective
- An awareness of overall costs to the NHS

In general patients should not be led to expect a particular drug but rather a generic or group/class title should be used. In addition the patient should not be used as an intermediary between the hospital and GP. Where there are requests for shared care prescribing the agreement should be in existence before the patient is asked to consult the GP.

Background

Prescribing costs are 10% of the entire NHS bill; the 1^0 Care Sector (GP's) accounts for 80% of this. However, according to the Audit Commission Report (Towards More Rational Prescribing in General Practice 1994) up to 30% of prescribing in 1^0 Care is **hospital led**. Thus decisions made in the 2^0 Care arenas do have a major impact on drug usage in 1^0 Care.

This policy addresses some of the issues at the $1^0/2^0$ Care interface and adopts solutions based on national guidance on prescribing. In general it is the issue of the clinical responsibility for drug therapy rather than the cost of such therapy that is important.

[The main guidance documents include the principles found in EL (91) 127. (Responsibility for prescribing between hospitals and GP's), EL (94) 55 (Priorities and planning guidance of the NHS) and EL (94) 72 (Purchasing and Prescribing). EL (95) 5 -Purchasing High Tech Healthcare for Patients at Home, removed the responsibility for GP prescribing in the areas of CAPD, TPN and IV antibiotics for HIV/AIDS and CF. Revised national guidance supersedes most of these – responsibility for prescribing between Primary and Secondary / Tertiary Care January 2018.

General Principles

Where prescribing for an individual patient has been established there should be no change as a result of this policy. The policy is meant to address the lack of clarity that is apparent between 1^0 and 2^0 Care over the responsibility for prescribing. It does not affect the individual GP's freedom to prescribe even where this may differ from this policy.

The CCG supports the view that expenditure on prescribing should be seen as a legitimate investment of health resources to maintain and improve the health of the population. In many cases there is considerably more evidence of the efficacy of drug treatments, than of other non-drug interventions. Providers should ensure that the contracts they agree each year with Commissioners allow them to adopt appropriate clinical practice with regard to drug prescribing.

EL (91) 127 and its successor document (2018) state a minimum requirement for drug provision, which hospitals should adhere to (unless the duration of treatment is less than the minimum supply requirement).

- 7 days for Hospital discharge
- 7 days for Accident and Emergency patients
- 14 days for outpatients where the clinical condition requires " immediate" treatment (that is, to start within 5 days).

When outpatient drug treatment is not 'immediately' required, then it is preferable (to enable compliance with local practice formularies) for the consultant to indicate the therapeutic class rather than the specific agent (unless there are good clinical reasons, which should be stated, to specify the particular drug.) In such a case no provision of drug would be made by the hospital. It is anticipated that this would apply to the majority of outpatient consultations. It will be necessary to ensure swift and accurate transfer to the GP of the Consultant recommendation for class of drug and duration of treatment.

General policy Guidance

1. GP's should indicate in their referral letter when opinion only is being requested. Consultants should comply with these requests, except where there is a compelling clinical need to treat the patient (as in the case of immediate treatment referred to in EL(91)127).

2. Where a Consultant suggests a treatment he/she should indicate the therapeutic class rather than a specific drug unless there are clinical reasons (which should be stated) to do otherwise.

3. Medicines, dressings and appliances initiated by the hospital but not available in the community must be supplied by the hospital.

4. Medicines administered in hospital and for take home on discharge will be supplied by the hospital unless part of a recognised “Patients Own Drugs” scheme.

5. The cost of new drug therapies and recommendations made by NICE will be borne in year as a cost-pressure by the acute Trust.

6. Where a drug therapy is initiated or suggested by the Hospital Consultant that does not conform to the agreed hospital formulary, the reason for this should be indicated to the GP. If the GP is unwilling to accept the prescribing responsibility then the drug will be provided by the hospital.

7. Drugs initiated by hospital medical staff which are unlicensed or are being used for an unlicensed indication, should be supplied by the hospital until there is agreement between the Consultant and GP on shared care. Where a drug has been in widespread use (within a specialty) for over 2 years for an unlicensed indication such agreement may not be necessary, but the GP must still be informed of the unlicensed nature of the drug and be given the opportunity to refuse to take prescribing responsibility.

8. Clinical responsibility for a drug treatment remains with the hospital if the therapy is commenced whilst the patient is an inpatient or outpatient **and** requires specialist initiation, stabilisation and monitoring of the patient's responses.

