

## **MEDICINES STANDARD B3: WORKING WITH THE PHARMACEUTICAL INDUSTRY**

NHS employees and contractors link with the pharmaceutical industry in a number of ways, as a source of information, through the receipt of sponsorship as part of a joint working arrangement to improve patient outcomes.

Positive interaction with the pharmaceutical industry for the benefit of patients is encouraged, and the aim of this guidance is to ensure that such interactions are subject to the appropriate probity and governance arrangements.

This guidance must be read in conjunction with the CCG [Standards of Business Conduct policy](#) (incorporating conflicts of interest).

### **DEFINITIONS**

The pharmaceutical industry, referred to in this document as 'The Industry' includes:

- Companies, partnerships or individuals involved in the manufacturing, sale, promotion or supply of medicinal products subject to the licensing provisions of the Medicines Act.
- Companies, partnerships or individuals involved in the manufacture, sale, promotion or supply of medical devices, appliances, dressings, and nutritional supplements which are used in the treatment of patients within the NHS.
- Trade associations representing companies involved with such products.
- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product that is being considered by, or would be influenced by, decisions taken by Dorset Clinical Commissioning Group.
- Pharmaceutical industry related industries, including companies, partnerships or individuals directly concerned with enterprises that may be positively or adversely affected by decisions taken by Dorset Clinical Commissioning Group.
- CCG Staff are individuals on the CCG payroll for permanent or fixed term posts.

### **REBATE SCHEMES AND DISCOUNTS**

In line with the direction of the Department of Health and the 2014 Prescription Price Regulation Scheme (PPRS) NHS Dorset CCG will not participate in rebates paid to the commissioning body for the supply of medicines with a positive NICE technology appraisal.

Medicines that have been approved for entry to the formulary will do so based on clinical and cost effectiveness evidence, through the processes advised in [NICE guidance on developing and updating local formularies](#) (December 2012).

From September 2017 NHS England will establish a Regional Medicines Optimisation Committee which will give some guidance on formulary inclusion and this information will be brought to the DMAG for local adaptation.

Patient Access schemes for NICE approved medicines may be entered into by providers commissioned to prescribe medicines for the CCG, but Patient Access Schemes are not regarded as suitable for use in Primary care. For more information on patient access schemes refer to the [Pharmaceutical Price Regulation Scheme guidance](#) (Department of Health, last updated December 2015).

Member practices may be offered rebates and discounts by manufacturers for medicines that are dispensed by them or personally administered. When this is the case, they should ensure that this does not result in an increased cost to the NHS and that prescribing is not influenced by the presence of such rebates and discounts. Practices should ensure that any financial rewards meet GP contractual obligations as set out in Annex 8 of the GMS contract, Human Medicines Regulations 2012 and the Bribery Act (2010), as well as [GMC Good Medical Practice: Honesty in financial dealings](#) no.78. "You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients".

If a CCG member practice has benefitted financially from the use of a specific medicine through discounts or rebates applied, then any GP partners or employees of that practice, involved in medicines decision making or advice on that medicine should declare their interest to the chair of the relevant meeting and in a declaration of interest form submitted to the CCG.

Declarations of interest processes are included in the terms of reference for the Dorset Medicines Advisory Group, Medicines Optimisation Group, Formulary Group and relevant sub groups for this purpose.

Member practices should also keep a register of gifts and hospitality as required by the [NHS \(General Medical Service Contracts\) Regulations 2004](#).

## **SAMPLES OF MEDICINES**

Samples of prescription medicines should not be accepted by CCG Staff. In the case of evaluation of an appliance, dressing or other prescribable device, or for palatability tests of supplements etc., samples may only be sought as part of a pre-planned and documented review exercise.

Any samples received in unsolicited mail should be safely returned to sender as soon as possible.

Member practices and providers to the CCG should consider their use and acceptance of samples in the context of this policy and the individual organisation policies.

## **INDUSTRY EMPLOYEES: APPOINTMENTS WITH CCG SUPPORT STAFF**

For the purposes of promoting a particular medicine, treatment or other prescribable appliance or device, all contacts with the pharmaceutical industry should be referred to the Medicines Team. Contact will initially be via an appointment request form (see [appendix 1](#)). A flow chart summarising the process of requesting an appointment with the Medicines Team can be found in [appendix 2](#).

