Greater Manchester Medicines Management Group (GMMMG) Clinical Standards Board for Medicines:

Policy: Engagement with the Pharmaceutical Industry

Revision History:

The latest version will be held on the GMMMG website.

Date	Actioned by	Comments/Summary of changes	Version
June 2013	B Reddy, Regional Drug and Therapeutics Centre www.rdtc.nhs.uk	Draft written for approval by GMMMG	V01
18.07.13	B Reddy	Minor updates following GMMMG approval	V02
11.10.16	B Reddy	Updates made following review and to include new GM wide joint project working received from AW.	V03
5.12.16	B Reddy	Updated following comments from GMMMG, however put on hold until development of Industry Joint Working Group and memorandum of understanding.	V04

Approval:

This document must be approved by the following before distribution:

Name	Title	Date of Approval	Version
GMMMG	GMMMG Policy: Engagement with the Pharmaceutical Industry	18.07.13	Final

Engagement with the Pharmaceutical Industry

Purpose:

This policy sets out the principles and standards which should be applied when GMMMG CSB and its officers and members engage with the Pharmaceutical Industry.

This policy covers GMMMG CSB and its three subgroups: Formulary and Managed Entry, Pathways and Guidelines Development group and High Cost Drugs subgroups.

Members support staff and any other persons acting on behalf of GMMMG CSB should adhere to the principles contained within this document when liaising with the pharmaceutical Industry.

These same principles and standards should apply equally to sponsorship by other profit making organisations and also non-profit-making or charitable organisations.

1. Introduction

1.1. The DH Guidance published in 2008 encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous. Such advantages need to be clearly stated and evidence presented to support these claims.

1.2. In the past, contact between the Pharmaceutical Industry and primary health care professionals have revolved around the purchase or promotion of specific products and the provision of sponsorship e.g. to support educational events or training. More recently, the Industry has begun to focus on enhancing its links with the NHS. Many companies have developed internal structures to encourage closer liaison with GP practices, CCG Boards and health care professionals working for CCGs or CSU's.

1.3. Although the NHS and pharmaceutical companies already work together in a number of ways, there are tensions that can create barriers to effective partnerships. Many in the NHS are suspicious that pharmaceutical companies will exploit their intellectual assets for profit, while pharmaceutical businesses are understandably focused on safeguarding their investments in research and development, and ensuring a return.

1.4. It is essential therefore that all projects or dealings with the Industry are **open** and **transparent** and are subject to the widest scrutiny to enable likely pitfalls to be highlighted at an early stage. This policy is in addition to the GMMMG declarations of interest policy and outlines the standards that members and support will adhere to when liaising with Industry.

1.5. The Greater Manchester Medicines Management Group (GMMMG) and its officers interact with the Pharmaceutical Industry in three main ways:

- Source of information on medicines (to aid the work of the Formulary and Managed Entry Subgroup).
- Working in partnership to aid the delivery of education meetings and materials.

- Partnership working with industry on GM wide projects.

2. Main Principles

2.1 In line with the NHS Code of Conduct three public service values underpin the work of the NHS:

- **Accountability** – everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgements 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; and
- **Openness** – there should be sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public

2.2 In addition where GMMMG CSB, its members or its officers enters into any joint working ventures with the pharmaceutical industry, their conduct should also adhere to the following values:

- ✓ Transparency and trust
- ✓ Appropriateness of projects
- ✓ Truthfulness and fairness.
- ✓ Patient focused
- ✓ Value for money
- ✓ Reasonable contact
- ✓ Responsibility
- ✓ Impartiality and honesty
- ✓ Compliance with the GMMMG CSB Declarations of Interest Policy

2.3 If a member, officer or support member is approached by a member of the pharmaceutical industry regarding GMMMG involvement in a project or joint working arrangement then the GMMMG Industry Task and Finish Group (see later) must be informed and all further communication should go via this group and should not be directed at individuals.

2.4 If individual GMMMG members are approached by the industry due to their membership of GMMMG, then these interactions should be declared on a separate register for internal GMMMG use. This applies to all members – voting or non-voting and support. Any such interactions should be declared to the professional secretary as soon as possible. It is the responsibility of members to declare any interactions.

2.5 All queries regarding formulary or new drugs should be referred to the Professional Secretary of the Formulary and Managed Entry Subgroup.

