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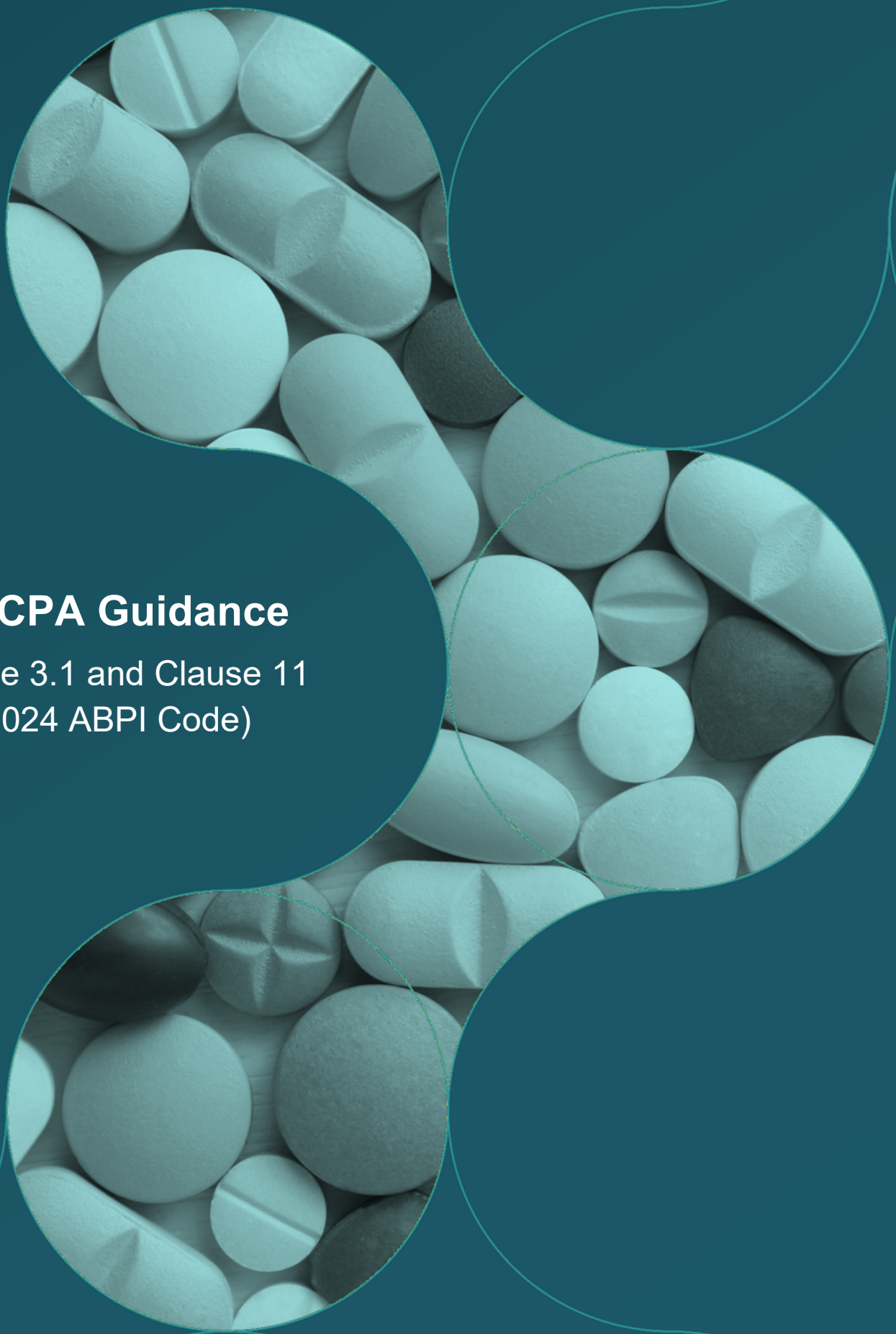

PMCPA Guidance

Clause 3.1 and Clause 11 (2024 ABPI Code)

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01 September 2025

Clause 3.1 and Clause 11 guidance (2024 ABPI Code)

The PMCPA cannot approve any materials or activities: it can only give informal advice based on its interpretation of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice ("the Code"). In the event of a complaint being received about any matter referred to in this document, it would be considered in the usual way; the Code of Practice Appeal Board would make the final decision if a case went to appeal. Each complaint is considered upon its own merits and based upon the allegations raised by the complainant.

