2021

PMCPA Prescription Medicines

ABPI CODE OF PRACTICE

for the

PHARMACEUTICAL INDUSTRY 2021

together with the

PRESCRIPTION MEDICINES

CODE OF PRACTICE AUTHORITY

Constitution and Procedure

1 2021.

31 2021

23. 2021 2021 2022.

THE PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The Prescription Medicines Code of Practice A' thority (PMCPA) was established by the Association of the British Pharmace' tical Ind' stry (ABPI) in 1993 to operate the Code of Practice for the Pharmace' tical Ind' stry independently of the Association itself.

Complaints sho' ld be s' bmitted to the Director of the Prescription Medicines Code of Practice A' thority, 7th Floor, So' thside, 105 Victoria Street, London SW1E 6QT, telephone 020 7747 8880, email . . .

Complaints made ' nder the Code are considered by the Code of Practice Panel and, where req' ired, by the Code of Practice Appeal Board. Reports on cases are p' blished by the A' thority and are available on req' est and on the A' thority's website . . . .

The PMCPA is a division of the ABPI which is a company limited by g' arantee registered in England and Wales, No 09826787. Registered of ce: 7th Floor, So' thside, 105 Victoria Street, London SW1E 6QT.

Contents

The table below provides a comparison of the 2021 Code clauses to the relevant 2019 Code clauses, to support familiarisation with the changes. The numbers in brackets beside each clause or supplementary information throughout the 2021 Code are those from the 2019 Code.

2021 Code Clauses		2019 Code Clauses
Grey Section – Overarching Requirements		
1		1.1, 2 .2, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1. , 1. , 1.10, 13.2, 17 , 23.2 , 24.1 , 27.1
	/	
2	U	2
3		1.11, 1.12, 3.1, 12.1, 26.1, 2
4		13.1, 13.3, 24.1, 25.1, 25.2, 26.5, 27.7, 27.
5		.1, .2, .3, .7, .10, 11.1, 2 .6
6	, ,	7.2, 7.4, 7. , 7. , 7.11, .1, .2
7	U	10.2, 10.3
		14.1, 14.2, 14.3, 14.4, 14.5, 14.6
		15.1, 16.1, 16.2, 16.3, 16.4
10	/	1 .1 , 1 .3, 1 .3 , 22.1, 22.1 , 22.2, 22.3, 22.4, 22.5, 24.2, 27.3
Blue Section – Promotion to Health Professionals and Other Relevant Decision Makers		
11	A A	3.1, 3.2
12		4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4. , 4. , 4.10
13	A A	5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5. , 5.
14	,	6.2, 7.3, 7.6, 7.7, 7.10
15	,	.4, .5, .6, . , . , 12.1
16		10.1, 11.2, 11.3, 2 .1, 2 .4
17		15.1, 15.2, 15.3, 15.4, 15.5, 15.6, 15.7, 15. , 15. , 15.10
Green Section – Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations		
1	,	7.1, 7.5
1		1 .1, 1 .2
20		20, 24.2
21		17.1, 17.2, 17.3, 17.4, 17.5, 17.6, 17.7, 17. , 17. , 17.10
22	-	13.4
Yellow Section – Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public, Including Patients and Journalists		
23		1 .1, 1 .2
24		21, 23.1, 23.2, 23.3, 23.4 (27.)
25	, ,	27.4, 27.5, 27. , 12.2
Pink Section – Specific Requirements for Interactions with the Public, Including Patients and Journalists, and Patient Organisations		
26	,	1 .2 , 26.1, 26.2, 26.3, 26.4
27		27.1, 27.2, 27.3, 27.5, 27.6

ABPI PRINCIPLES

The following principles for pharmaceutical companies are seen by the ABPI as key to how we operate as an industry and build trust and enhance our reputation. Companies are expected to implement and work to embed these into their organisation.

Patients are at the heart of o' r ind' stry. We aspire to ens' re that everything we do will ' ltimately bene t patients. O' r primary contrib' tion to society is to research and develop high q' ality medicines and to enco' rage their appropriate and rational ' se. Patient safety is paramo' nt.

Ethical relationships with stakeholders are critical to o' r mission of helping patients, g' iding the appropriate ' se of o' r medicines and ens' ring the appropriate and timely exchange of scienti c information.

An important g' ide for s' ch ethical relationships is adherence to the ABPI Code of Practice which, among other things, sets the standards and drives an ethical c' lt' re in the ind' stry. This is delivered thro' gh self-reg' lation. O' r ind' stry, and the individ' als within it, are committed to s' pporting that c' lt' re, working within both the letter and the spirit of the ABPI Code and all relevant laws and reg' lations.

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ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY INTRODUCTION

The pharmaceutical industry in the United Kingdom is committed to benefiting patients by operating in a professional, ethical and transparent manner to ensure the appropriate use of medicines and

interpreted as an attempt to gain preferential treatment or wo' ld contravene yo' r professional code of practice'.

Patient organisations are likely to be covered by Charity Commission r' les as well as their own codes. The pharmace' tical ind' stry takes note of all relevant codes and g' idance as well as the ABPI Code.

The ind' stry recognises that transparency is an important means of b' ilding and maintaining con dence. The operation of the Code, incl' ding the complaints proced' re, is a demonstration of the ind' stry's commitment to transparency as are the req' irement to declare pharmace' tical company involvement in activities and materials and the p' blication of detailed reports of cases considered ' nder the Code. The ind' stry's global agreement to disclose certain clinical trial data is another example of the ind' stry's commitment to transparency. Companies also have to p' blish the s' mmary details and res' lts of non-interventional st' dies as well as the monetary val' e of certain s' pport to patient organisations.

Other transparency changes, effective in 2012 and 2013, incl' ded disclos' re of the total amo' nt of fees paid to cons' ltants for certain services and the total amo' nts paid to sponsor attendance at meetings organised by third parties. As set o' t in the 2014 Code, starting in 2015 transparency was extended in relation to disclos' re of fees and sponsorship provided to health professionals, other relevant decision makers and healthcare organisations, incl' ding naming the recipients in many instances.

The Code req' ires disclos' re of donations, grants and sponsorship to patient organisations and when contracting with patient organisations or individ' als representing patient organisations to provide services for companies. Certain contracted services provided by the p' blic, incl' ding patients and jo' rnalists, will also now be disclosed on an ann' al basis; this will start with 2022 data to be disclosed by 30 J' ne 2023.

In each case where a breach of the Code is r' led, the company concerned m' st give an ' ndertaking that the practice in q' estion has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the f' t' re. An ' ndertaking m' st be accompanied by details of the action taken to implement the r' ling. At the concl' sion of a case, a detailed case report is p' blished.

Additional sanctions are imposed in serio' s cases. These can incl' de:

- the a' dit of a company's proced' res to comply with the Code, followed by the possibility of a req' irement for the pre-vetting of f' t' re material
- recovery of material from those to whom it has been given
- the iss' e of a corrective statement
- a p' blic reprimand
- advertising in the medical, pharmace' tical and n' rsing press of brief details of cases in which companies were r' led in breach of Cla' se 2 of the Code, were req' ired to iss' e a corrective statement or were the s' bject of a p' blic reprimand
- s' spension or exp' lsion from the ABPI.

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The Prescription Medicines Code of Practice A' thority (PMCPA) arranges for advertising and meetings to be reg' larly monitored.

The PMCPA also provides informal g' idance abo' t the Code and its operation.

The commitment of the pharmace' tical ind' stry to bringing high q' ality and effective medicines and vaccines to patients s' pports the UK's health and economy.

Pharmace' tical companies invest over £4.5bn a year in researching and developing new prod' cts, for the bene t of patients.

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The Association of the British Pharmace' tical Ind' stry exists to make the UK the best place in the world to research, develop and ' se new medicines. It represents companies of all sizes which invest in discovering the medicines of the f' t' re.

The ABPI represents companies which s' pply more than 80% of all branded medicines ' sed by the NHS and are researching and developing the majority of the c' rrent medicines pipeline.

The Code has been reg' larly revised since its inception in 1958 and is drawn ' p in cons' ltation with the British Medical Association, the Royal Pharmace' tical Society, the Royal College of N' rsing, the Medicines and Healthcare prod' cts Reg' latory Agency of the Department of Health, the Competition and Markets A' thority and the Serio' s Fra' d Of ce. Anyone is welcome to send s' ggestions for amendments or additions to the Code to the PMCPA.

It is a condition of membership of the ABPI to abide by the Code in both the spirit and the letter. The Code applies to both members and af liate members of the ABPI. Companies which are not members of the ABPI may give their formal agreement to abide by the Code and accept the j' risdiction of the PMCPA, and over sixty have done so. Th' s the Code is accepted by virt' ally all pharmace' tical companies operating in the UK.

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The Code is administered by the PMCPA, which is responsible for the provision of advice, g' idance and training on the Code as well as for the complaints proced' re. The PMCPA operates independently of the ABPI itself. The relationship between the PMCPA and the ABPI is set o' t in a protocol of agreement. Financial information abo' t the PMCPA is p' blished in its ann' al report.

PMCPA p' blications can all be fo' nd on its website, **www.pmcpa.org.uk**, or are s' pplied on req' est.

Complaints ' nder the Code are considered by the Code of Practice Panel and, where req' ired, by the Code of Practice Appeal Board. Reports on completed cases are p' blished by the PMCPA on its website. The PMCPA also p' blishes a list of ongoing cases on its website.

Complaints sho' ld be s' bmitted to the Director of the Prescription Medicines Code of Practice A' thority, 7th Floor, So' thside, 105 Victoria Street, London, SW1E 6QT, telephone: 020 7747 8880, email: **complaints@pmcpa.org.uk.**

1.13

1.23 A company can provide s' pport for individ' al health professionals or other relevant decision makers to attend events/meetings. in this context is the provision of a nancial contrib' tion, in whole or in part, whether paid directly or indirectly to individ' al health professionals or other relevant decision makers to attend events/meetings.