The industry employee should use the request form ([appendix 1](#)) to outline the product(s) that they wish to promote and the field of treatment. A senior pharmacist will then assess whether the item is a current priority, and thus whether to offer an appointment.

An appointment with a senior pharmacist may be by telephone or in person and supporting material for assessment may be requests in advance of the meeting for prior evaluation. When appointments are granted, the industry should seek to provide clinically relevant information, and avoid sales pitch approaches.

If the medicine or other prescribable item is not regarded as a priority to the medicines team then appointments will not be granted.

Where pharmaceutical industry colleagues wish to promote non-drug services, for example analytical and commissioning tools then they should use the Pharmaceutical Industry NHS Collaborative – Dorset (known as the PINC-D group) as the main route for offering such support. A copy of the PINC-D terms of reference can be found in [appendix 3](#).

If the industry offerings are in line with CCG priorities then industry colleagues may seek non-drug or appliance appointments with other CCG support employees. This may be undertaken using the application form in [appendix 4](#), and a flow chart summarising the process of joint working proposals and interactions with PINC-D can be found in [appendix 5](#).

CCG employees accepting such appointments must not enter into discussions about drugs without a CCG pharmacist present.

## **PAN DORSET FORMULARY**

The main health organisations in Dorset have agreed a joint approach to management and maintenance of a pan Dorset formulary. Access to this is via [www.dorsetformulary.nhs.uk](http://www.dorsetformulary.nhs.uk).

Organisations wishing to see their medicines or other prescribable product on the formulary should follow the local procedures for doing so. See [appendix 6](#), which contains a flow chart summarising how medicines are approved for use locally.

## **TRAINING EVENTS AND SPONSORSHIP OF MEETINGS**

Occasionally the CCG may seek sponsorship support. This must be handled in line with the [CCG Standards of Business Conduct policy](#), that states:

*“CCG staff may accept commercial sponsorship for courses, conferences, post/project funding, meetings and publications if they are reasonably justifiable and in accordance with the principles set out in this policy. In cases of doubt advice should be sought from your line*

*manager. Permission (with details of the proposed sponsorship) must be obtained from the relevant director in writing in advance and a copy of this permission must be sent to the Governing Body Secretary.”*

Any such sponsorship must **not** include promotion of drugs or products that are not on the CCG (pan-Dorset) formulary and individuals organising events where sponsorship has been accepted should liaise with the Medicines Team to ensure that this is the case. This includes “exhibition” style meetings where two or more companies support the meeting with table top stands either alongside or external to the meeting.

Organisers should work with the Pharmaceutical Industry colleagues to ensure that the meeting arrangements meet the requirements of the [ABPI and the PMCPA code of practice](#). This includes:

*“Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training”*

## **WORKING TOGETHER**

The CCG supports the principle of closer working relationships between industry and the NHS and the publication “[Joint working with the pharmaceutical industry, guide and case studies](#)” (Association of British Pharmaceutical Industries (ABPI), 2013).

Joint working relationships between NHS Dorset CCG and the pharmaceutical industry must promote and enhance equitable access to evidence based, high quality healthcare for the people of Dorset. This collaboration will support projects that address local and national priorities, and will maintain the freedom of clinicians to prescribe the most clinically appropriate and effective treatment for patients.

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.

The CCG supports joint working where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills and experience and or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

Any such collaboration would be neutral, free from preference for using one company’s product over other clinically appropriate or cost effective products or services.

The Governing Body Secretary will maintain a register of sponsorship and collaborative agreements. This register will record submitted and approved proposals as well as proposals not approved and the applicable reason(s). The register will be open to inspection by the public.

[Appendix 7](#) provides examples of scenarios encountered in the CCG support service and member organisations, suggested approaches and best practice.

## REFERENCES

[The Code of Practice for the Pharmaceutical Industry](#) (January 2014)

CCG [Standards of Business Conduct policy NICE guidance on developing and updating local formularies](#) (December 2012).

[Pharmaceutical Price Regulation Scheme guidance](#) (Department of Health, last updated December 2015).