This guidance is not a substitute for a detailed study of the 2024 Code and does not replace the need for pharmaceutical companies, including their employees, third parties and the like to follow the ABPI Code and all other applicable codes, laws and regulations to which they are subject. It also does not identify all the requirements that must be followed for each activity, as they may vary significantly depending on the nature of the activity.

Please note that some of the cases cited in this document refer to previous editions of the Code where the clause numbers may differ from the current 2024 Code.

Contents

1. Provision of information about unauthorised medicines/indications

Clauses 3.1 and 11.1 prohibit the promotion of a medicine prior to the grant of its marketing authorisation. Clause 11.2 requires that promotion must be in accordance with the marketing authorisation and must not be inconsistent with the summary of product characteristics (SPC). These are also requirements of UK law.

Promotion prior to the grant of a marketing authorisation is an example of an activity likely to be in breach of Clause 2 of the Code. Clause 2 requires that activities or materials must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. A ruling of a breach of Clause 2 is a sign of particular censure.

Clause 1.17 defines “promotion” as “any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines”. This is followed by a list of materials and activities that come within that definition and a number that do not. Companies should be aware that if a non-promotional item is used for a promotional purpose, it would come within the definition of promotion.

The definition of promotion is broad. The proactive provision of information by a pharmaceutical company about an unlicensed medicine or indication is likely to be seen as promotion and in breach of the Code, unless the company can clearly demonstrate otherwise. There are certain exemptions set out in the Code, some of which are referred to in this guidance document.

Clause 1.17 states, among other things, that the term promotion does not include, “replies made in response to unsolicited individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature”.

The supplementary information to Clause 1.17, Replies Intended for Use in Response to Individual Enquiries, further states:

> An unsolicited enquiry is one without any prompting from the company. In answering any unsolicited enquiry, a company can offer to provide further information. If the enquirer subsequently requests additional information, this can be provided and would be exempt from the Code as long as the additional information met the requirements of the exemption. A solicited enquiry would be one where a company invites or prompts a person to make a request. For example, material offering further information to readers would be soliciting a request for that information and placing documents on exhibition stands

amounts to an invitation to take them; neither can take the benefit of this exemption.

Replies intended for use in response to enquiries which are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not look like promotional material.

The reason for the exemption in the Code is to allow pharmaceutical companies to answer specific questions from health professionals and other relevant decision makers. One area that frequently comes up in this context is questions about unauthorised medicines/indications or off-label questions. To ensure that the exemption is only used in relation to genuine enquiries, the word 'unsolicited' (i.e. not prompted by the company) is used. This is to clearly separate the promotion of medicines from the role of, for example, medical information departments. Clause 1.17 relates to interactions with health professionals and other relevant decision makers. For information regarding responding to enquiries from patients, the public or journalists, see Clause 26 of the Code and its supplementary information.

Clause 1.17 supplementary information states that price lists for unlicensed medicines which include no product claims and make clear that the products are unlicensed can be sent to health professionals and other relevant decision makers at reasonable intervals or in response to enquiries. They must not be used proactively in a manner which could be seen to be promoting unlicensed medicines, such as by displaying them on exhibition stands.

The supplementary information to Clause 11.1 provides information about conditional marketing authorisations, early access to medicines schemes and compassionate use.

Clause 11.3 states that a medicine with a temporary supply authorisation must not be promoted unless it is part of a campaign that has been approved by the health ministers. The supplementary information to Clause 11.3 provides further information.

2. Legitimate exchange of medical and scientific information during the development of a medicine

The supplementary information to Clause 3.1 states that the legitimate exchange of medical and scientific information during the development of a medicine is not prohibited, provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause. In this regard, the context in which the exchange takes place and the audience will be important factors in determining whether the activity is acceptable under the Code.

Example cases

There have been a number of Code cases in this area, for example:

- Case AUTH/2868/8/16
- Case AUTH/2978/9/17
- Case AUTH/3250/10/19
- Case AUTH/3469/2/21

For the legitimate exchange of medical and scientific information during the development of a medicine, data presented should be new and pivotal and should enhance current medical or scientific knowledge. Delegates must be able to adequately participate in the debate. It must not be a one-way flow of information. This facilitates the possibility of genuine challenge and exchange of views on the data being presented.