9. A shared care agreement will only be entered into:-

- when the patient's condition is stable
- when prior agreement has been reached between the GP and Consultant
- when the GP is able to monitor treatment (and adjust the dose if necessary)
- **and** when clinical responsibility has been transferred to the GP.

When there is uncertainty about where the clinical responsibility rests it will be deemed to be in secondary care if the patient is still attending hospital for that condition.

10. Drugs which are undergoing, or included in, a hospital based clinical trial shall remain the responsibility of the hospital for prescribing until conclusion of the trial when paragraph 6 may apply.

11. Hospitals should be aware of the practice of 'loss-leaders' which, while tempting for the hospital budget, may have serious and long lasting repercussions for the 1^0 Care drug budget. The impact on the 1^0 Care drug budget should be evaluated and assessed before accepting any such offers. Financial penalties may be imposed by the CCG where Acute Providers fail to take this into account.

Appendix 2

Ensuring Effective Shared Care Agreements

Introduction

Successful shared care arrangements (SCA) enable the combination of the best of both primary and secondary care for the benefit of the patient. They allow the seamless transfer of patient treatment from the secondary care sector to general practice.
While 'protocols' and guidelines may be of use they, in themselves, do not constitute an adequate basis for shared care operation. The issue of patient safety is always paramount.

This document outlines the minimum data set required for shared care and identifies the conditions with which shared care can prosper. This will provide a structural basis for discussions with secondary care clinicians when considering entering into a shared care arrangement.

Effective shared care relies on:

- **Individual, patient by patient arrangements**

SCA should be patient specific and encompass all aspects relevant to that particular patient. While 'protocols' and 'guidelines' may be of use they, in themselves, do not constitute an adequate basis for shared care operations.

- **A reasonably predictable clinical situation**

Clinical responsibility should be considered for transfer to primary care only where it is agreed that the patient's clinical condition is stable or predictable.

- **Willing and informed consent of all parties**

Including patients, carers and doctors. Consenting parties must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily.

- **A clear definition of responsibility**

The shared care arrangement should identify the areas of care for which each partner has responsibility and where, if any, the specialist resources are available to the general practitioner. This should be patient specific.

- **A communication network**

Agreed communication should include a telephone contact point when problems arise and fax and email contacts if appropriate. Responses should be received within 24 hours. Progress reports should be produced to an agreed timescale with regular review.

- **A clinical summary**

This should include a brief overview of the disease and more detailed information on the treatment being transferred for which each partner has managerial and clinical responsibility. At a minimum it should identify

► the product's licensed indications:
► therapeutic classification:
► dose, route of administration and duration of treatment:
► adverse effects (their identification, management, importance and incidence)
► monitoring requirements and responsibilities:
► clinically relevant drug interactions and their management:
► storage and reconstitution: peer reviewed references for product usage:
► contacts for more detailed information.
► date of development
► review date
► audit information

► key references

- **Emergency support**

Contact numbers should include those for out-of-hours information with responses supplied by senior clinicians..

- **Training**

Training required by general practitioners and their staff should be identified and provided to a satisfactory standard by the specialist department seeking the shared care arrangement.

- **Funding**

Funding queries should be directed to the CCG. A number of “shared care” medicines will be excluded from national tariff.

Appendix 3

Budget Setting Methodology for GP Practice Prescribing Budgets

Introduction

HSC 1998/228 sets out the principles, which should be adopted in setting prescribing budgets for practices. The overall objectives are: -

- Fair and adequate prescribing budgets to meet the needs of patients
- To improve the cost and clinical effectiveness of prescribing
- Transparent approach with the opportunity for practices to comment

In deciding the level of affordable funding, the CCG takes into account the following factors: -

- The likely price inflation on drugs
- The impact of national service frameworks, NICE Guidance and other drug developments
- The overall financial position of the CCG
- Any potential efficiency savings

This paper sets out the proposed budget setting methodology for allocating prescribing resources to individual practices within the overall Resource Envelope (RE) allocated to prescribing.

It does not attempt to analyse the basis of the RE, this is outside the specific purpose of this paper.

Methodology

The principles of the methodology are based on ensuring that the RE is allocated in an equitable manner and is based on quantifiable data.

The model used this year is based on the utilisation of the national model for prescribing budgets. The model takes into account ASTRO(09)-PUs , Low Income Scheme Index (LISI), the proportion of those aged 70 years and over claiming disability living allowance (DLA), and the standardised mortality ratio. To ensure effective use of money for all practices, the budgets are capped at either end so that practices do not lose or gain large amounts.