[Joint working with the pharmaceutical industry, guide and case studies](#) (ABPI, November 2013)

[Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry](#) (Department of Health /Association of British Pharmaceutical Industries (ABPI), 2010)

[Joint Working – A quick start reference guide for NHS and pharmaceutical industry partners](#) (ABPI, May 2012)

[Association of British Pharmaceutical Industries \(ABPI\) and Prescription Medicines Code of Practice Authority \(PMCPA\) code of practice](#) (2014)

ABPI public register of payment to healthcare professionals and organisations:  
[www.disclosureuk.org.uk](http://www.disclosureuk.org.uk)

**APPENDIX 1: FORM FOR PHARMACEUTICAL REPRESENTATIVES TO REQUEST AN APPOINTMENT WITH THE MEDICINES TEAM**

Pharmaceutical Industry Representative Request Form for an appointment with Dorset CCG  
Head of Medicines Optimisation and Prescribing and/or Senior Pharmacist

Name:	
Company represented:	
Date of request:	
Contact telephone number Inc. STD code:	
Email Address:	
Reason for requesting appointment:	

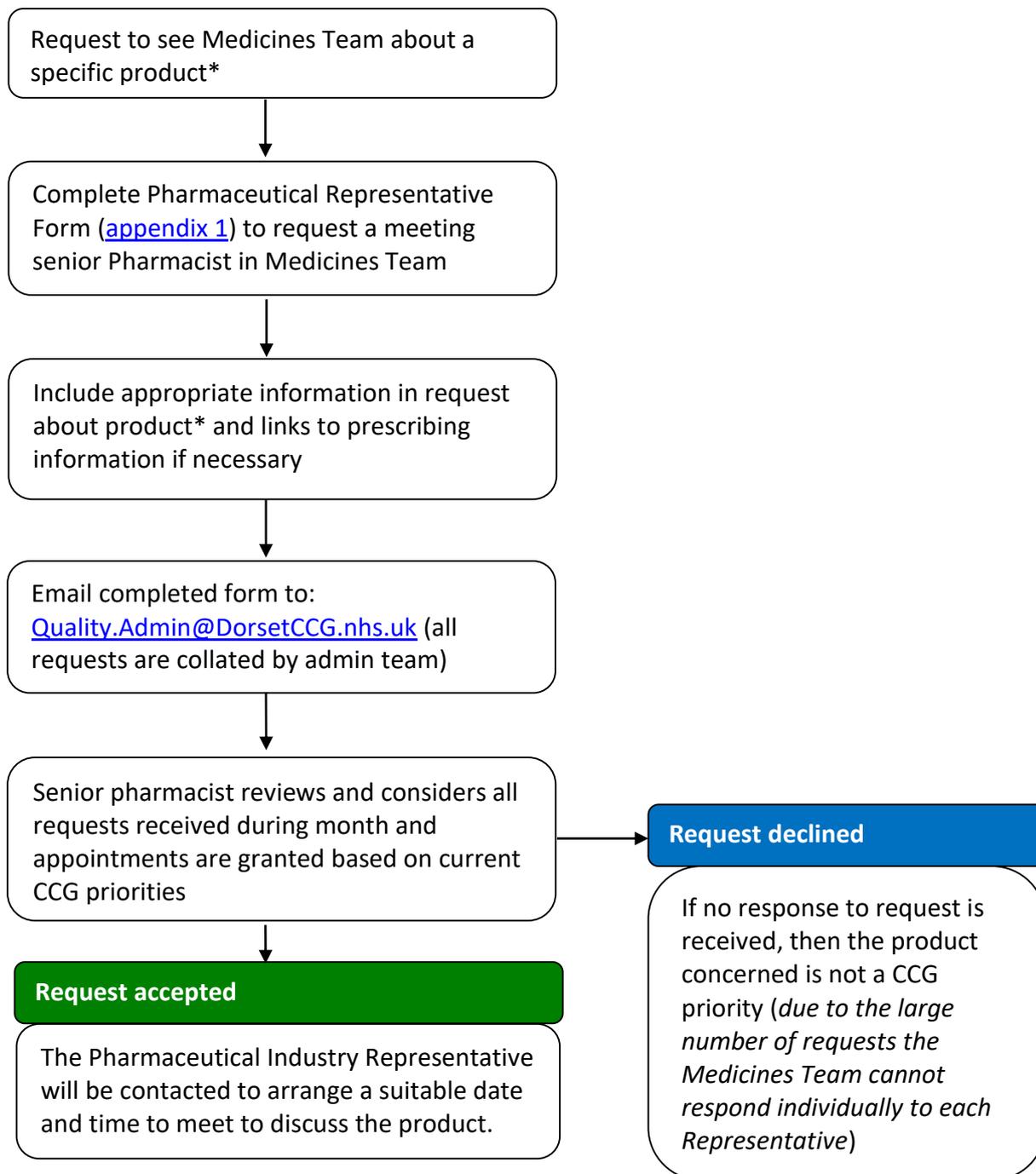
Please return this form to: [Quality.Admin@DorsetCCG.nhs.uk](mailto:Quality.Admin@DorsetCCG.nhs.uk)