The legitimate exchange of medical and scientific information during the development of a medicine is often carried out at learned society meetings and congresses etc. However, if the activity is advertised from an exhibition stand it is very likely to be seen as promotion and in breach of the Code. Consideration should also be given to the geographical separation of the different activity types within the congress/event venue. There should be no connection or overarching theme between the promotional and non-promotional activities.

The legitimate exchange of medical and scientific information is carried out during the *development* of a medicine. Whether a medicine is still 'in development' is decided on a case-by-case basis. There is no defined time period in the Code, however, if a marketing authorisation has been *applied* for in *any* country, the medicine is unlikely to be seen as still 'in development'. Companies should also take particular care when an unlicensed medicine is already available for use, for example, in a compassionate use programme. Each case would be considered on its individual merits.

The legitimate exchange of medical and scientific information during the development of a medicine is not limited to medicines without a marketing authorisation. However, it would be more difficult for a company to establish that a medicine with a marketing authorisation is 'in development' in relation to an unlicensed indication being discussed, particularly if the licensed medicine was available in a dosage form that could be used for the unlicensed indication.

The checklist below can be used by companies to help them decide if the activity is the legitimate exchange of medical and scientific information during the development of a medicine. It is not intended to be an exhaustive list.

Is the activity the legitimate exchange of medical and scientific information during the development of a medicine?	
The answers to the following questions should be 'Yes':	☑
Is the medicine being discussed still in development?	☐
Is the information to be exchanged new and pivotal?	☐
Does the material presented have a scientific non-promotional appearance?	☐
Is the audience comprised of those likely to be able to contribute meaningfully to the exchange of information?	☐
Are the arrangements and logistics of the meeting appropriate to facilitate the possibility of genuine challenge and exchange of views for the number of attendees?	☐
Does the agenda allow for adequate time for exchange/debate?	☐
Have the speakers/chair been adequately briefed that discussion and an exchange of information/debate is essential?	☐
Are contingencies developed if few/no questions are asked by the attendees to support and/or stimulate debate?	☐
Does the company have a reasonable expectation that the exchange of information will enhance the current medical and scientific knowledge of the entity/product being discussed?	☐
Are staff and third parties involved with the meeting clear about the absolute need to avoid promotion?	☐
Is the information being presented a balanced, fair and true representation of current data such that a clinical/scientific debate/exchange would be of value?	☐
Is it clear to all attendees the data being presented is to elicit views, debate and or challenge?	☐
Is the company involvement in the activity clear?	☐
Are appropriate disclaimers in place to make the licensing status of the product clear?	☐
Is there a process in place to collate and assess information gained during the exchange?	☐
Is there sufficient time between the meeting and the expected licence application date for the company to act, if needed, upon information gained from this exchange to impact/shape the development of the medicine?	☐

Is the activity the legitimate exchange of medical and scientific information during the development of a medicine?	
If the answer to any of the following questions is 'Yes', there may be a compliance issue:	⚠
Is the product licensed in any country?	☐
Is the product already licensed for one indication and available in a dosage form that could be used for the unlicensed indication being discussed?	☐
Has a marketing authorisation been applied for in any country?	☐
Is the unlicensed medicine already available for use – for example, compassionate use or named patient programme?	☐
Did representatives (as defined by Clause 1.19) choose/invite any attendees or attend the meeting?	☐
Additional questions to consider:	?
What will the exchange provide for the company?	
How close is the company to filing for marketing authorisation in any country?	

3. Advance notification of new products or product changes which may significantly affect expenditure

The supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes which May Significantly Affect Expenditure, describes certain, limited, activities that can take place prior to the grant of a marketing authorisation in order to assist the NHS with financial planning or the revision of a service delivery due to the introduction of a new treatment pathway. NHS organisations and others involved in the purchase of medicines need to estimate their likely budgets in advance and there is a need for them to receive advance information about the introduction of new medicines, or changes to existing medicines, which may significantly affect their level of expenditure, including that which might arise from changes in the patient pathway and/or service delivery. The purpose of advanced notification is to inform of potential budget impact and not to persuade of value.

Companies can only provide advance notification if their new product or product change will mean that NHS organisations and others will spend significantly more or less to treat patients. When this information is required, the medicines concerned (or the changes to them) will not be the subject of marketing authorisations (though applications will often

have been made) and it would thus be contrary to the Code for them to be promoted. Companies wishing to provide advance notification must ensure that information is also provided wherever possible for inclusion in national horizon scanning databases.