In addition to the above principle High Cost Drugs (HCD) are “ring fenced”, at practice level. A practice has little control over this element but it does have a material effect on their prescribing budget.

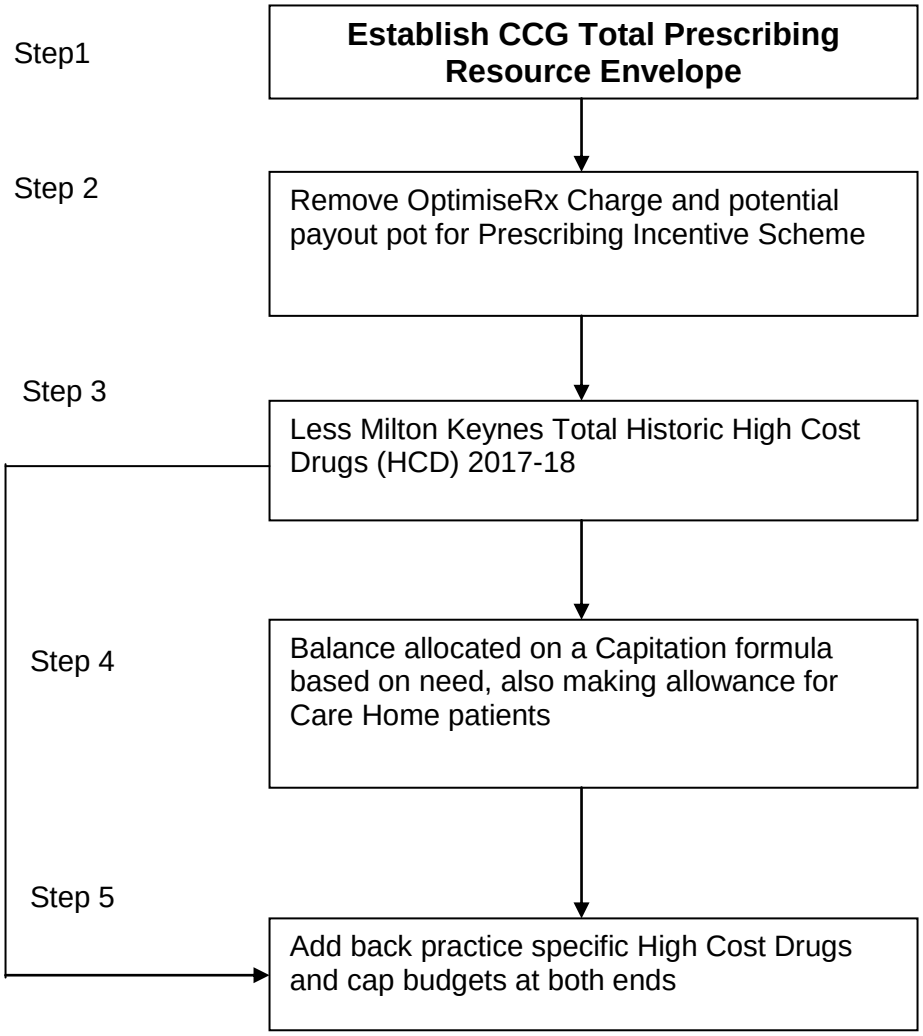
It is recognised within the budget setting methodology that patients living in care homes have a greater requirement for medicines than the elderly living in their own homes. Additional ASTRO-PUs are allocated according to the number of patients in care home beds that a practice has on its list (23 extra ASTROPUs per patient to the practices for each patient in a care home)

Levies against the prescribing budget

The license fee for OptimiseRx is top sliced. It still provides a reasonable return on investment and practices should accept the suggested switches in order to benefit from the cost savings.

An amount equal to £1 per head of population is made available to practices under the prescribing incentive scheme. The aim of the scheme is to encourage quality in prescribing and also rationalise expenditure. Practices must achieve individual quality targets and a financial target.

Figure 1 demonstrates the proposed allocation methodology and the supporting notes provide further details of the individual elements within the formula.



Appendix 4

Policy on Sponsorship and Joint Working between CCG and Pharmaceutical Industry and other industries

Policy background

This policy is based upon the Department of Health guidance paper, *Commercial Sponsorship – Ethical Standards for the NHS*, issued in November 2000, *Best Practice Guidance on Joint Working between NHS and Pharmaceutical Industry and other relevant Commercial Organisations 2008* and is in accordance with the CCG Standing Financial Instructions.