Appointments are granted at the discretion of Dorset CCG with regard to current priorities and workload. **If you do not hear from the Medicines Management Team within one month of sending this form then please assume that your request for an appointment has been declined. You may re-apply at intervals not less than 6 months.**

Dorset CCG use only:

	<i>Please tick:</i>			
Appointment approved:	Yes:		No:	
Date and time suggested:				
Representative contacted and appointment booked:				

## APPENDIX 2: FLOW CHART SUMMARISING PROCESS OF PHARMACEUTICAL REPRESENTATIVES MEETING WITH THE MEDICINES TEAM



Please note:

- *\*All requests for appointments should be with the intention of discussing a specific product*
- *Directors at the CCG will usually refer requests to discuss medicines and devices back to the medicines team, and therefore approaching Directors will not circumvent the usual processes in place to request an appointment.*

## **APPENDIX 3: TERMS OF REFERENCE FOR THE PINC-D GROUP**

The Pharmaceutical Industry NHS Collaborative – Dorset (PINC-D) is a NHS Dorset CCG facilitated group with an industry chair. The group was formed to increase and improve transparency between the clinical commissioning group and interested industry partners. The purpose is to share information on the CCG's priorities and 5 year plan with Industry colleagues to support potential collaboration, and communication.

### **Membership**

- All relevant organisations within the pharmaceutical industry, with a presence in Dorset (and where appropriate medical devices industries) are invited to put forward a suitable employee to be a member of this group.
- The employee suitability is at the discretion of the individual pharma company, but it should be noted that this is a non-promotional arena, and it would not be appropriate to raise product specific issues at PINC-D meetings.
- It would be expected that each organisation would not field more than one member for room booking and hospitality practicalities.

### **Behaviour/expectations**

The industry Chair will be elected by industry members of the group and is for a 2 year period. The Chair, with the support of the CCG retains the right to review suitability of membership of individual if this is inappropriately used as a sales opportunity.

### **Aims**

- To recognise the health priorities and implementation strategy of Dorset CCG.
- To improve transparency and communication between the industry and the CCG.
- To identify support and resources to help deliver CCG priorities and development and review of patient pathways..
- To identify skill sets available to the CCG via industry colleagues such as project management, audit, IT, marketing, facilitation, chairing and data sources.
- The group will seek to develop a skills “bank” of resources and skill sets of the members which can be called upon to support service developments.

### **Meeting frequency**

The CCG will aim to hold approximately 9 meetings per annum at CCG premises. The agenda will be driven by CCG priorities and the Clinical Commissioning programme work plans, with each meeting a specific programme area. one meeting per year will be focussed on medicines management priorities.

Following each meeting, a set of notes and any relevant presentations will be circulated to the group. In addition the required contact method for proposals of how a company can support or help in the implementation of the programme will be included in the notes, and a form to offer further information provided.

**APPENDIX 4: FORM FOR PHARMACEUTICAL REPRESENTATIVES TO PROPOSE JOINT WORKING / OFFER A SERVICE**

Pharmaceutical Industry Representative Contact form to propose joint working / service offering with Dorset CCG

Name:	
Company represented:	
Date of completing form:	
Contact telephone number Inc. STD code:	
Email Address:	
Details of proposal:	