The supplementary information to Clause 3.1 states that:

> Non-promotional information can be provided as advance notification, but it **must**:
>
> i. relate to a product which:
>
> - contains a new active substance, or
> - contains an active substance prepared in a new way, such as by the use of biotechnology, or
> - is to have a significant addition to the existing range of authorised indications, or
> - is to have a novel and innovative means of administration
>
> ii. only be directed to those responsible for making policy decisions on budgets and not those only expected to prescribe
>
> iii. state whether or not a new medicine or a change to an existing medicine is the subject of a UK marketing authorisation
>
> iv. state the likely cost or savings and budgetary implications which must be such that they will significantly change the organisation's likely expenditure (the budgetary implication might include the need for service redesign)
>
> v. be factual and limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product or indication into context in the therapeutic area concerned.
>
> The information provided **must not**:
>
> vi. be promotional in style – product logos should be avoided but company logos may be used; the brand name of the product may be included in moderation but it should not be stylised or used to excess
>
> vii. include mock up drafts of either summaries of product characteristics or package leaflets.
>
> If requested, further information may be supplied or a presentation made.

If the product or indication has a significant budgetary implication but any of the other conditions as stated in the supplementary information to Clause 3.1 are not met, then the

proactive provision of information about the unauthorised medicine or indication is likely to be seen as promotion in breach of the Code.

The MHRA Blue Guide states that companies can disseminate limited factual information to persons such as health authorities or trust hospital budget holders where that information may be significant to the planning of their expenditure over future years. The information should focus on the cost implications and be targeted at those who need to make budgetary decisions rather than to prescribers.

There is no specific time period described in the Code for advance notification, however, it should be conducted within a period of time in which it is reasonable to expect NHS budget holders to be able to make an informed decision from the information.

Companies should be careful about the level of information provided, particularly when an individual holds a budgetary/policy/service design role in addition to their main role as a prescribing health professional. Companies should also carefully consider who in the company provides the advance notification and ensure those involved are adequately briefed and appropriately trained on all the requirements.

Example cases

There have been a number of Code cases in relation to advance notification activities, including:

- Case AUTH/3768/5/23
- Case AUTH/2739/11/14
- Case AUTH/2327/6/10

4. Promotion at international events/meetings held in the UK

The supplementary information to Clause 11.1 states that promotion at international events/meetings held in the UK may, on occasion, pose certain problems with regard to medicines or indications for medicines which do not have a marketing authorisation in the UK although they are so authorised in another major developed country.

The international meetings referred to in this supplementary information are those organised and run by learned societies, not those organised by pharmaceutical companies.

The display and provision of promotional material for such medicines is permitted at international events/meetings in the UK provided that the following conditions are met:

- the event/meeting must be truly international, of high scientific standing and with a significant proportion of the attendees from countries outside the UK in which the product is licensed

- the medicine or indication must be relevant and proportional to the purpose of the event/meeting
- promotional material for a medicine or indication that does not have a UK marketing authorisation must be clearly and prominently labelled to that effect
- in relation to an unlicensed indication, UK approved prescribing information must be readily available for a medicine authorised in the UK even though it will not refer to the unlicensed indication
- the names must be given of countries in which the medicine or indication is authorised which must include at least one major developed country; and it must be stated that registration conditions differ from country to country
- the material is certified in accordance with Clause 8, except that the signatories need certify only that in their belief, the material is a fair and truthful presentation of the facts about the medicine.

5. Guidance issued following health technology assessments

On occasion guidance issued by bodies such as the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) is inconsistent with a medicine's summary of product characteristics (SPC). If the recommendation from such bodies is for use outside the marketing authorisation then this cannot be promoted by the pharmaceutical company; drawing attention to such guidance in company materials or by representatives etc. may be in breach of Clause 11.2.

6. Pharmaceutical personnel

Staff in the field who visit health professionals and other relevant decision makers to provide medical information have various job titles throughout the industry, including "medical science liaison". For the purposes of this guidance document, these staff will be referred to as MSLs.

Documentation such as job descriptions, key skills, objectives, SOPs etc. and training are particularly important in clearly setting out the role of an MSL.

The Code does not prohibit employees having hybrid roles with promotional and non-promotional responsibilities. However, it is important to consider all the arrangements, whether the activities are compatible with each other if they are undertaken by one individual, and how the activities are perceived. In the event of a complaint each case would be judged on its own merits.