The first purpose of this guidance is to assist staff in the CCG achieve their objectives and vision of a modern, dependable national health service delivering excellent healthcare, by building effective and appropriate working relationships with key partners, such as the pharmaceutical industry.

The learning from a number of partnership projects has confirmed that joint working can provide real benefits to patients whilst supporting the strategic objectives of the delivery partners. Accordingly, The Department of Health encourages CCG organisations and staff to consider joint working as a realistic option for the delivery of high-quality healthcare.

The second purpose of this guidance is to inform and advise CCG staff of their main responsibilities when considering entering into joint working arrangements with the pharmaceutical industry. Specifically, it aims to:

- Assist CCG employers and staff in maintaining appropriate ethical standards in the conduct of CCG business
- Highlight that CCG staff are accountable for achieving the best possible health care within the resources available.

Joint Working with the Pharmaceutical Industry

Joint working between the pharmaceutical industry and the CCG must be for the benefit of patients or the CCG and preserve patient care. Any joint working between the CCG and the pharmaceutical industry should be conducted in an open and transparent manner. All such activities, if properly managed, should be of mutual benefit, with the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the CCG, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

For the purpose of this guidance, joint working is defined as follows:
Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

Core Values

An extract from the "*Code of Conduct: Code of Accountability in the NHS*" (2nd rev ed, 2004), states that: "There are three crucial public service values which underpin the work of the health service:

Accountability - everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgments of propriety and professional codes of conduct

Probity - there should be an absolute standard of honesty in dealing with the assets of the NHS: integrity should be the hallmark of all personal conduct in decisions affecting patients, staff and suppliers, and in the use of information acquired in the course of NHS duties

Openness - there should be sufficient transparency about CCG activities to promote confidence between the organisation and its staff, patients and the public"

Further, based on relevant pieces of additional guidance which are still extant, when the CCG and its staff enter into joint working with the industry, their conduct should also adhere to the following values:

- Transparency and trust,
- Appropriateness of projects,
- Patient focused,
- Value for money,
- Reasonable contact,
- Responsibility,
- Impartiality and honesty,
- Truthfulness and fairness.

Responsibility of CCG Employers and Staff

As described in *'Standards of business conduct for CCG staff,* and *Commercial Sponsorship – Ethical Standards for the* NHS (2000)*,* CCG employers and employees need to maintain and demonstrate certain general standards and behaviours, as defined, when dealing with commercial organisations.

All health professionals, including independent contractors and locum practitioners, working under NHS terms and conditions, are intended to be covered by this guidance.
For the purposes of this document, the term 'staff' is used as a convenience to refer to all such people.

CCG staff should be aware that when engaging with the pharmaceutical industry their representatives must follow the "*ABPI Code of Practice for the Pharmaceutical Industry*" – this is a condition of their membership. To that extent, the CCG would be expected to only engage with members of the ABPI (Association of the British Pharmaceutical Industry). The Code of Practice for the pharmaceutical industry is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK through a self-regulatory system. If CCG staff believe that an industry representative has broken the Code, they can report their complaint to the Director of the Prescription Medicines Code of Practice Authority (PMCPA) at complaints@pmcpa.org.uk

Additional Principles

By applying all the above-mentioned values, CCG staff will have met the majority of the relevant requirements of existing guidance. However, employers should ensure that monitoring arrangements are established to ensure that staff record and monitor any joint working arrangement for which the CCG body is accountable. Specifically:

• All staff should be aware of CCG guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant CCG guidance;

• Contract negotiations are conducted with the necessary ethos and values mentioned above and where there is evidence of an unauthorised or disadvantageous arrangement, CCG staff should act swiftly to deal with the situation and bring it within their local arrangements and patient and clinical needs;

• All funding agreements either through joint working projects or other arrangements are recorded and monitored, and should also be conducted in a transparent and
open way while the costs and benefits of it are properly measured and weighed with other proposals;
• Confidentiality of information received in the course of duty should be respected and should never be used outside the scope of the specific exercise;
• CCGs which entered into joint working arrangements should register and evaluate their outcomes and share them on request with other CCGs;
• Local guidance and policy should take into account the ethical and contractual implications of commercial collaborations with external stakeholders while reviewing and amending its content when necessary;
• Joint working arrangements should be at a corporate, rather than individual level.
• Monitoring arrangements are established to ensure that staff register any sponsorship and are held accountable for it;
• All joint project propositions are officially documented and reviewed through use of a register as part of the monitoring arrangements;
• Establish how clinical and financial outcomes should be assessed through a risk assessment form.