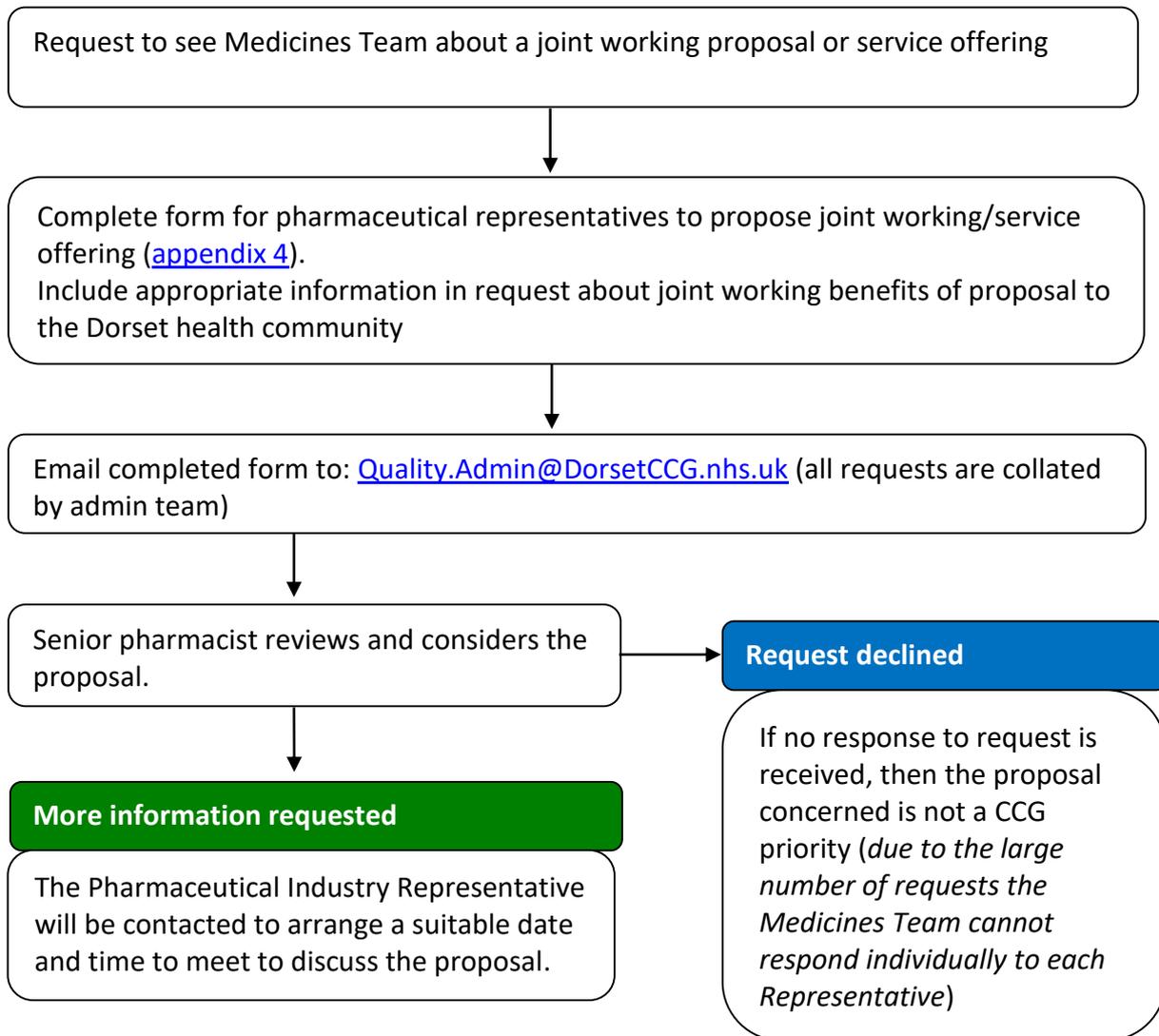
Please return this form to the relevant email/fax (provided via membership of PINC-D group)

Appointments are granted at the discretion of Dorset CCG with regard to current priorities and workload. **If you do not hear from the CCG within one month of sending this form then please assume that your request has been declined. You may re-apply at intervals not less than 6 months.**