It is not possible to set out the role of an MSL in detail here as these vary from company to company. Such roles could include responding to unsolicited, specific, individual requests

for information from health professionals and/or other relevant decision makers, following up adverse drug reaction reports, identifying investigators for clinical trials, information gathering from certain groups such as key opinion leaders, budget holders etc, responding to enquiries from health professionals wishing to run their own studies, responding to requests for more detailed information on licensed products and licensed indications, responding to requests for more information in relation to budgetary implications of the introduction of new products or new indications for existing products, training company staff and providing disease area information, etc.

The Code defines a 'representative' in Clause 1.19 as calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. This is a wide definition and can cover the activities of employees that companies might not call representatives. For example, in some companies, certain activities undertaken by MSLs and/or market access employees, among others, might meet the definition of a representative.

When considering whether employee roles or the activities of some employees fall under the definition of a representative, companies need to also consider the broad definition of promotion in Clause 1.17. An important consideration is whether the activities are reactive or proactive and whether there is a direct or indirect reference to a specific medicine.

Companies are reminded that employees who can be defined as representatives (Clause 1.19) must also meet the requirements set out in Clause 9 and 17 of the Code. Companies must ensure all employees are aware when their role meets the definition of a representative.

In the event of a complaint, each case would be considered on its individual merits (e.g. Case AUTH/3244/9/19).

The following are examples of the types of activities that MSLs might undertake and the relevant clauses of the Code when considering each activity as a discrete entity.

Provision of disease area information

If MSLs call upon health professionals and/or other relevant decision makers to discuss disease, and there is no reference, either direct or indirect, to specific medicines, then this activity is covered by an exemption to the definition of promotion given in Clause 1.17. This states, among other things, that the term promotion does not include information relating to human health or diseases provided there is no direct or indirect reference to specific medicines.

If specific medicines are referred to, either directly or indirectly, then the activity could not take the benefit of that exemption and would be likely to be seen as promotion of those medicines.

It is an established principle under the Code that a medicine can be promoted without its name being mentioned. Whether a reference to, for example, class of medicine or mechanism of action amounts to a reference to a specific medicine should be decided on a case-by-case basis: context is important. There may be other product features, such as method of administration, that could indirectly identify a specific medicine depending on the current treatment landscape for that condition.

It would be a breach of the Code to promote a medicine or the indication before receiving the relevant marketing authorisation. In the event of a complaint, the company may have to demonstrate that in providing disease area information, they were not using this as an opportunity to solicit questions about the company's medicine.

In certain circumstances it might be acceptable to provide a very general explanation as to the company's interest in the disease area without such an explanation being viewed as promoting an unlicensed indication or medicine.

Promotion of licensed products and indications

The proactive provision of information about licensed medicines/indications by MSLs calling upon health professionals/other relevant decision makers will likely be considered promotional.

If this is part of the MSL's role, then they are covered by the Code's specific requirements for representatives (see Clauses 9 and 17).

Companies will need to be extremely careful to ensure that such promotional activity is very clearly separated from the non-promotional activities of MSLs. This distinction must be clear to all whom they interact with. MSLs must not carry out a promotional activity and a non-promotional activity in the same call.

Ideally, promotional and non-promotional calls on a particular health professional, even if conducted on different days, should be performed by different staff to help avoid confusion on the part of the health professional. It is accepted, and more commonly seen in smaller companies, that one individual may perform multiple roles, and this is not prohibited by the Code. However, internal and external perception should always be borne in mind and appropriate governance put in place.

Provision of information on products or indications that are not licensed

The basis for such activity relates to the exemption to the definition of promotion given in Clause 1.17. This states, among other things, that the term promotion does not apply to replies made in response to unsolicited individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature. Relevant supplementary

information states that replies intended for use in response to enquiries which are received on a regular basis may be drafted in advance provided that they are used only when they directly and solely relate to the particular enquiry. Documents must not look like promotional material.

Companies must be able to demonstrate that such company employees are responding to unsolicited, specific, individual enquiries from health professionals and/or other relevant decision makers. Responding with misleading or inaccurate information would be in breach of the Code. Material would also be in breach of the Code if it went beyond that needed to answer the enquiry.

Unless the company can clearly demonstrate otherwise, the proactive provision of information about unlicensed medicines and/or unlicensed indications (or any other off-label information) by staff will likely be considered promotional and is thus prohibited.