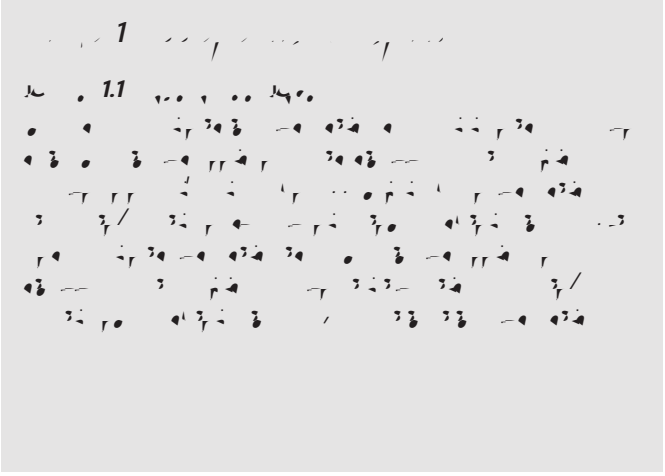
1.24 means a legal person/entity or individ' al that represents a company or interacts with other parties on behalf of a company or relating to a company's medicine, s' ch as distrib' tors, wholesalers, cons' ltants, contract research organisations, professional congress organisers, contracted sales forces, market research companies, advertising agencies, media b' yers, providers of services related to events, p' blic relations services, non-clinical services, non-interventional st' dies management services etc.

Companies are responsible ' nder the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instr' ctions which they have been given.

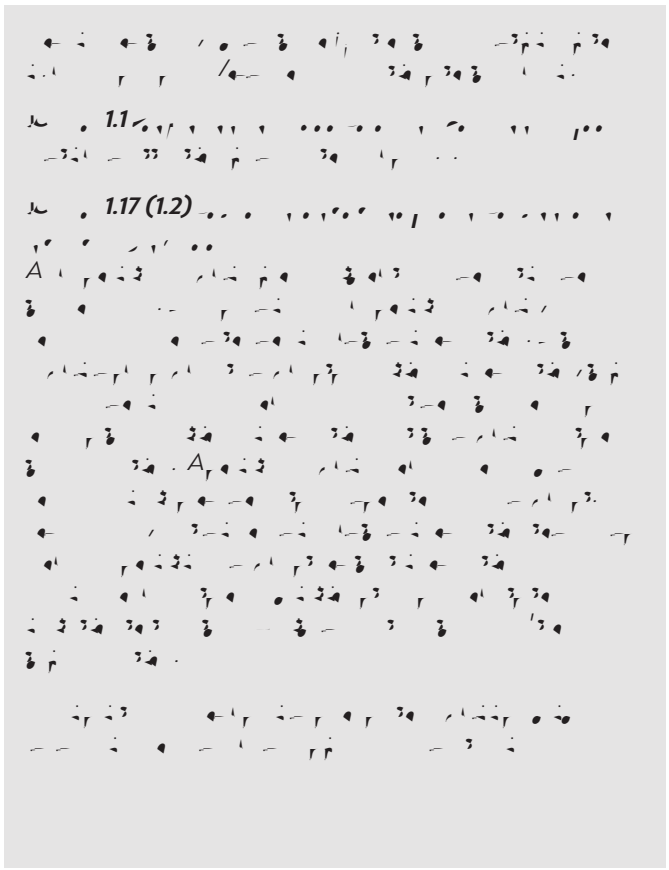
1.25 (1.10) means a direct or indirect transfer of val' e, whether in cash, in-kind or otherwise, made, whether for promotional p' rposes or otherwise, in connection with the development or sale of medicines. A direct transfer of val' e is one made directly by a company for the bene t of a recipient. An indirect transfer of val' e is one made on behalf of a company for the bene t of a recipient or thro' gh an intermediate and where the company knows or can identify the recipient that will bene t from the transfer of val' e.

The following are not transfers of val' e for the p' rposes of the Code:

- transfers of val' e that are solely related to OTC medicines
- ordinary co' rse p' rchases and sales of medicines by and between a company and a health professional or a healthcare organisation
- samples of medicines provided in accordance with Cla' se 21
- transfers of val' e provided in accordance with Cla' ses 10.4, 10.5 and 19.2
- s' bsistence provided to health professionals and other relevant decision makers in accordance with Cla' se 10.1.



Cla' se n' mbers in brackets refer to the 2019 Code of Practice.



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Activities or materials m' st never be s' ch as to bring discredit ' pon, or red' ce con dence in, the pharmace' tical ind' stry.

3.1 (3.1) A medicine m' st not be promoted prior to the grant of the marketing a' thorisation which permits its sale or s' pply.

3.2 (26.1) Prescription only medicines m' st not be advertised to the p' blic. This prohibition does not apply to vaccination and other campaigns carried o' t by companies and approved by the health ministers.

3.3 (29) When an ' ndertaking has been given in relation to a r' ling ' nder the Code, the company concerned m' st ens' re that it complies with that ' ndertaking.

3.4 (1.11) Companies m' st comply with all applicable codes, laws and reg' lations to which they are s' bject.

3.5 Gifts for personal bene t (s' ch as sporting or entertainment tickets, social co' rtesy gifts) are prohibited and m' st not be given, either directly or indirectly, to any individ' al health professional, other relevant decision maker or individ' al associated with a healthcare organisation or patient organisation.

Providing or offering cash, cash eq' ivalents or the provision of services that confer a personal bene t to the recipient is prohibited.

Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

Clause numbers in brackets refer to the 2019 Code of Practice.

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5.1 (9.1) High standards m' st be maintained at all times.

5.2 (9.2) All material and activities m' st recognise the special nat' re of medicines and respect the professional standing or otherwise of the a' dience to which they are directed and m' st not be likely to ca' se offence.

5.3 (9.3) The name or photograph of a member of a health profession m' st not be ' sed in any way that is contrary to the conventions of that profession.

5.4 (9.7) Extremes of format, size or cost of material m' st be avoided. Informational or ed' cational materials m' st be inexpensive, directly relevant to the practice of medicine or pharmacy and directly bene cial to the care of patients.

5.5 (9.10) Material relating to medicines and their ' ses, whether promotional or not, and information relating to h' man health or diseases which is sponsored by a pharmace' tical company or in which a pharmace' tical company has any other involvement, m' st clearly indicate the role of that pharmace' tical company.

The only exception to this is market research material if it is s' ch that the name of the company involved is not req' ired to be staten3ID 1.toey or in wh, m' ss (oey or (at)40 (e that(it it)]TJETEMC /P ÆLang (en-US)/MCID 8560 ÆDC BT10 0 0 10 63.779368

Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

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7.1 (10.2) Q' otations from medical and scienti c literat' re or from personal comm' nications m' st be faithf' lly reprod' ced, acc' rately re ect the meaning and c' rrent views of the a' thor and otherwise comply with the Code. The precise so' rce of the q' otation m' st be identi ed.

7.2 (10.3) Q' otations relating to medicines taken from p' blic broadcasts, for example, on radio and television, and from private occasions, s' ch as medical conferences or symposia, m' st not be ' sed witho' t the formal permission of the speaker.

8.1 (14.1) Promotional material m' st not be iss' ed ' nless its nal form, to which no s' bseq' ent amendments will be made, has been certi ed by one person on behalf of the company in the manner provided for by this cla' se, s' bject to the provisions of the s' pplementary information to this cla' se where relevant. This person m' st be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a prod' ct for dental ' se only, a UK registered dentist.

The person certifying on behalf of the company m' st not be the person responsible for developing or drawing ' p the material.

8.2 (14.2) All events/meetings involving travel o' tside the UK, ' nless the company's only involvement is to s' pport a speaker to present at the meeting, m' st be certi ed in advance as set o' t in Cla' se 8.1 or by an appropriately q' ali ed person signatory (AQP signatory). That person does not need to be either a registered medical practitioner or a pharmacist registered in the UK.

8.3 (14.3) The following m' st be certi ed in advance in a manner similar to that provided for by Cla' se 8.1:

ed' cational material for the p' blic or patients iss' ed by companies which relates to diseases or medicines b' t is not intended as promotion for those medicines

material relating to working with patient organisations as described in Cla' se 27 and its s' pplementary information

material relating to collaborative working as described in Cla' se 20 and its s' pplementary information

material and items for patient s' pport whether provided directly to patients or to health professionals to be passed on to patients as described in Cla' ses 19.2, 26.3 and associated s' pplementary information

the written agreement for donations and grants, incl' ding where relevant internal company and service provider instr' ctions as described in Cla' se 23 and its s' pplementary information

(25.2) protocols relating to non-interventional st' dies.

8.4 (14.4) The names of those nominated as signatories as set o' t in Cla' ses 8.1 and 8.2, together with their q' ali cations, m' st be noti ed in advance to the Advertising Standards and O' treach Unit, Vigilance and Risk Management of Medicines Division of the Medicines and Healthcare prod' cts Reg' latory Agency (MHRA), and to the Prescription Medicines Code of Practice A' thority (PMCP2

Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

The certi cate for events/meetings involving travel o' tside the UK m' st certify that the signatory has examined all the proposed arrangements and that, in their belief, they are in accordance with the relevant reg' lations relating to advertising and the Code.

8.6 (14.6) Companies m' st preserve certi cates. Material in the form certi ed and information indicating the persons to whom it was addressed, the method of dissemination and the date of rst dissemination m' st also be preserved. In relation to certi cates for events/meetings involving travel o' tside the UK, details of the programme, the ven' e, the reasons for ' sing the ven' e, the a' dience, the anticipated and act' al costs and the nat' re of the hospitality and the like m' st also be preserved.

Companies m' st preserve certi cates and the relevant accompanying information for not less than three years after the nal ' se of the material or the date of the event/ meeting and prod' ce them on req' est from the MHRA or the PMCPA.