3. Provision of Information to GMMMG and its Subgroups.

3.1 A key role of the Pharmaceutical Industry is to provide useful information on new and existing medicinal products. However it is not possible to meet with all pharmaceutical industry representatives to discuss all products.

3.2 Therefore the following process for engagement has been devised:

a) The RDTC (Wolfson unit) or GM Shared service team will be the main point of contact for all Pharmaceutical Industry representatives wishing to discuss information pertaining to new medicinal products or new information regarding existing products. Any pertinent information will then be disseminated to the relevant groups.

b) Initially representatives will be asked to send information for consideration by GMMMG or its Subgroups via email either to the RDTC prescribing support team (rdtc.rxsupp@nuth.nhs.uk) or the GM shared service medicines management team (gmcsu.medsman@nhs.net). This ensures a more effective use of staff time. Information should be as detailed as possible, for example to include, published clinical trial data including safety, cost impact and any educational material to be left with GPs and Community Pharmacists. This allows GMMMG and its subgroups to identify which medicines should be included within work plans at an early stage and will allow a full discussion of the product in question.

c) Following this if a meeting is deemed necessary then representatives will be seen by appointment only **and** only when the product they wish to discuss has been identified by GMMMG as being a priority for Greater Manchester. Meetings will be arranged directly with RDTC or GM Shared service staff.

3.3 Information may be used in one of two ways.

- For horizon scanning purposes to inform whether a product is added to the work plan for discussion by GMMMG or its subgroups. This information request will normally be from the Professional Secretary to the Formulary and Managed entry subgroup.

- Or to inform a review or evaluation document; this will be used by the GMMMG or its subgroups to help make a decision around use of the product. The review may be written by RDTC prescribing support team or the GM Shared service, both of whom will request information (clinical trial data or cost impact information) via email.

3.4 ***Presentation of Information at GMMMG/GMMMG Subgroup meetings.***
Due to time constraints Representatives will not be able to present information directly to GMMMG or GMMMG subgroup membership. All information will be disseminated via the Professional Secretary as appropriate.

3.5 ***New Drug or Formulary Applications*.**
Applications (for discussion of a new drug or addition or changes to the formulary) cannot be made by the pharmaceutical industry. All applications received must be made by healthcare professionals working within Greater Manchester; this is to ensure that any medicine discussed has been identified as being of clinical relevance and a priority to the Greater Manchester health economy.

3.6 ***Decision Making.***
Decisions around which drugs are recommended or included within the formulary are made on the best available evidence. GMMMG will promote treatments for which there is good

evidence of clinical effectiveness in improving the health status of patients and will not recommend a treatment that is shown to be ineffective. Where possible the group will compare the cost of a new treatment to the existing care provided and will also compare the cost of the treatment to its overall benefit, both to the individual and the community. Treatments that have been shown to produce an improvement in patient related outcomes will be prioritised over those that don't. For further details around how decisions are made please see terms of reference for individual groups. Further detail is contained within terms of reference available on the GMMMG website.

3.7 ***Commenting on draft recommendations or pathways***

The GMMMG consultation process includes a period of time where GM Health Care Professionals are able to comment on draft recommendations or treatment pathways in development. The consultation takes place via the website. The pharmaceutical industry is invited to comment on **factual inaccuracies** only. All subgroups are however happy to receive comments relating to notification of incorrect information, addition of safety content or details of new data that may not have been considered at the time of the recommendation. Please forward these to the Professional Secretaries of the group/subgroup in question. (See GMMMG website for further details)

3.8 **Rebate Schemes**

GMMMG prefers that pharmaceutical companies supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS; However GMMMG have agreed that the GM Shared Services will process any rebate applications, received via GMMMG from pharmaceutical, nutrition and device companies, through the GMMMG Rebate Scheme ethical framework ; they will then make the outcomes available to GM CCGs for individual consideration. It will be up to GM CCGs to decide whether to take up any offer made and manage the claims directly with the relevant company. Please also see Rebate Statement by the Formulary and Managed Entry Subgroup.

3.9 All high cost drugs schemes that are available prior to NICE (including free of charge schemes) or on the launch of a new high cost medicines (i.e. rebates, discounted or outcome based schemes) must be evaluated by the High Cost Drugs Subgroup. This group will review these schemes after a decision has been made regarding efficacy and appropriateness of prescribing by the Formulary and Managed Entry Subgroup.