Best Practice Toolkit on Joint Working
A toolkit on joint working between the NHS and pharmaceutical industry, focusing on learning from useful examples with a view to recommending and spreading best practice, is available on the DH website.

Sponsorship
For the purposes of this policy, "sponsorship" means the funding of CCG work from an external source, including funding of all or part of the costs of staff, research, training, pharmaceuticals, equipment, meeting rooms, meetings costs, meals, gifts over £25, hospitality, hotel and transport costs, provision of free services, buildings or premises.

Code of Conduct
The principle of impartiality and openness are set out in the Code of Conduct that forms part of the Department of Health Circular and is attached as an Annex to this policy.

Staff declaration of interests
The principles set out in the Code of Conduct are given practical application for individual members of staff through the *Declaration of Interests* form which members of staff complete annually or if their circumstances change.

Register of sponsorship arrangements
Sponsorship arrangements entered into by staff of the Clinical Commissioning Group, will be entered into the Register kept by the Director of Finance. This Register is open to public inspection on request.

Implications for the local CCG community
The Department of Health guidance on sponsorship applies to NHS Trusts, Clinical Commissioning Groups and contracted practitioners. The CCG board and staff should therefore encourage all CCG managers and health professionals to develop their understanding of the constraints and issues surrounding work with the pharmaceutical and other industries. Service agreements with the Clinical Commissioning Group must include a requirement that sponsorship interests are fully declared, that appropriate ethical standards including patient confidentiality are met, and that clinicians' judgement will always be based upon clinical evidence that the product is best for their patients. The principle of loss leaders in secondary care is opposed and must be prohibited through service agreements.

Research Ethics Committee
The Research Ethics Committee is requested to guard against the unwitting promotion of drugs of unproven quality that may be the subject of proposed quasi-scientific research.

Promotional messages
Promotional messages should not be included in any patient information or health promotion material supplied by the CCG.

Educational meetings
Sponsorship of educational meetings held under CCG auspices by pharmaceutical companies should not be accepted if the products concerned are not in line with the CCG's approach to rational prescribing. CCG run Protected Learning Events will be funded by the CCG.

Training of nurses and other health professional staff
Sponsorship of nurse or other health professional staff training by pharmaceutical or other companies should only be accepted if such training is demonstrated to be impartial and broadly in line with the prescribing advice strategy or other guidance on clinical and cost effectiveness, and with the training needs assessment.

Hospitality and provision of meals associated with meetings
Hospitality provided in relation to any meeting must be secondary to the purpose of the meeting. The level of hospitality must be appropriate and not out of proportion to the occasion, and the costs must not exceed that which could be reciprocated by the CCG or which the recipients would normally adopt if paying for themselves. Hospitality in association with formal public meetings of boards is not appropriate. Where meetings are sponsored by external sources, that fact must be disclosed in the papers relating to the meeting and in any published proceedings.

Advice on the implementation of this policy
Responsibility for implementing and upholding this policy rests with the Director of Finance, from whom advice should be sought when in any doubt about how to proceed. In addition, in relation to working with the pharmaceutical industry, the Pharmaceutical Advisers have particular insight into relationships, and its members are available to advise on methods and safeguards for collaborative working. This policy will be reviewed in the light of new guidance from the Department of Health.

ANNEX

Code of Conduct

(to be read in conjunction with MK CCG Standing Orders Appendix A – Standards of Business Conduct for NHS Staff)

Staff and independent contractors working in the CCG are expected to:

- Act impartially in all their work

- Refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgment or integrity, and to avoid seeking to exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused.

- Declare and register gifts, benefits, or sponsorship of any kind, in accordance with time limits agreed locally, (provided they are worth at least £25), whether refused or accepted. In addition gifts should be declared if several small gifts worth a total of over £100 are received from the same or closely related source in a 12-month period.

- Declare and record financial or personal interest (e.g. company shares, research grant) in any organization with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgment is not influenced by such considerations.

- Make it a matter of policy that offers of sponsorship that could possibly breach the Code be reported to the Executive of the Clinical Commissioning Group.

- Not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others.

- Ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products and services.

- Beware of bias generated through sponsorship, where this might impinge on professional judgment and impartiality.

- Neither agree to practice under any conditions, which compromise professional independence or judgment, nor impose such conditions on other professionals.

Examples of Joint working

General principles

- Milton Keynes Clinical Commissioning Group will not accept any offer of support, financial or otherwise, from the Pharmaceutical Industry to initiate or maintain initiatives that are not in line with its strategic priorities.