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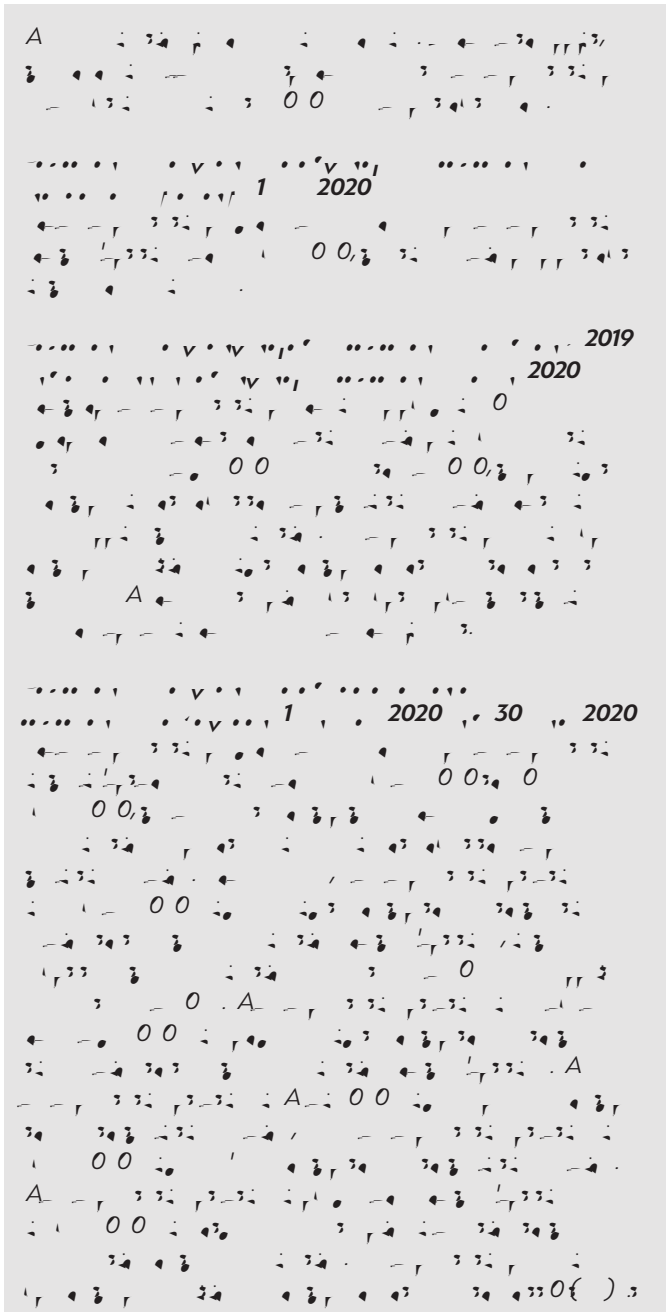
Clause numbers in brackets refer to the 2019 Code of Practice.



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10.1 (22.1) Pharmace' tical companies may hold, sponsor or s' pport delegates to attend a wide range of events/meetings, providing s' ch events/meetings meet the req' irements of the Code. This may incl' de s' pport of health professionals not known to the company via a healthcare organisation by way of registration fees, accommodation and travel.

Companies m' st not provide hospitality to health professionals, other relevant decision makers etc except in association with scienti c meetings, promotional meetings, scienti c congresses and other s' ch meetings and training.

The content and arrangements for any event or meeting m' st also, to the extent relevant to the partic' lar event/meeting, f' l l the following criteria:

- the event/meeting m' st have a clear ed' cational content; it sho' ld be the programme that attracts delegates to attend and not the associated hospitality or ven' e
- the content m' st be appropriate and relevant to attendees
- the ven' e m' st be appropriate and conducive to the main p' rpose of the event/meeting; lavish, extravagant or del' xe ven' es m' st not be ' sed
- any associated s' bsistence (food and drink), accommodation and travel costs m' st be strictly limited to the main p' rpose of the event/meeting, m' st be of secondary consideration and m' st be appropriate and not o' t of proportion to the occasion (see Cla' se 10.7)
- companies m' st not sponsor, s' pport or organise entertainment (s' ch as sporting or leis' re activities, etc)
- any hospitality provided m' st not extend to an accompanying person ' nless that person q' ali es as a proper delegate or participant at the meeting in their own right. In exceptional cases of established clear health needs of the delegate (eg disability or inj' ry), similar hospitality may be provided for an accompanying person.

10.2 (New Cla' se, previo' sly 22.1 SI) No payment may be offered or paid to individ' als to compensate merely for the time spent in attending events/meetings.

Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

10.3 (New Cla' se and part of Cla' se 27.3) Sponsorship of patient organisations (incl' ding individ' als representing patient organisations to attend events/meetings) m' st have a written agreement in place setting o' t what has been agreed incl' ding, where possible, a breakdown of agreed costs. (The req' irements for the written agreement are set o' t in Cla' se 27.2.)

10.4 (18.3) Attendees of company organised events/meetings may be provided with inexpensive pens, pencils and notepads when req' ired for ' se at those events/meetings. They m' st not bear the name of any medicine or any information abo' t medicines b' t may bear the name of the company providing them. No individ' al attendee sho' ld receive more than one pen or pencil or one notepad.

10.1 (22.1)

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10.1 (22.1)

Clause numbers in brackets refer to the 2019 Code of Practice.

10.10 (22.5)

10.11 ( )

Promotion to Health Professionals and Other Relevant Decision Makers

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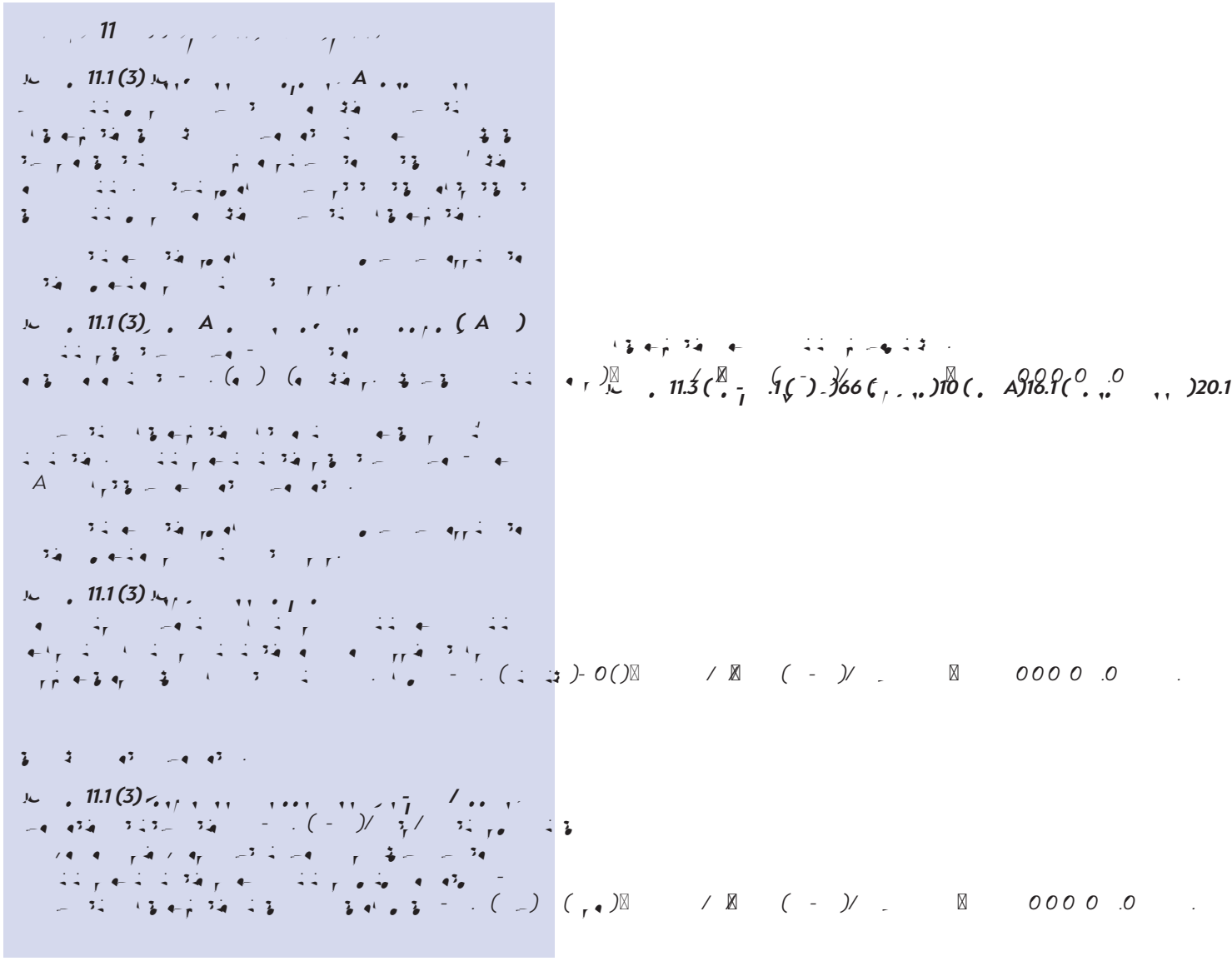
11.1 (3.1) A medicine m' st not be promoted prior to the grant of the marketing a' thorisation which permits its sale or s' pply s' bject to the provisions of Cla' se 11.3 below.

11.2 (3.2) The promotion of a medicine m' st be in accordance with the terms of its marketing a' thorisation and m' st not be inconsistent with the partic' lars listed in its s' mmary of prod' ct characteristics s' bject to the provisions of Cla' se 11.3 below.

11.3 (New Cla' se) A medicine with a temporary s' pply a' thorisation m' st not be promoted ' nless it is part of a campaign that has been approved by the health ministers.



Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

12.1 (4.1) The prescribing information listed in Cla' se 12.2 m' st be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements (see Cla' se 13). The prescribing information m' st be positioned for ease of reference and m' st not be presented in a manner s' ch that the reader has to t' rn the material ro' nd in order to read it, for example, by providing it diagonally or aro' nd the page borders. The prescribing information m' st form part of the promotional material and m' st not be separate from it.

12.2 (4.2) The prescribing information consists of the following:

the legal classi cation of the prod' ct

the cost (excl' ding VAT) of either a speci ed package of the medicine to which the advertisement relates, or a speci ed q' antity or recommended daily dose, calc' lated by reference to any speci ed package of the prod' ct, except in the case of advertisements in jo' rnals printed in the UK which have more than 15 per cent of their circ' lation o' tside the UK and a' diovis' al advertisements and prescribing information provided in association with them

and

i. the name of the medicine (which may be either a brand name or a non-proprietary name)

ii. a q' antitative list of the active ingredients, ' sing approved names where s' ch exist, or other non-proprietary names;

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12.1 (4.1)

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Clause numbers in brackets refer to the 2019 Code of Practice.

Clause numbers in brackets refer to the 2019 Code of Practice.

are recommended to consult the summary of product characteristics before prescribing.

The website referred to above must provide either:

the information set out in Clauses 12.2 and 12.3 (except that the non-proprietary name of the medicine or the list of active ingredients, as required by Clause 12.3, must appear immediately adjacent to the most prominent display of the brand name in a size such that the information is easily readable and information about cost, as required by Clause 12.2, need not be included on the website where the abbreviated advertisement appears only in journals printed in the UK which have more than 15 per cent of their circulation outside the UK), or

the summary of product characteristics.

13.5 (5.5) The non-proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately adjacent to the most prominent display of the brand name in bold type of a size such that a lower case 'x' is no less than 2mm in height or in type of such a size that the non-proprietary name or list of active ingredients occupies a total area no less than that taken up by the brand name.

13.6 (5.6) Abbreviated advertisements must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]'.

13.7 (5.7) When required by the licensing authority, abbreviated advertisements must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.

It should be borne in mind that abbreviated advertisements must be no larger than 420 square centimetres in size. In abbreviated advertisements of no more than 310.8 square centimetres (A5), each side of the triangle should be no less than 3mm. In abbreviated advertisements larger than A5 (but no larger than 420 square centimetres) each side should be no less than 5mm. The other relevant requirements of Clause 12.10 apply equally to the use of the black triangle symbol on abbreviated advertisements.

13.8 (5.8) Abbreviated advertisements may contain a concise statement consistent with the summary of product characteristics, giving the reason why the medicine is recommended for the indication or indications given.

13.9 (5.9) Marketing authorisation numbers and references must not be included in abbreviated advertisements.

15

15.1 (9.4) Promotional material m' st not imitate the devices, copy, slogans or general layo' t adopted by other companies in a way that is likely to mislead or conf' se.

15.2 (9.5) Promotional material m' st not incl' de any reference to the Commission on H' man Medicines, the Medicines and Healthcare prod' cts Reg' latory Agency (MHRA) or the licensing a' thority, ' nless this is speci cally req' ired by the licensing a' thority.

15.3 (9.6) Reprod' ctions of of cial doc' ments m' st not be ' sed for promotional p' rposes ' nless permission has been given in writing by the appropriate body.

15.4 (9.8) Postcards, other exposed mailings, envelopes or wrappers m' st not carry matter which might be regarded as advertising to the p' blic, contrary to Cla' se 26.1.

15.5 (9.9) The telephone, text messages, email, faxes, a' tomated calling systems and other digital comm' nications m' st not be ' sed for promotional p' rposes, except with the prior permission of the recipient.

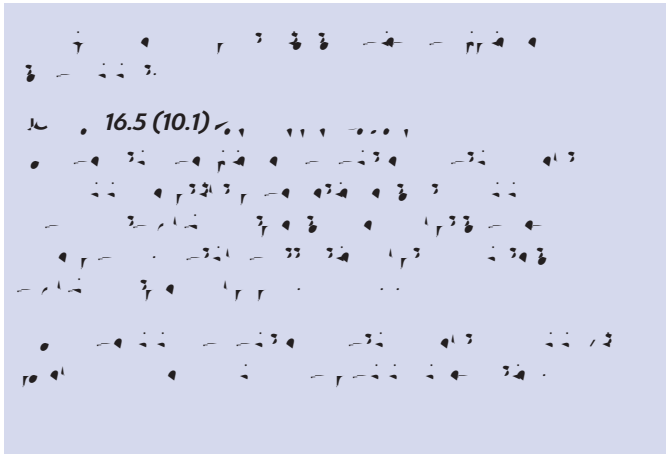
15.6 (12.1) Promotional material and activities m' st not be disg' ised.

16

16.1 (28.1) Promotional material abo' t prescription only medicines directed to a UK a' dience which is provided on the internet m' st comply with all relevant req' irements of the Code.

16.2 (28.4) A medicine covered by Cla' se 16.1 may be advertised in a relevant, independently prod' ced electronic jo' rnal intended for health professionals or other relevant decision

Cla' se n' mbers in brackets refer to the 2019 Code of Practice.



16.5 (10.1)

17

17.1 (15.1) Representatives m' st be given adeq' ate training and have s' f cient scienti c knowledge to enable them to provide f' ll and acc' rate information abo' t the medicines which they promote.

17.2 (15.2) Representatives m' st maintain a high standard of ethical cond' ct in the discharge of their d' ties and comply with all relevant req' irements of the Code.

17.3 (15.3) Representatives m' st not employ any ind' cement or s' bterf' ge to gain an interview. No fee sho' ld be paid or offered for the grant of an interview.

17.4 (15.4) Representatives m' st ens' re that the freq' ency,

17.3 (15.3)

17.4 (15.4)

Clause numbers in brackets refer to the 2019 Code of Practice.

Interactions with Health Professionals, Other Relevant Decision Makers and Healthcare Organisations

1

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Cla' ses 6 and 14 may also be relevant.

18.1 (7.1) Upon reasonable req' est, a company m' st promptly provide health professionals and other relevant decision makers with acc' rate and relevant information abo' t the medicines which the company markets.

18.2 (7.5) S' bstantiation for any information, claim or comparison m' st be provided as soon as possible, and certainly within ten working days, at the req' est of health professionals or other relevant decision makers. The validity of indications approved in the marketing a' thorisation can be s' bstantiated by provision of the s' mmary of prod' ct characteristics.

1

4 (6) / 63.77 (1) / X (365 5

Clause numbers in brackets refer to the 2019 Code of Practice.

20

(20)

20.1 Collaborative working which either enhances patient care or is for the bene t of patients or alternatively bene ts the NHS and, as a minim m, maintains patient care is acceptable providing it is carried o t in a manner compatible with the Code. Collaborative working is generally between one or more pharmace tical companies, healthcare organisations and other organisations. Joint working is a limited form of collaborative working as set o t in Cla se 20.4.

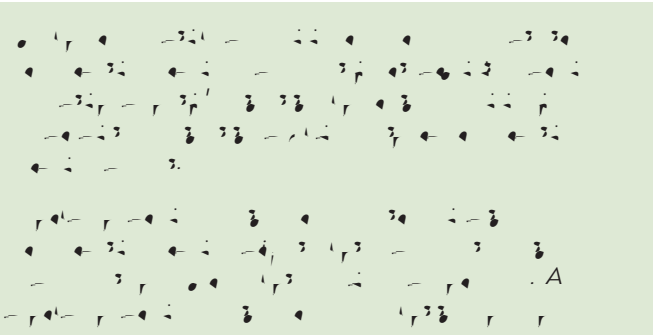
20.2 Collaborative working, incl ding its implementation, m st have and be able to demonstrate the pooling of skills, experience and/or reso rces from all of the parties involved for the joint development and implementation of patient and/or healthcare centred projects. There m st be a shared commitment to s ccessf l delivery from all parties, and each party m st make a signi cant contrib tion.

20.3 In addition to Cla se 20.2, collaborative working m st:

- enhance patient care or be for the bene t of patients, or alternatively bene t the NHS and, as a minim m, maintain patient care
- not constit te an ind cement to health professionals or other relevant decision makers to prescribe, s pply, recommend, b y or sell a medicine
- be carried o t in an open and transparent manner
- be prospective in nat re
- be doc mented with a formal written agreement which is kept on record
- have a s mmary of the collaborative working agreement p blicly available before arrangements are implemented.

Material relating to collaborative working m st be certi ed, incl ding the s mmary of the collaborative working agreement. The collaborative working agreement does not need to be certi ed. Only the nal doc ments etc for any collaborative working project need be certi ed. All doc ments etc sed d ring the development of the project sho ld be of the same standard as certi ed material, b t there is no req irement to certify s ch material. Material sed in the delivery of the collaborative working project m st also meet the req irements of Cla se 8.3, for example, ed cational material for the p blic or patients which relates to diseases or medicines sed d ring the delivery of collaborative working m st be certi ed.

All collaborative working sho ld adhere to all relevant



Clause numbers in brackets refer to the 2019 Code of Practice.

21

21.1 (17.1) Samples of a prod' ct may be provided only to a health professional q' ali ed to prescribe that prod' ct. They m' st not be provided to other relevant decision makers.

21.2 (17.2) No more than fo' r samples of a partic' lar medicine may be provided to an individ' al health professional d' ring the co' rse of a year.

Samples of a partic' lar medicine may be provided to a health professional for no longer than two years after that health professional rst req' ested samples of it.