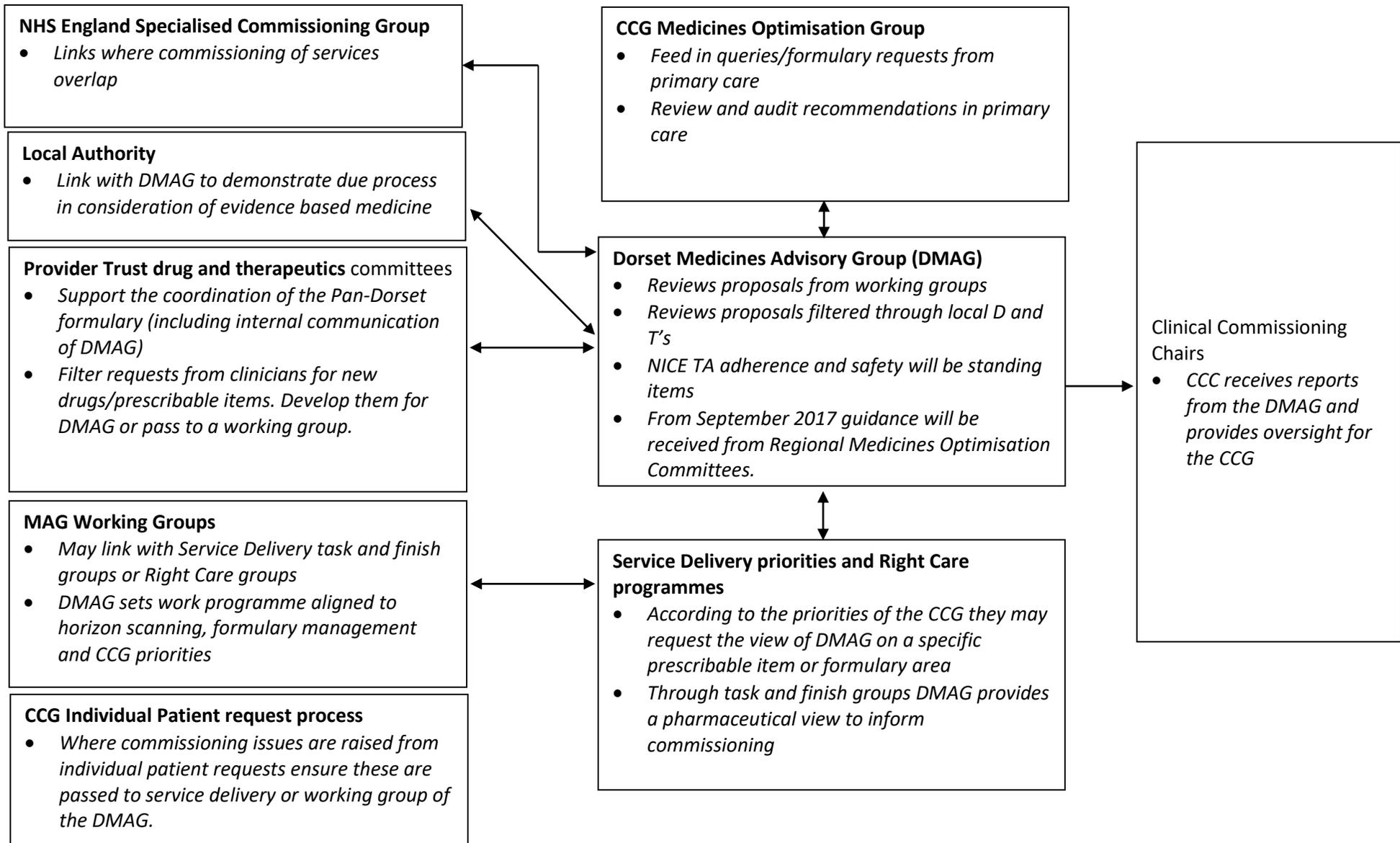
Dorset CCG use only:

		<i>Please tick:</i>		
Request approved:	Yes:		No:	
Representative contacted:				

**APPENDIX 5: FLOW CHART SHOWING PROCESS FOR PROPOSE JOINT WORKING / SERVICE OFFERING FROM PHARMACEUTICAL REPRESENTATIVES**