4. Educational Meetings or Materials.

4.1 GMMMG may on occasion organise educational events and if so may wish to invite Pharmaceutical Industry involvement, if their involvement is compatible with the GMMMG policies and/or recommendations.

4.2 If sponsorship is considered appropriate, multiple pharmaceutical companies will be approached. GMMMG will endeavour to offer all companies with a product in the GMMMG formulary an equal opportunity of providing sponsorship for meetings and educational events.

4.4 Where pharmaceutical companies are offered a stand to provide medical information a standard fixed fee will be agreed and applied equally to all companies.

4.5 Ideally GMMMG would prefer that Companies promote mainly products included in the GMMMG Formulary or those that have been approved for use within the Greater Manchester Health Economy. However GMMMG will not endorse any promotional or commercial materials produced by the pharmaceutical industry even if the products are contained within the formulary. All communications regarding GMMMG recommendations or guidance to healthcare professionals will come directly either via the website or other means.

4.5 Please note that sponsorship of a speaker at a meeting will not give a pharmaceutical company the right to choose the speaker or decide on the content of the talk or session.

5. Joint working with Industry

Joint working is defined as:
'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'

5.1 There may be occasions where the Pharmaceutical Industry can provide resources which can help Greater Manchester achieve improved outcomes in patient care whilst also providing benefit to the company. On these occasions a joint working with the industry may be beneficial to both parties and can be considered as per the ABPI/DH toolkit.

5.2 Any joint projects that would fall under the '*medicines optimisation workstream'* and will fall under the remit of the GMMMG CSB. Any projects that fall under *innovation or research* will be led and managed by the Joint Industry Group and Health Innovation Manchester. The following process relates to medicines optimisation joint working projects only.

5.3 The GMMMG CSB will specify prioritised therapeutic areas that any proposed projects should cover. These will be available on request and the prioritised areas will be identified according to the needs of the GM population. Submissions should be sent to the generic shared service medicines management email address (gmcsu.medsman@nhs.net) for logging.

5.4 A specific task and finish group will be set up to review any joint project submissions received. Membership of such a task and finish group will be agreed by GMMMG CSB during the scoping phase and members will be chosen in such a way that any perceived conflicts of interest are reduced and any interaction with industry is open and transparent i.e. those involved in clinical decision making such as formulary or new drugs recommendations should not be included in any task and finish group to approve or agree industry projects. The governance under which the task and finish group will operate must be signed off by GMMMG prior to the group being set up. However all partners affected by any schemes or proposals put forward must be represented in any discussions.

5.5 Where collaborations have been approved by the task and finish group then the proposal must be presented or put forward (by a Task and Finish group representative) at a full GMMMG CSB meeting for approval before any agreement is made. Legal advice may also be necessary. GMMMG CSB will retain control of all projects.

5.6 GMMMG or its representatives will not agree to practise under any condition that compromises professional independence or judgement, or imposes such conditions on other health care professionals.

5.7 Pilot projects will be used, where feasible, to further assess the suitability of the projects for joint working before any longer term arrangements are made.

5.8 There will be a "specific agreement" for each joint venture which will contain information on the points below. These will be presented in full to a GMMMG meeting.

- What the pharmaceutical company will provide

- What GMMMG or its constituent CCGs will provide
- The benefits for the pharmaceutical company
- The benefits for the GM Health Economy
- The time scale for the venture, with a break clause should the agreement fail to reach expectations.

5.9 If any of the "specific agreements" are broken then the joint venture will be terminated immediately.

5.10 Each company that enters into a joint venture with GMMMG will be acknowledged for resources provided; however the GMMMG CSB **will not** endorse a particular product or company as a result of the joint venture. All clinical decisions will be kept completely separate to any joint working projects. Decisions will continue to be made on the best available evidence taking into consideration evidence of efficacy, safety, projected cost, affordability and value and patient benefits, as outlined in the GMMMG CSB terms of reference.

6. References

6.1 Commercial sponsorship: Ethical standards for the NHS (Department of Health)
http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135

6.2 Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry (Department of Health /Association of British Pharmaceutical Industries (ABPI))
http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840