Notwithstanding the above, when a new medicine is marketed which is an extension of an existing prod' ct,

22

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22.1 (13.4) Non-interventional st' dies that are prospective in nat' re and involve the collection of patient data m' st be cond' cted for a scienti c p' rpose. They m' st comply with the following criteria:

there m' st be a written st' dy plan (observational plan/ protocol) and written contracts between the health professionals and/or the healthcare organisations, instit' tes, academic fac' lties etc where the st' dy will take place and the pharmace' tical company sponsoring the st' dy, which specify the nat' re of the services to be provided and the payment for those services

in co' ntries where ethics committees are prepared to review s' ch st' dies, the st' dy protocol m' st be s' bmitted to the ethics committee for review

any rem' neration m' st be reasonable and re ect the fair market val' e of the work

the st' dy m' st not constit' te an ind' cement to prescribe, s' pply, administer, recommend, b' y or sell any medicine

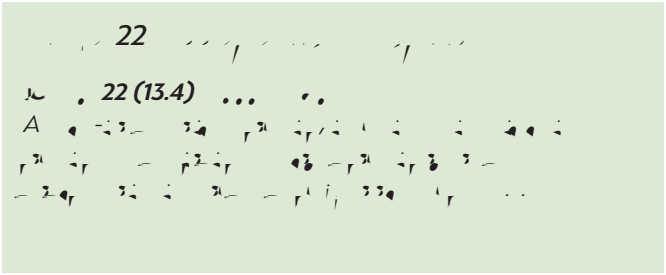
the company's scienti c service m' st certify the protocol and s' pervise the cond' ct of the st' dy

the st' dy res' lts m' st be analysed and s' mmaries made available within a reasonable period of time to the company's scienti c service, which shall maintain records of s' ch reports; the s' mmary report sho' ld be sent to health professionals who participated in the st' dy. If the st' dy res' lts are important for the assessment of bene t/ risk, the s' mmary report sho' ld be immediately forwarded to the relevant competent a' thority

representatives may only be involved in an administrative capacity and s' ch involvement m' st be s' pervised by the company's scienti c service which will also ens' re that the representatives are adeq' ately trained for the role; s' ch involvement m' st not be linked to the promotion of any medicine.

22.2 To the extent applicable, companies are enco' raged to comply with Cla' se 22.1 for all other types of non-interventional st' dies, incl' ding epidemiological st' dies and registries and other st' dies that are retrospective in nat' re.

22.3 Companies m' st p' blish the s' mmary details and res' lts of non-interventional st' dies of marketed medicines in a manner consistent with their parallel obligations with respect to clinical trials, as set o' t in Cla' se 4.6.



Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

Interactions with Health Professionals, Other Relevant Decision Makers, Healthcare Organisations, Patient Organisations and the Public, Including Patients and Journalists

CLAUSES 23–25

23

23.1 Donations and grants are f' nds, bene ts-in-kind or services freely given for the p' rpose of s' pporting healthcare, scienti c research or ed' cation, with no conseq' ent obligation on the recipient organisation, instit' tion and the like to provide goods or services to the bene t of the pharmace' tical company in ret' rn. Donations and grants to individ' als are prohibited.

In general, donations are physical items, services or bene ts-in-kind which may be offered or req' ested. Grants are the provision of f' nds.

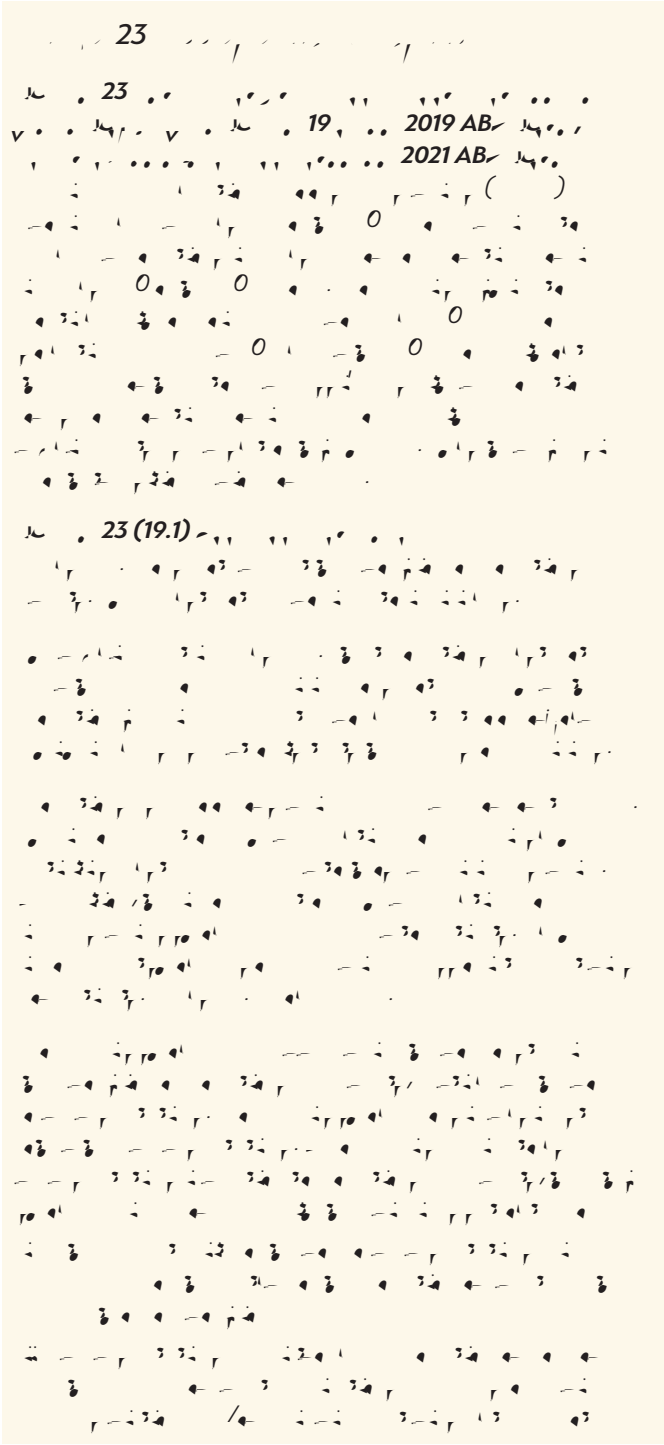
23.2 (19.1 and 19.2) Donations and grants to healthcare organisations, patient organisations or other organisations are only allowed if they:

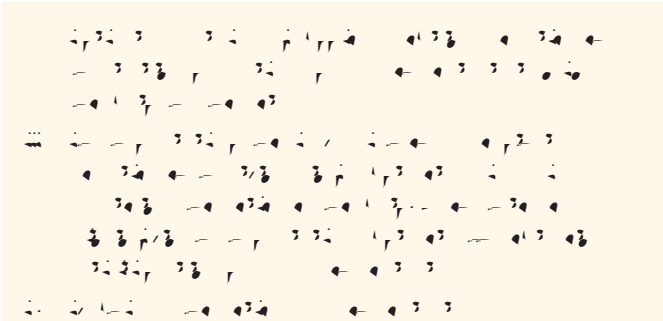
- are made for the p' rpose of s' pporting healthcare, scienti c research or ed' cation
- do not constit' te an ind' cement to recommend and/or prescribe, p' rchase, s' pply, sell or administer speci c medicines
- are prospective in nat' re
- do not bear the name of any medicine altho' gh they may bear the name of the company providing them.

In addition:

- there m' st be a written agreement in place for each donation or grant. The arrangements for the written agreement for donations and grants to patient organisations are set o' t in Cla' se 27.2 and for other organisations in the s' pplementary information to Cla' se 23.2
- the written agreement, and where relevant, internal company and service provider instr' ctions m' st be certi ed in advance as set o' t in Cla' se 8.3
- all information relating to the donation or grant sho' ld be kept on record by the company
- donations and grants m' st be p' blicly disclosed ann' ally as set o' t in Cla' ses 28 and 29.

Company involvement sho' ld be made clear for donations and grants to the extent possible.





Clause numbers in brackets refer to the 2019 Code of Practice.

Clause numbers in brackets refer to the 2019 Code of Practice.

incl' des payments in relation to research and development work, incl' ding the cond' ct of clinical trials.

24.5 (23.3) In addition to the information req' ired to be made p' blic by Cla' se 24.4, companies m' st p' blicly disclose ann' ally details of payments made to contracted individ' als in relation to market research (' nless the company concerned does not know the identities of those participating in the market research).

24.6 (23.4 and part of Cla' se 27.8) Fees, expenses and the like d' e to contracted individ' als/organisations in relation to Cla' ses 24.3, 24.4 and 24.5 m' st be disclosed.

The relevant disclos' re req' irements are:

fees and expenses paid for contracted services between companies and instit' tions, organisations or associations of health professionals

fees and expenses paid for contracted services to health professionals and other relevant decision makers, or to their employers on their behalf

the disclos' re for contracted services provided by each patient organisation m' st incl' de:

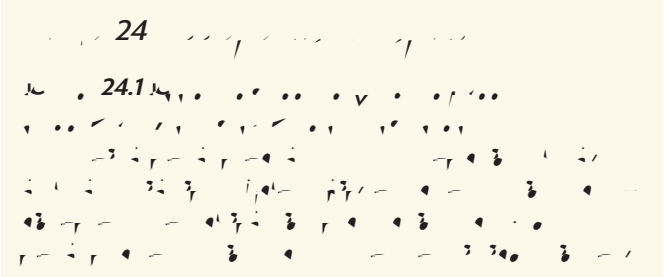
- the total amo' nt paid per patient organisation per calendar year, incl' ding a description of the services provided that is s' f ciently complete to enable the reader to ' nderstand the nat' re of the services provided witho' t the necessity to div' lge con dential information
- fees and expenses sho' ld be disclosed separately