- Joint initiatives between Milton Keynes Clinical Commissioning Group and the Pharmaceutical Industry must promote evidence-based medicine and support only those drugs that have an acceptable evidence-base.

- Milton Keynes Clinical Commissioning Group will consider the implications for the entire Milton Keynes Health and Social Care Community and other key stakeholders of any proposed project prior to commissioning the project.

- Sponsorship will not be accepted for projects that have the prime objective of increasing the usage of a specific brand of Pharmaceutical or other product.

- Any learning or products (protocols, guidelines, etc) developed through sponsored projects will be shared with other NHS organisations.

- Milton Keynes Clinical Commissioning Group will consider supporting the dissemination of lessons learned from the set projects but retains the right of approval of associated literature and material.

- Milton Keynes Clinical Commissioning Group will pursue joint working with all interested ethical pharmaceutical companies of good standing regardless of their size.

Specific examples

Offer from a company to provide for training of staff.
The CCG should be careful to ensure that staff are not pressurised by sponsors of training, to alter their own activity to accord with sponsors' wishes, where these are not backed up by appropriate evidence. Training provided by industry may be above board if it is unbiased and has mutual benefit for both the CCG and the sponsoring company, is evidence based and the hospitality is appropriate. However participants should assess whether they may be influenced unduly and also bear in mind what benefits the company might derive (e.g. exposure to NHS, professional contacts, potential allies to use later, names of who to influence, often without the participants realizing).

A manufacturer of specialist equipment offers to sponsor a nurse post in the CCG.
The CCG should not accept the sponsorship if it would require the nurse to recommend the sponsor's in preference to other clinically appropriate appliances, nor if it requires the CCG to recommend patients to use a particular dispensing service or withhold information about other products.

A manufacturer of a particular type of Nicotine Replacement Therapy offers to provide their product at a reduced rate within the CCG.
This arrangement is acceptable provided that there is a clear clinical view that these products are appropriate to particular patients and there is no obligation to also prescribe these products to other patients for whom an alternative product would be at least as beneficial.

A pharmaceutical company offers to provide starter packs at a discounted price.
This type of sponsorship is unacceptable.

High tech home health care provider offers to supply equipment at reduced rate in return for business linked to a specific product.

The CCG contracts team shall advise the company that any contract will not prejudice the provision of the most appropriate service to patients, and will not bear any relation to other contracts.

A manufacturer offers to pay the travelling costs or accommodation costs for clinicians invited to a conference to view medical products.
Only clinicians with a specific interest in the products should attend and the travel costs incurred should be paid for by the CCG, unless the Chief Officer or Director of Finance gives approval for the potential supplier to take responsibility for the costs. Such decisions should be taken at Director of Finance level.

The Department of Health has show-cased a number of joint working projects in its toolkit. Of relevance to primary care are:-

- A local programme to identify and target patients with suspected COPD
- A project providing telephone support to patients to help them understand the importance of lifestyle interventions in chronic diseases
- A well being support service for patients with severe mental illness
- A project to develop individual care plans, better patient education and regular disease monitoring for patients with COPD
- Happy hearts programme to identify patients at risk of heart disease, diabetes and stroke
- A find and treat strategy for CHD and diabetes

Checklist for Assessment of Collaborative Working with the Pharmaceutical Industry or their Agents or Affiliated Companies

If any responses to the following are **No,** the agreement should be further assessed as it will contravene the policy.

GENERAL

- Is the agreement in the best interests of patients? Y/N
- Is professional judgement unaffected? Y/N
- Is patient and NHS data confidentiality maintained? Y/N
- Is the agreement upright and honest? Y/N

CONTRACTUAL

- Does a contractual agreement exist (where possible)? Y/N
- Is the agreement lawful? Y/N
- Is there no reason to suspect the company will be unable to fulfill obligations? Y/N

CLINICAL EVIDENCE

- Is the agreement evidence based? Y/N
- Does the agreement represent best clinical practice? Y/N
- Is the agreement compatible with national and local arrangements for prescribing? Y/N

FINANCIAL

- Does the agreement represent value for money? Y/N
- If the agreement is linked to the purchase of a particular product, has there been a competitive tender process in line with CCG SFIS? Y/N
- Have costs and benefits been assessed in relation to alternative options? Y/N
- Is there provision within the agreement for financial audit? Y/N
- Have the future potential implications of the agreement been considered? Y/N
  (e.g. continuing cost of treatment initiated during a trial) and are on-going and future purchasing decisions are unaffected by the agreement?

