PMCPA | Prescription Medicines Code of Practice Authority

GUIDANCE ABOUT CLAUSE 18

THE PROVISION OF BENEFITS IN CONNECTION WITH THE SALE, PURCHASE OR PROMOTION OF MEDICINES

The provision of benefits in connection with the sale, purchase or promotion of medicines. This guidance reflects the requirements of the 2016 Code.

It is important to bear in mind Clause 18.1 which prohibits inducements and inappropriate payments. It states that:

> 'No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3.'

Companies must ensure that any item/benefit provided to the NHS as part of the purchase of medicines does not amount to an inducement and that it otherwise complies with the Code. Clause 18.1 applies to the provision of such items etc to individuals. The provision of certain items may have to be disclosed as transfers of value (Clause 24 refers).

There are of course detailed legal provisions. The Human Medicines Regulations apply to both the pharmaceutical company and the recipient. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for administering relevant UK law and gives strong support to the ABPI Code. It is consulted on any changes to the ABPI Code and its operation.

The Bribery Act 2010 is also important. This applies to individual recipients and organisations and is also relevant to activities outside the UK. The Serious Fraud Office is responsible for administering this aspect of UK law.

The PMCPA cannot approve any materials or activities, it can only give informal advice based on its interpretation of the Code. In the event of a complaint being received about a matter upon which advice had been sought, 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. This paper focuses on Clauses 18, 19 and 20 and their supplementary information but other clauses of the Code might also be relevant including Clauses 2 and 9.1. Companies should always bear in mind the overall impression created by their activities and materials.

PROMOTION

Clause 1.2 of the Code 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.

TERMS OF TRADE

Measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the pharmaceutical industry on 1 January 1993 are outside the scope of the Code (see Clause 1.2) and are excluded from the provisions of Clause 18.1. Other trade practices are subject to the Code. The terms 'prices', 'margins' and 'discounts' are primarily financial terms.

Schemes which enable health professionals to obtain personal benefits, for example gift vouchers for high street stores, in relation to the purchase of medicines are unacceptable even if they are presented as alternatives to financial discounts.

PACKAGE DEALS

Clause 18.1 does not prevent the offer of package deals which are commercial arrangements whereby the purchase of a particular medicine is linked to the provision of certain associated benefits as part of the purchase price, such as apparatus for administration, the provision of training on its use or the services of a nurse to administer it. The transaction as a whole must be fair and reasonable and the associated benefits must be relevant to the medicine involved.

FREE GOODS

Free goods are not explicitly referred to in Clause 18.1. The Code would, nonetheless, apply to their provision. It is a commercial decision on the part of a company as to whether it is appropriate to supply free goods and an arrangement including some free goods, such as, '10 for the price of 9', could potentially be considered a term of trade. The provision of unlimited free goods would not be acceptable under Clause 18.1.

OUTCOME OR RISK SHARING AGREEMENTS

Clause 18.1 does not preclude the use of outcome or risk sharing agreements where a full or partial refund of the price paid for a medicine, or some other form of recompense, is due if the outcome of the use of the medicine in a patient fails to meet certain criteria. That is to say its therapeutic effect does not meet expectations. Clear criteria as to when a refund or other recompense would be due must be settled in advance and set out in the agreement. Any refund or recompense must always go to the relevant NHS or other organisation and never to individual health professionals or practices etc.

PATIENT ACCESS SCHEMES

Patient access schemes are acceptable in principle under the Code but they must be carried out in conformity with its requirements.

The 2014 Pharmaceutical Price Regulation Scheme describes patient access schemes as 'schemes proposed by a pharmaceutical company and agreed with the Department of Health (with input from the National Institute for Health and Care Excellence) in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines'. Corresponding arrangements apply in the devolved nations.

MEDICAL AND EDUCATIONAL GOODS AND SERVICES (MEGS)

Medical and educational goods and services cannot be linked to a specific product and therefore could not form part of an agreement to purchase specific medicines. MEGS are items or services that enhance patient care, or benefit the NHS and maintain patient care, and can be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit. MEGS must not bear the name of any medicine but may bear the name of the company providing them. Clause 19.1 refers.

The provision of MEGS in the form of donations, grants and benefits in kind to institutions, organisations or associations that are comprised of health professionals and/or that provide healthcare or conduct research are only allowed if: they comply with Clause 19.1 or are made for the purpose of supporting research; they are documented and kept on record by the company; they do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine; and details are publicly disclosed as donations, grants or benefits in kind or as research and development transfers of value.

JOINT WORKING

The Department of Health defines joint working between the NHS and the pharmaceutical industry as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Clause 20 refers.

Joint working between one or more pharmaceutical companies and the NHS and others is acceptable, provided that it is carried out in a manner compatible with the Code. It must not constitute an inducement to a health professional or other relevant decision maker to prescribe, supply, recommend, buy or sell any medicine. Treatments must be in line with nationally accepted clinical guidance where such exists. It must be ensured that all of the benefits of joint working which are due to the NHS go not to individuals or practices, but to an NHS or other organisation. Joint working must always benefit patients.

A joint working agreement can be based on the use of a particular medicine of a company party to the agreement, but only if the requirements set out in the supplementary information to Clause 20 about the content of the written agreement are complied with, and the parties have satisfied themselves that the use of the medicine will enhance patient care. Goods and services provided by the company as part of the joint working agreement must be relevant to the medicines involved and the agreement as a whole must be fair and reasonable. Any goods and services so provided must themselves contribute to patient care.

A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.

TRANSFERS OF VALUE

Certain transfers of value made by companies for example in connection with joint working or the provision of MEGS, must be publicly disclosed in accordance with Clause 24.

GENERAL POINTS

Much thought must be given to how, when and by whom the NHS and others are told about arrangements for the activities above. Whether representatives and others who satisfy the definition of a representative set out in Clause 1.7 should have a role in relation to the activities should be very carefully considered bearing in mind the requirements of the Code.

Summary slides are attached.

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THE PROVISION OF ITEMS ETC IN CONNECTION WITH THE SALE AND PURCHASE OF MEDICINES

Companies should bear in mind:

- The prohibition on gifts, pecuniary advantages or benefits in association with the promotion of medicines or as an inducement to prescribe etc as set out in Clause 18.1
- Some arrangements need to be disclosed as a Transfer of Value (Clause 24). Additional publication requirements apply to Joint Working (Clause 20)
- All arrangements should be reviewed in relation to the requirements of UK law including the Bribery Act 2010

	Can it be linked to product?	Disclose as Transfer of Value	Other conditions, Code clauses and supplementary information (SI)
Terms of trade	✓	✗	Financial terms – prices, margins and discounts. No personal benefits *(Clause 1.2 and SI to Clause 18.1).*
Package deals	✓	✗	Purchase linked to associated benefits. Must be fair and reasonable *(SI to Clause 18.1).*
Free goods	✓	✗	Overall arrangement should not be an inducement to prescribe *(Code silent but Clause 18.1 relevant).*
Outcome or risk sharing agreements	✓	✗	Any refund/recompense to healthcare organisation not individuals *(SI to Clause 18.1).*
Patient access schemes	✓	✗	*(SI to Clause 18.1).*
Medical and educational goods and services (MEGs)	✗	✓	Enhance patient care or benefit NHS whilst maintaining patient care. Not to individuals *(Clause 19).*
Joint working	✓	✓	Must benefit patient. Treatments must be in line with nationally accepted clinical guidance *(Clause 20).*

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