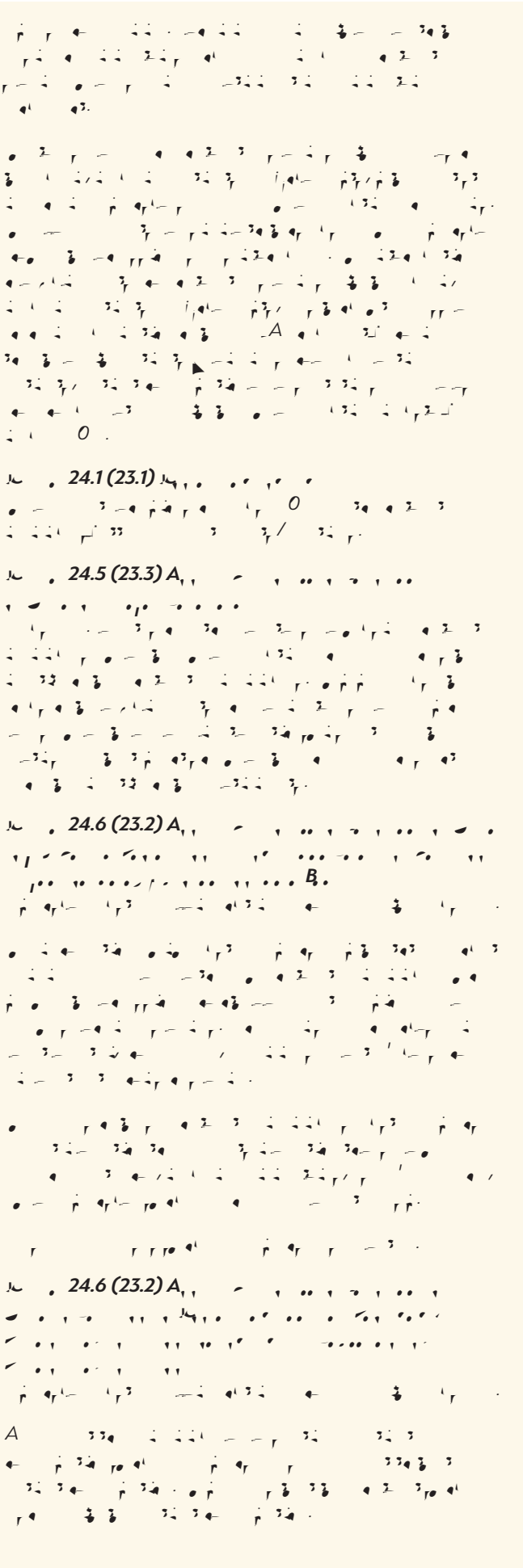
the disclos' re for contracted services provided by members of the p' blic, incl' ding patients and jo' rnalists, m' st incl' de:

- the total n' mber of members of the p' blic contracted to perform services, the total amo' nt paid to members of the p' blic per calendar year and a description of the types of services provided that is s' f ciently complete to enable the reader to ' nderstand the nat' re of the services provided witho' t the necessity to div' lge con dential information
- a breakdown of the total payments to each gro' p of individ' als, ie the p' blic, patients and jo' rnalists, witho' t the necessity to div' lge con dential information.

In addition, companies sho' ld disclose fees and expenses separately.

Contracts for UK individ' als representing patient organisations sho' ld be made with the patient organisation and disclosed against the patient organisation as set o' t in Cla' se 29.





Cla' se n' mbers in brackets refer to the 2019 Code of Practice.

25

25.1 (27.4) No company may req' ire that it be the sole f' nder or sponsor of a healthcare organisation or patient organisation or any of its programmes.

25.2 (27.5) A company m' st not make p' blic ' se of a healthcare organisation or patient organisation's logo and/or proprietary material witho' t the organisation's written agreement. In seeking s' ch permission, the speci c p' rpose and the way in which the logo and/or proprietary material will be ' sed m' st be clearly stated.

25.3 (27.9) Companies m' st ens' re that all sponsorship is clearly acknowledged from the o' tset. The wording of the declaration of sponsorship m' st be ' nambig' o' s and acc' rately re ect the extent of the company's involvement and in ' ence over the material.

25.4 (12.2) Market research activities, clinical assessments, post-marketing s' rveillance and experience programmes, post-a' thorisation st' dies (incl' ding those that are retrospective in nat' re), and the like m' st not be disg' ised promotion. They m' st be cond' cted with a primarily scienti c or ed' cational p' rpose.

Specific Requirements for Interactions with the Public, Including Patients and Journalists, and Patient Organisations

26

26.1 (26.1) Prescription only medicines must not be advertised to the public. This prohibition does not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.

26.2 (26.2) Information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product.

Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

26.3 (18.2 SI) Items for patient support made available to patients, for example, by completing a request card enclosed with a medicine, should be inexpensive, related to either the condition under treatment or general health, and must be appropriately documented and certified in advance as required by Clause 8.3. Care must be taken that any such activity meets all the requirements of the Code and in particular Clause 26.4.

Companies cannot run or sponsor competitions or quizzes for patients if prizes are offered.

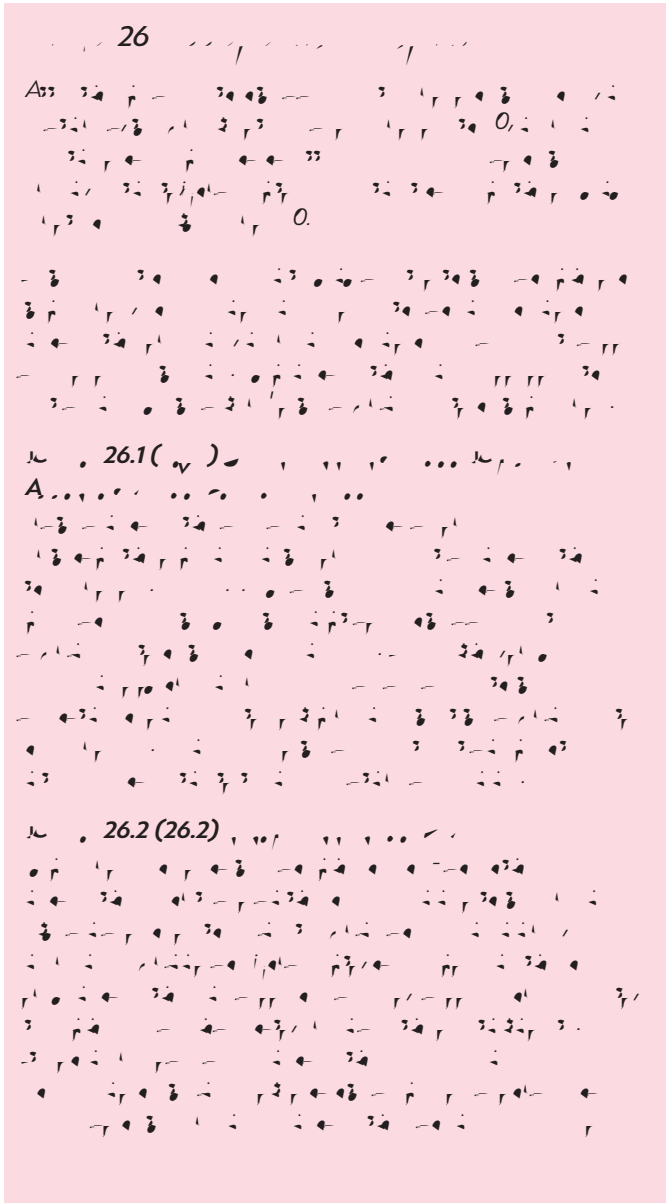
26.4 (26.3) Any material which relates to a medicine and which is intended for patients taking that medicine must include the statement below or a similar one:

> '**Reporting of side effects** If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [a website address which links directly to the MHRA Yellow Card site].
>
> By reporting side effects, you can help provide more information on the safety of this medicine.'

When the material relates to a medicine which is subject to additional monitoring, an inverted black equilateral triangle must be included on it together with the statement below or a similar one:

> 'This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See [a website address which links directly to the MHRA Yellow Card site] for how to report side effects.'

26.5 (26.4) Requests from individual members of the public for advice on personal medical matters must be refused and the enquirer recommended to consult their own doctor, or other prescriber or other health professional.



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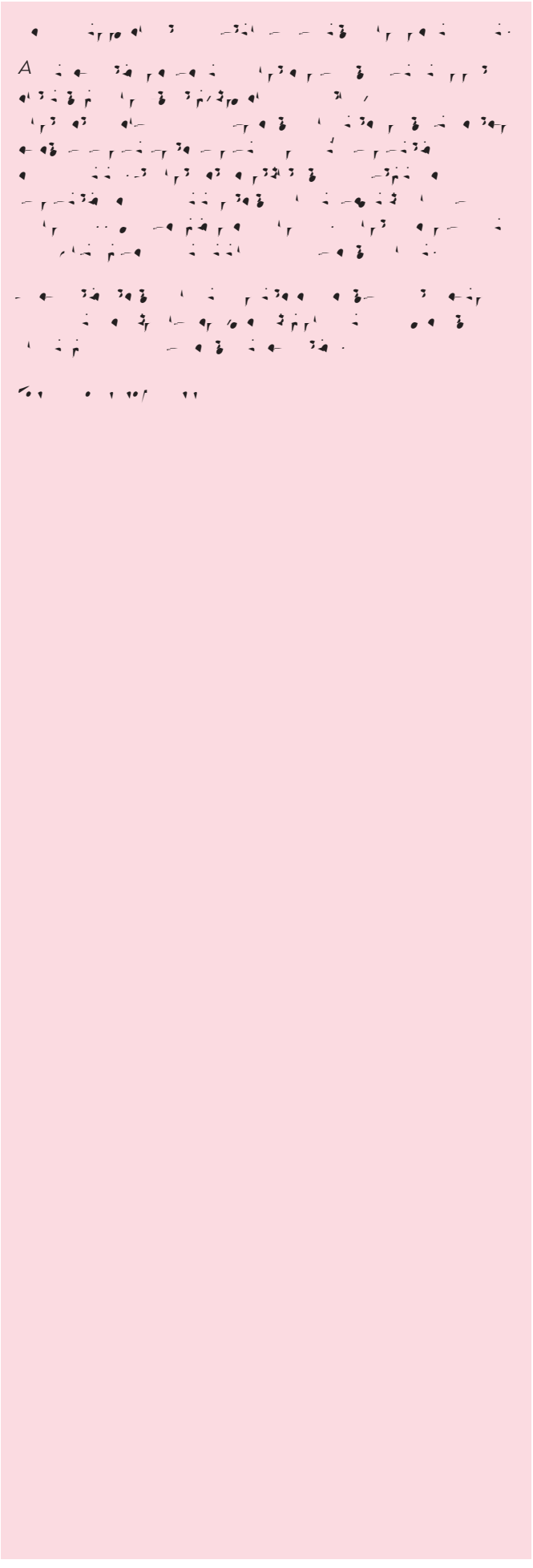

Clause numbers in brackets refer to the 2019 Code of Practice.