## APPENDIX 6: HOW MEDICINES ARE APPROVED FOR USE LOCALLY



## APPENDIX 7: SCENARIOS SEEKING INDUSTRY SUPPORT

Scenario 1	Questions & answers
<p>The pan Dorset medicines interface working group (made up of senior pharmacists in the NHS organisations in Dorset) have developed an allergy card as part of a patient safety initiative and are seeking industry funding for printing and issue of the cards. What is the correct process for seeking such support?</p>	<p><b>Q:</b> Does this fall within the definitions of an ABPI joint working project?</p> <p><b>A:</b> No, the industry has not been involved to date and the time and cost does not fall into the ABPI definitions.</p>
	<p><b>Q:</b> Is there a resource already out there that would be suitable? I.e. has a company already supported the development of something similar elsewhere in the UK?</p> <p><b>A:</b> Not known, the industry has not been involved to date.</p>
	<p><b>Q:</b> Can industry fund?</p> <p><b>A:</b> In order to gain support from the pharma industry on such a project, the ideal situation would be to involve them from the very beginning of the project. In this case, the route could be to seek the advice of the PINC-D chair on organisations that may be interested. In future the “skills bank” may identify companies with specific patient safety interests.</p>
	<p><b>Q:</b> If this becomes industry sponsored would it have to have a company logo attached?</p> <p><b>A:</b> Not necessarily, but you would have to put onto the card, “this printing has been funded by XXcompany” as a bare minimum.</p>
	<p><b>Q:</b> Is this something that it is appropriate to seek industry funding for, or should the NHS fund such a patient safety initiative?</p> <p><b>A:</b> As this is a patient safety initiative, and is wholly NHS led and developed then it is not appropriate to seek industry funding at the end of the project, purely for the printing. The organisations contributing to the development and design should have considered funding at the beginning and how they intended to fund the printing. It is more appropriate for the printing to be shared between the represented organisations.</p>
<p><b>Best Practice</b></p> <p>If this had been set up as a joint/partnership working project from the beginning, then an agreement could have been set up which laid out the terms of working between the NHS and industry. This would include resource contribution, including time and money, as well as considerations of printing, marketing and distribution once the product has been developed. In this case, and industry partners interested in taking on this development and distribution role, could be sought from the PINC-D at the outset.</p>	

Scenario 1	Questions & answers
Scenario 2 - Supporting a Professional Network	Things to consider
<p>A professional network for health professionals across a range of provider organisations has been in existence in Dorset for some years, and has been sponsored by the Pharmaceutical industry. The event is held in an evening in a hotel conference room arrangement. A Pharma company has historically covered the cost of hospitality for the event.</p> <p>The changes in ABPI rules mean that in future should such an arrangement continue, the pharma company must have the full slide set and agenda approved by their head office. An alternative would be for this to be shared between two or more companies. In order to do that, the organiser of the meeting has asked if the CCG could pay the venue fees and then invoice the companies offering to sponsor the meeting.</p> <p>The Head of Medicines Management has been asked if this arrangement can be approved?</p>	<p>The first thing to consider is whether the commissioning organisation should support this and any other professional networks, and whether this is the role of the commissioner. Most specifications for commissioned services include the role of the provider in supporting training. In addition, the “laundering” of money in this manner, will mean that the CCG would have to maintain a record of the hospitality received and the money received from the companies. Such a receipt of monies must be declared by the CCG in the register of interests and will be published as a disclosure on the ABPI website. The CCG would have to consider if such a disclosure and receipt would suggest any conflict of interest in the operations of the CCG.</p> <p><b>Best Practice</b></p> <p>If this is a proper business network, with formal agendas and slide sets with hospitality secondary to the business event, then the option of hosting it in an “exhibition” manner with more than one company funding it is appropriate, and arrangements can be made to have the provider organisations organising the events to manage and declare the sponsorship. An alternative would be to use a venue where they are happy to invoice industry representatives directly, or have them pay the hotel on the night. See main policy for the nature of exhibitions for sponsorship. The network lead would need to ensure that any fees received are accurately recorded and that the pharma company can record for disclosure purposes accurately.</p>

Scenario 3 - Funded Lunches	Things to consider
<p>In some localities, meetings at lunchtimes often have hospitality provided. It has become custom and practice to have industry representatives provide these lunches. Some localities also specify the store and standard of lunch to be provided, in some cases the industry rep will speak about the product they are promoting, in others, the locality will provide a list of attendees for the representative after the event.</p> <p>Is this appropriate sponsorship?</p>	<p>The locality should consider whether it is appropriate to seek sponsorship for hospitality for events which are part of NHS business as member practices of the CCG. If hospitality is sought and received, then a register of gifts and hospitality must be maintained as per the NHS and GMC regulations.</p> <p>If a rep has agreed to provide lunch, then it is not appropriate to demand where the food is sourced. Any attendees of the meeting should be made aware that the food is provided by a company and that it is noted on the agenda.</p> <p>There is no such thing as a free lunch, and if the locality has sought out funded lunch, then the company funding it will expect to get an appropriate time slot to promote their product, this is likely to be more than 5 minutes and meeting times should be co-ordinated appropriately.</p> <p>From 2015, any hospitality costing in excess of £100 will be publically available on a disclosure database hosted by the ABPI. Localities and practices hosting locality meetings should ensure that the hospitality received is recorded and declared where appropriate and ensure that the pharma company has accurate information for disclosure purposes.</p>