AUDIT

- Is there provision within the agreement for financial audit? Y/N
- Has the CCG Head of Prescribing and Medicines Management been notified ? Y/N

OUTCOME MEASURES

- Does the agreement include monitoring of clinical and financial outcome measures? Y/N
- Is there provision for break clauses for the CCG to terminate the agreement if outcomes are not satisfactory? Y/N

The answers to the following MUST be NO otherwise the agreement may contravene the policy:-

- Is there any potential conflict of interest? Y/N
- Is there any reason to suspect the company will be unable to fulfill obligations? Y/N
- Are there any on going or future purchasing decisions affected by the agreement? Y/N
- Is the NHS expected to pick up recurrent costs of the scheme? Y/N
  If the answer if yes – needs to be considered as a SDO.

Assessment undertaken by …….

Date of assessment ……..

APPENDIX B

MILTON KEYNES CCG SPONSORSHIP FOR PROFESSIONAL OR SCIENTIFIC MEETINGS

To
Of (State Company)
Thank you for agreeing to sponsor the meeting on
Title of Meeting
Course Organiser

Sponsorship is accepted on the understanding that:-

- The meeting organiser retains overall control of the event and the content of the event
- The sponsor does not have the automatic right to present teaching or promotional material
- Where the organiser considers additional value may be gained from a presentation by the sponsor, that the content of the material is agreed in advance.
- The sponsor does not use the CCG contact to promote products outside the meeting.
- Any stand the sponsor uses to promote products is to be outside the main meeting room, where this is possible.
- Attendance at the meeting by the sponsor is at the discretion of the course organiser.
- Where course material is provided by a pharmaceutical company there is no promotion of specific products (the name of the company supporting the meeting is acceptable)

Please confirm that you accept the terms detailed above:

Signed: Date:

Print Name:

Position/Company:

APPENDIX C

NOTIFICATION OF COLLABORATIVE WORKING FOR MILTON KEYNES CCG REGISTER

Name of Pharmaceutical Company	
Date	
Details of proposed collaborative work	
Does the project concur with the check list	Y/N
If not please give details of the area of discrepancy:	
Is the collaborative acceptable to the CCG	Y/N
If not please give reasons for refusal	
Signed	Date
Print Name	
Position and Organisation	

Appendix 5

Policy for the use of Unlicensed and off-label Medicines

Introduction

Under the 1968 Medicines Act ALL medicinal products are required to have a Product Licence (PL) issued on behalf of the Department of Health. The PL defines the therapeutic or diagnostic purpose for which the product may be sold or promoted. The purpose for which a product is licensed together with information about approved doses, contra indications, side effects etc. is specified in the current Summary of Product Characteristics (SPC) for each product.

The majority of medicines that are prescribed will have been manufactured in accordance with a marketing authorisation or product licence. However, there are occasions when there is no licensed medicine available, or where an available licensed product is used at a dose or for an indication not covered by its licence (off-label use). It is acknowledged that prescribing out of licence is relatively common for children. In primary care up to a third of the prescriptions are unlicensed/off label. The Joint Standing Committee on Medicines of the Royal College of Paediatrics and Child Health and the Neonatal and Paediatric Pharmacists Group has produced a position statement on the unlicensed use of medicines in children. This is provided later. When considering paediatric prescribing, the following paragraphs should be read in the context of that position statement.

Licensed Medicines

As a general rule, licensed medicines should always be prescribed and administered in accordance with their SPC recommendations. Should an Adverse Drug Reaction (ADR) then occur the manufacturer and Trust/prescriber would generally share liability. However, if a drug is used outwith its product licence, **then the legal liability rests with the prescriber rather than with the consultant or manufacturer.**

Unlicensed Medicines / Indications / Unlicensed Doses

These may be:

- administration of a medicine by its licensed route to treat a disease not included in its PL
- administration of a medicine by an unlicensed route to treat a disease included or not in its PL
- clinical trial material
- products not on sale in the UK – awaiting a PL or withdrawn from sale in the UK
- products prepared for a specific patient e.g. TPN
- products prepared from a supplier with a 'Specials Licence'

The Department of Health guidance states that "A practitioner prescribing an unlicensed product does so entirely on his own responsibility, carrying the total burden for the patient's welfare and, in the event of an adverse reaction, may be called upon to justify his actions. Under these circumstances, it may be advisable for the practitioner to check his position with his medical defence union before prescribing such unlicensed products."