27

27.1 (27.1) When pharmaceutical companies interact with patient organisations or any other organisations such as disability organisations, carer or relative organisations and consumer organisations, companies must:

respect the independence of the organisations

assure the independence of the organisations, in terms of their political judgement, policies and activities

ensure relationships are based on mutual respect, with the views and decisions of each partner having equal value

not promote or request the promotion of a particular prescription only medicine

ensure the objectives and scope are transparent and support provided by companies must always be clearly acknowledged.

27.2 (27.3) When companies provide donations, grants or sponsorship (including (27.3) of e

Annual Disclosure Requirements

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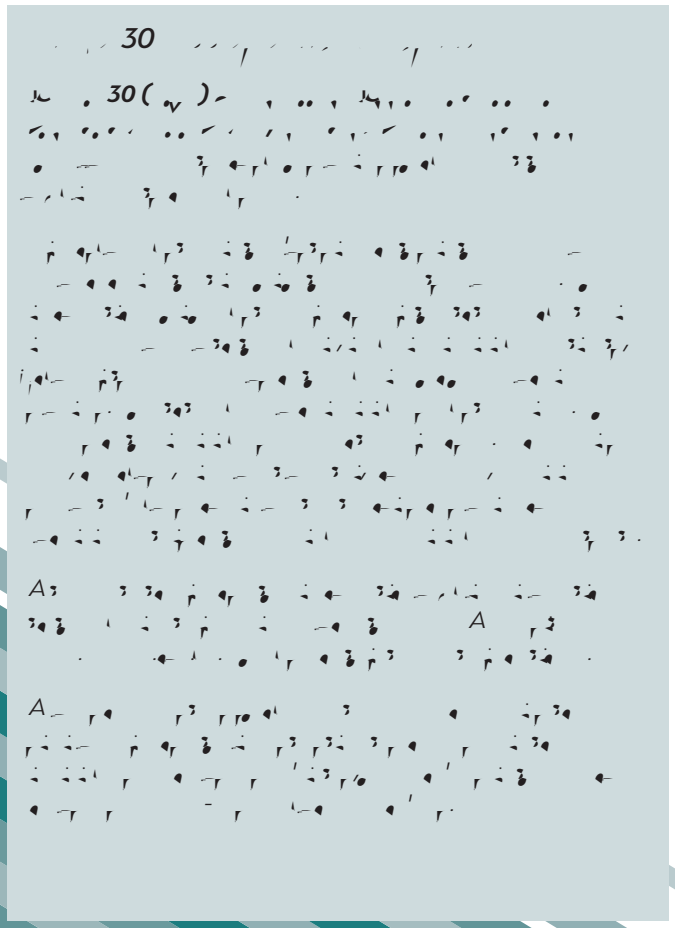
28.1

Cla se n mbers in brackets refer to the 2019 Code of Practice.

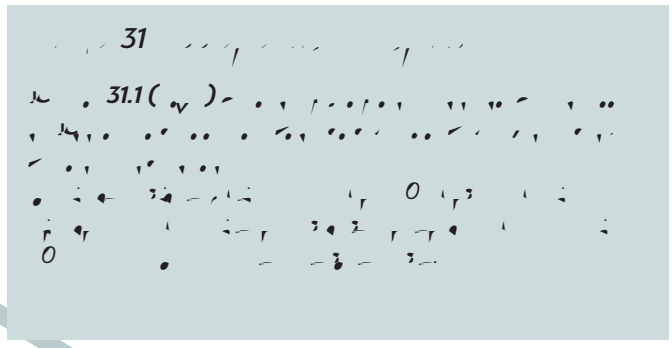


31

31.1 (24.4) Disclos' res m' st be made ann' ally in respect of each calendar year and m' st be in the rst six months after the end of the calendar year in which the transfers of val' e/ payments were made.

31.2 (24.5) The information disclosed m' st remain in the p' blic domain for at least three years from the time of rst disclos' re.

31.3 (24.6) Companies m' st doc' ment all disclos' res and retain the records for at least ve years after the end of the calendar year to which they relate.



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PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY CONSTITUTION AND PROCEDURE

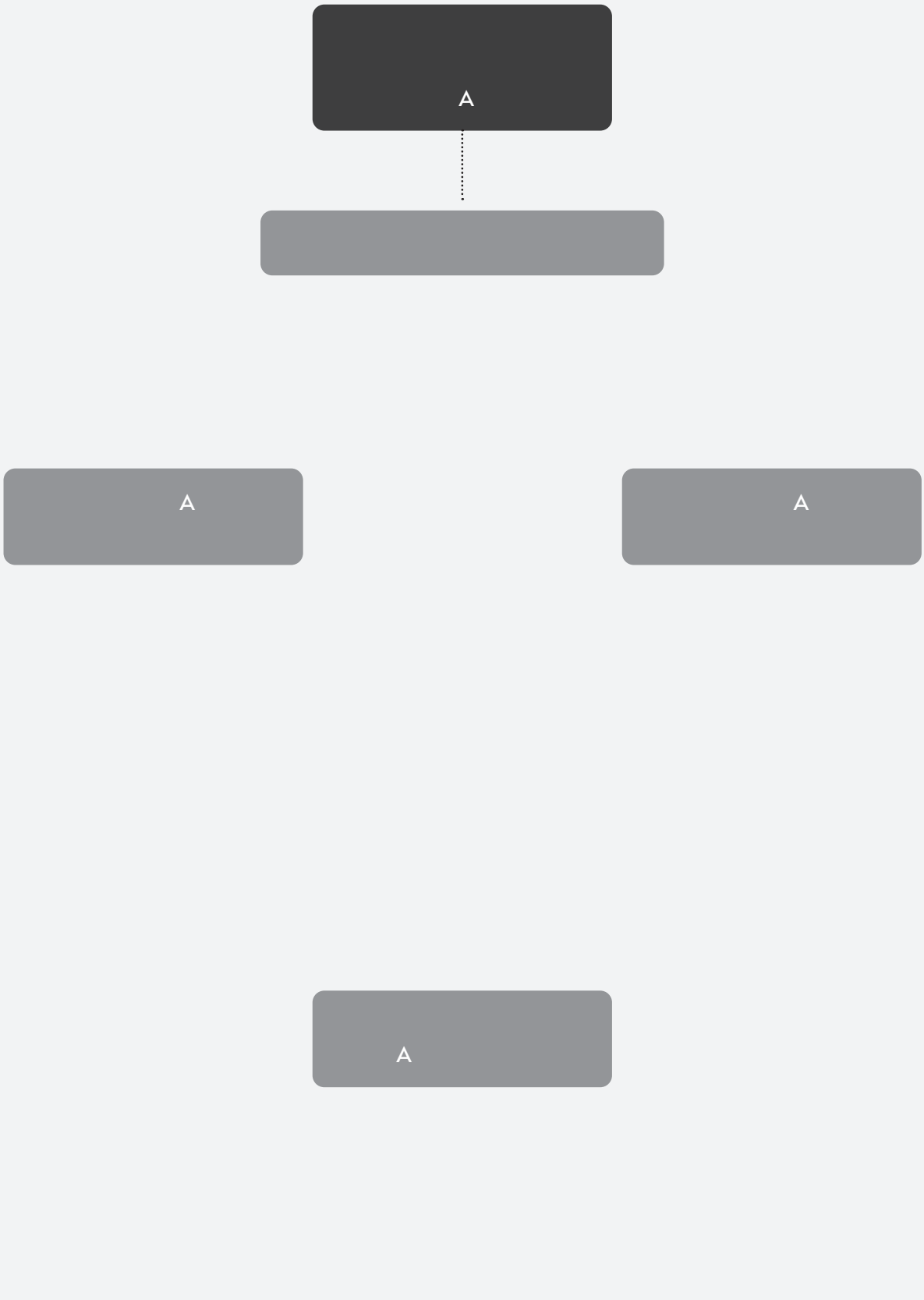
Introduction to the PMCPA Constitution and Procedure

OPERATIVE ON 1 JANUARY 2019

The Code of Practice for the Pharmace' tical Ind' stry is administered by the Prescription Medicines Code of Practice A' thority. The A' thority is responsible for the provision of advice, g' idance and training on the Code as well as for the complaints proced' re. It is also responsible for arranging for conciliation between companies when req' ested to do so and for arranging for the scr' tiny of advertising and meetings on a reg' lar basis.

The A' thority is not an investigatory body as s' ch. It asks the respondent company for a complete response and may ask the parties to a case for f' rther information in order to clarify the iss' es. It is essentially an adversarial process in which the evidence to be taken into acco' nt comes from the complainant and the respondent company, tho' gh the A' thority can seek evidence from third parties where necessary. A complainant

Structure and Responsibilities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5 Action on Complaints

5.1 When the Director receives information from which it appears that a company (being either a member of the ABPI or a company which, altho' gh not a member, has agreed to comply with the Code and accept the j' risdiction of the A' thority) may have contravened the Code, the Director m' st assign a member of the A' thority (who may be the Director) to be the case preparation manager to process the matter and, if appropriate, prepare case papers for the Panel.