Provision of information on products or indications that are not licensed but which have significant budgetary implications

Such activities are covered by the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes which May Significantly Affect Expenditure.

Please also see section 3 above.

Advice regarding the role and activities of MSLs

The following is intended to assist companies. Some of the points below may also be relevant to other employees who are not MSLs but who have non-promotional responsibilities as part of their role:

i. The overall governance of MSLs should be the responsibility of the medical director or similar, and they should have a reporting line into the medical/scientific side of the business as opposed to sales/commercial. If the MSL role also includes responsibilities that meet the definition of a representative as defined in Clause 1.19, a dotted line to the sales/commercial side of the business may be acceptable.

ii. MSLs must be appropriately trained and fully conversant with the requirements of the Code.

iii. Non-promotional activities must be kept separate from promotional activity.

iv. MSLs must not carry out a promotional activity and a non-promotional activity in the same call. Ideally, such company employees should not call upon a particular individual for both promotional and non-promotional purposes and generally promotional and non-promotional activities with a particular health professional/other relevant decision maker should be performed by separate staff.

The nature of the interaction must be obvious to the health professional/other relevant decision maker.

v. MSLs can arrange meetings to present information in response to an unsolicited, specific, individual enquiry about an unlicensed product or indication. Sales representatives must not join such meetings. Unsolicited questions at that meeting about a licensed product or indication can be answered by the MSL but the discussion should be limited and non-promotional in nature. MSLs must not set out to use a non-promotional meeting to also promote licensed indications and/or products.
An off-label/unlicensed enquiry might be from a group of health professionals where one person has asked the question and wants a number of colleagues to hear the answer. This needs to be treated with care and company employees must not suggest or presume that others might also be interested in the answer. It must be an unsolicited request from the enquirer, ideally in writing. The presenter should make clear at the beginning of the presentation that this is off-label/unlicensed information and reiterate the specific question asked and by whom. The presentation must not go beyond the specific question asked. If a second unrelated off-label question is asked during the presentation, the MSL should ask the enquirer to follow up individually after the presentation.

vi. The non-promotional activities of MSLs could be compromised by the presence of other company employees. MSLs should not do joint visits with sales representatives.

vii. Relationships with other company staff such as sales representatives should be carefully documented and explained to all parties.

viii. MSLs can train other employees such as sales representatives provided that the training materials meet all the relevant requirements of the Code. Particular attention is drawn to Clause 17.8 relating to representatives' briefing material and the need to have such material certified in accordance with Clause 8.

ix. The remuneration of those employed as MSLs should not be linked to the number of enquiries answered or the number of visits, meetings etc. A bonus scheme linked to the percentage of enquiries answered in a given timeframe may be acceptable. Remuneration should not be linked to sales in any particular territory or place, or to sales of a specific product or products and, in particular, may not include a bonus scheme linked to such sales. Bonus schemes linked to a company's overall national performance, for example sales in the UK, may be acceptable.

x. Materials for MSLs to use in a non-promotional context, such as presentation materials, internal instructions etc, must be accurate, not misleading and must not have the appearance or tone of promotional material. Materials must meet the

requirements of the Code – particular attention is drawn to Clauses 6.1 and 6.2. Companies should have an SOP or similar that describes how such material is created, reviewed and approved. Non-promotional material for health professionals/other relevant decision makers should be examined. It would not be a breach of the Code if such non-promotional material was certified, as long as it met the requirements of the Code for non-promotional material. Promotional material, however, must be certified and contain certain obligatory information (see Clause 12).

Non-promotional material should not be used for a promotional purpose. Companies can prepare presentations etc. in advance but they should be accompanied by clear instructions, including that the MSL must only present information needed to respond to the specific enquiry asked. Instructions need to be given as to the procedure for tailoring prepared materials to answer a specific enquiry.

Other relevant employees should be clearly instructed about the role of MSLs and the referral of enquiries to them. Clear company processes, evidence of training and adequate documentation, such as a form for the health professional to complete outlining the nature of the enquiry, would be helpful if a company was called upon to demonstrate that an enquiry was unsolicited.

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The Prescription Medicines Code of Practice Authority (PMCPA)

The Prescription Medicines Code of Practice Authority (PMCPA) was established by the Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI.

Complaints made under the Code are considered by the Code of Practice Panel and, where required, by the Code of Practice Appeal Board. Reports are published on the PMCPA's website: www.pmcpa.org.uk