Unlicensed medicines should only be requested where a licensed medicine cannot be used. In these situations the prescriber is advised to fully inform the patient of this course of action and, where appropriate, obtain their informed consent. Whenever an unlicensed medicine is prescribed the prescriber is professionally accountable for his judgement in so doing and may be called upon to justify his actions.

Prescribing non-licensed medicines or outside the terms of the product licence

A doctor may prescribe any medicine they consider appropriate. Where this falls outside the product licence the practitioner signing the prescription accepts clinical responsibility and liability for effects. The expectation is that a prescriber acts in accordance with appropriate current practice. A prescriber may be called upon to justify their prescribing by other professionals involved in supply and administration of medicines prescribed out-of-licence.

- Where appropriate the patient should be informed before prescribing and the patient should understand that the product might be less well understood than a licensed product.

- Where a prescriber recommends or advises the use of a medicine outside its product licence to another practitioner this shall be stated together with a justification of the unlicensed use.

- Where a prescriber directs administration of a medicine outside its product licence the nurse or professional administering shall be informed. Nurses administering licensed medicines used outside the produce license should be satisfied they have sufficient information to administer the medicine safely and that there is acceptable evidence for the use of the medicine for the intended indication. This does not mean withholding treatment. It means actively seeking information from the prescriber and other appropriate sources.

It is therefore essential in the above situations that:

i) There is a sufficient body of medical opinion (expressed in up to date text books or scientific literature) that the use of the drug in the situation in question is valid and reasonable.

ii) The patient (or parent) is informed that the drug is to be given in an unlicensed situation, told what that means and whether it is a normal or accepted practice.

iii) Patients should be consented for treatment in the normal way. The benefits of treatment versus non-treatment (or management of the condition in another way) should be discussed. The patient (or parent) should be given sufficient information about side effects of the drug and their verbal consent obtained. All this should be documented in the patient's notes. Where there is significant risk of an adverse event consent should be obtained in writing.

iv) Where there is insufficient supporting body of medical opinion, the use of a drug in an unlicensed situation should normally only be undertaken as part of a clinical trial or as an individual doctor/patient intervention where the doctor/Trust will be responsible for the consequence of such action and be able to justify it in court if necessary. Any such intervention should normally only occur with full explanation and written consent and with the approval of a consultant/ the patient's consultant

v) Where there is no previously established practice/insufficient supporting body of medical opinion, Clinical directors must always be made aware of drugs that are intended to be used in such unlicensed situations within their directorate and must give their prior approval to such use. If necessary, to confirm the legal and clinical position, the Clinical Director, should seek further information and advice.

vi) The patient's general practitioner or any other doctor taking on prescribing responsibility for them should be informed, allowing for the eventuality that they may refuse to accept the care of that patient.

Unlicensed medicines in paediatric practice.

The informed use of unlicensed medicines or of licensed medicines for unlicensed uses is necessary in paediatric practice. The following policy statement has been issued by The Joint RCPCH/NPPG Standing Committee on Medicines to guide prescribers.

- Those who prescribe for a child should choose the medicine which offers the best prospect of benefit for that child, with due regard to cost.
- The informed use of some unlicensed medicines or of licensed medicines for unlicensed uses is necessary in paediatric practice
- Health professionals should have ready access to sound information on any medicine they prescribe, dispense or administer, and its availability.

- **In general, it is not necessary to take additional steps, beyond those taken when prescribing licensed medicines, to obtain the consent of the parents, carers and child patients to prescribe or administer unlicensed medicines or of licensed medicines for unlicensed applications.**

To meet the need for accessible, sound information and guidance “BNF for Children” is deemed to be a suitable text. The latest edition should always be used. It will rarely be necessary to prescribe outside the recommendations in this text. In those instances, paragraph v) above applies.

General
In case of disputes or other issues relating to prescribing of unlicensed medicines, please contact the CCG Pharmaceutical Advisers who will be willing to advise (01908 278744).

REFERENCES

Milton Keynes NHS Trusts Joint Formulary via CCG intranet site

BNF for Children via CCG intranet site

Appendix 6

Milton Keynes Prescribing Advisory Group (MKPAG) Terms of Reference

These may be accessed at
https://www.formularymk.nhs.uk/includes/documents/MKPAG-ToR-Aug-2017-v3.pdf

Appendix 7

CCG Prescribing Group Terms of Reference

These may be accessed at
https://www.formularymk.nhs.uk/Terms-of-reference/

Appendix 8

Primary Care Rebate Schemes
These may be accessed at