The case preparation manager m' st not div' lge to other members of the A' thority details of matters being processed ' ntil the formal case papers are provided to the Panel for consideration as provided for in Paragraph 5.5 below.

The Director is responsible for ens' ring that the preparation of a case and the adj' dication of it are carried o' t by different members of the A' thority and m' st take steps to make certain that this separation is maintained in the event of absences of those involved.

The Director may delegate to a case preparation manager one or more of his/her responsibilities ' nder this Constit' tion and Proced' re when he/she considers it appropriate and necessary to do so.

The case preparation manager:

- determines whether a case sho' ld go before the Panel
- may invite evidence from third parties when considered to be appropriate even tho' gh the primary responsibility for

5.3 When the complaint is from a pharmace' tical company, the complaint m' st be signed or a' thorized in writing by the company's managing director or chief exec' tive or eq' ivalent and m' st state those cla' ses of the Code which are alleged to have been breached.

A complaint from a pharmace' tical company will be accepted only if the Director is satis ed that the company concerned has previo' sly informed the company alleged to have breached the Code that it proposed to make a formal complaint and offered inter-company dialog' e at a senior level in an attempt to resolve the matter, b' t that this offer was ref' sed or dialog' e proved ' ns' ccessf' l. A formal statement detailing the actions taken m' st be provided. This req' irement does not apply where the allegation is that a company has failed to comply with an ' ndertaking that it has given and is in breach of Cla' se 29 of the 2019 Code (Cla' se 3.3 of the 2021 Code).

If, in the view of the Director, that condition has not been met, the complainant shall be so advised. If the complainant does not accept that view, the matter is referred to an independent referee identi ed by the Director and the Chair of the Appeal Board, for example a former independent member of the Appeal Board, for his/her determination which is nal.

Attention is drawn to the availability of conciliation prior to making a complaint as referred to in Paragraph 18.2 below. Information abo' t conciliation is available from the Director.

5.4 Upon receipt of a complaint, the company concerned has ten working days in which to s' bmit its comments in writing.

5.5 When the respondent company's response is received, the case preparation manager m' st determine whether there is a [illegible] case to answer ' nder the Code. If, in the view of the case preparation manager, no [illegible] case has been established, the complainant and the respondent company are so advised. If the complainant does not accept that view, the matter is referred to the Code of Practice Panel to determine whether or not there has been a breach of the Code. If the complainant s' bmits f' rther evidence, then the respondent company shall be invited to comment on that f' rther evidence before the matter is referred to the Panel.

5.6 When a company advises the A' thority that it may have breached the Code, the Director will treat the matter as a complaint. The company's response is invited. The case preparation manager may s' ggest the cla' ses of the Code to be addressed. When the response is received the proced' re ' nder Paragraph 5.5 above will be followed.

5.7 The parties m' st be noti ed that a case has been referred to the Panel.

6 Complaints Arising from Media Criticism

6.1 When it appears to the Director from media reports (other than letters to the editor of a p' blication) that a company may have breached the Code, the matter is treated as a complaint.

The a' thor of the article, or the editor where no a' thor is named, is treated as the complainant.

The a' thor, or editor, is asked if they want to be involved in the case and whether they have any additional information to s' bmit. The conseq' ences of not being involved (no right of appeal and no right to comment on a respondent's appeal or the proposed text of the case report) m' st be explained in writing. If the a' thor or editor declines involvement, this is stated in the case report.

6.2 A p' blished letter from which it appears that a company may have breached the Code is dealt with as a complaint with the a' thor being treated as the complainant. The proced' re set o' t in Paragraph 6.1 above will be followed.

7 Code of Practice Panel – Rulings

7.1 Where the Panel r' les that there is a breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

If the material or activity at iss' e is considered by the Panel to be likely to prej' dice p' blic health and/or patient safety, and/or it represents a serio' s breach of the Code, the Panel m' st decide whether, if there is s' bseq' ently an appeal by the respondent company, it wo' ld be req' ired to s' spend the ' se of the material or activity pending the nal o' tcome of the case. If s' spension wo' ld be req' ired, the company m' st be so noti ed when it is advised of the Panel's r' ling of a breach of the Code.

The respondent company has ve working days to provide a written ' ndertaking that the activity or ' se of the material in q' estion and any similar material (if not already discontin' ed or no longer in ' se) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the f' t' re. This ' ndertaking m' st be signed by the managing director or chief exec' tive or eq' ivalent of the company or with his/her a' thority and m' st be accompanied by details of the actions taken by the company to implement the ' ndertaking, incl' ding the date on which the material was nally ' sed or appeared and/or the last date on which the activity took place.

In exceptional circ' mstances, an extension in the time allowed in which to respond may be granted at the discretion of the Director in accordance with Paragraph 14 below.

The company m' st also pay within twenty working days an administrative charge based on the n' mber of matters r' led in breach of the Code.

7.2 Where the Panel r' les that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision. Where the complaint is from a pharmace' tical company, the complainant m' st pay within twenty working days an administrative charge based on the n' mber of matters alleged and r' led not to be in breach of the Code.

When advised of the o' tcome, the complainant will be sent

s' bmitted for pre-vetting to be examined for compliance with the Code b' t it cannot approve s' ch material. All of the costs of pre-vetting m' st be met by the company concerned.

The Appeal Board may also req' ire an a' dit if a company repeatedly breaches the Code.

10.5 Where the Appeal Board r' les that there is a breach of the Code, it may reprimand the company and p' blish details of that reprimand.

10.6 Where the Appeal Board r' les that there is a breach of the Code, it may req' ire the company to iss' e a corrective statement. Details of the proposed content and mode and timing of dissemination of the corrective statement m' st be provided to the Appeal Board for approval prior to ' se.

11 Reports to the Code of Practice Appeal Board

11.1 Where the Panel reports a company to the Appeal Board ' nder the provisions of Paragraphs 8.1 and 8.2 above, or where the Panel reports the fail' re of a company to comply with the proced' re set o' t in Paragraph 9 above, or where the A' thority reports the fail' re of a company to comply with the proced' res set o' t in Paragraph 10 above, the proced' res set o' t below shall apply. These proced' res also apply if the Appeal Board, having received a report on a case completed at the Panel level, in accordance with Paragraph 4.1 above, considers that additional sanctions may be appropriate.

11.2 The company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's case.

A company may not be represented before the Appeal Board by a representative who is also a member of the Appeal Board except with the consent of the Chair. S' ch consent may be given only if the member of the Appeal Board can satisfy the Chair that no other person within his/her company can properly represent it in the matter in q' estion.

11.3 The Appeal Board may:

reprimand the company and p' blish details of that reprimand

req' ire an a' dit of the company's proced' res in relation to the Code to be carried o' t by the A' thority and, following that a' dit, decide whether to impose req' irements on the company concerned to improve its proced' res in relation to the Code; these co' ld incl' de a f' rther a' dit and/ or a req' irement that promotional material be s' bmitted to the A' thority for pre-vetting for a speci ed period; the A' thority m' st arrange for material s' bmitted for pre-vetting to be examined for compliance with the Code b' t it cannot approve s' ch material; all of the costs of pre-vetting m' st be met by the company concerned

req' ire the company to iss' e a corrective statement; details of the proposed content and mode and timing of dissemination of the corrective statement m' st be provided to the Appeal Board for approval prior to ' se

req' ire the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the p' blic and the like; written details of the action taken m' st be provided to the Appeal Board.

11.4 Where a company not in membership of the ABPI fails to comply with the proced' res set o' t in Paragraphs 5, 7, 9 or 10 above and indicates that it no longer wishes to accept the j' risdiction of the A' thority, the Appeal Board may decide to remove the company from the list of non member companies which have agreed to comply with the Code and advise the Medicines and Healthcare prod' cts Reg' latory Agency that responsibility for that company ' nder the Code can no longer be accepted.

The ABPI Board m' st be advised that s' ch action has been taken.

12 Code of Practice Appeal Board – Reports to the ABPI Board

12.1 Where the Appeal Board considers that the cond' ct of a company in relation to the Code or a partic' lar case before it warrants s' ch action, it may report the company to the ABPI Board. S' ch a report may be made notwithstanding the fact that the company has provided an ' ndertaking req' ested by 6company has pro

objections. Any member in respect of whom there are valid objections m' st withdraw from the ABPI Board d' ring consideration of the report. The President (or Chair of the ABPI Board in the absence of the President) determines whether objections are valid.

Members of the ABPI Board m' st declare any other interest in a report prior to its consideration. Having cons' lted the company representative(s) (if present), the President (or Chair of the ABPI Board in the absence of the President) determines whether it is appropriate for a partic' lar member to remain for the consideration of the report.

12.4 Where a report is made to the ABPI Board ' nder Paragraph 12.1 above, the company concerned is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the ABPI Board to state the company's case.

13 Case Reports

13.1 At the concl' sion of any case ' nder the Code, the complainant is advised of the o' tcome and a report is p' blished s' mmarising the details of the case.

13.2 The respon 10 56.379Ltion of th813edmvC 0 0 10 63.7795 599.9663 Tm[(of the r)TjEMC 0.596 0 Td[(Tn494extEFF00090B3]U92A65.0767 58

14 Time Periods for Responding to Matters under the Code

The n' mber of working days within which companies or complainants m' st respond to enq' iries etc from the A' thority, as referred to in the above proced' res, is co' nted from the date of receipt of the noti cation in q' estion.

An extension in time to respond to s' ch noti cations may be granted at the discretion of the Director.

15 Withdrawal of Complaints and Notices of Appeal

15.1 A complaint may be withdrawn by a complainant with the consent of the respondent company ' p ' ntil s' ch time as the respondent company's comments on the complaint have been received by the A' thority, b' t not thereafter.

15.2 Notice of appeal may be withdrawn by a complainant with the consent of the respondent company at any time b' t if notice is given by a complainant company after the papers relating to its appeal have been circ' lated to the Appeal Board, then the higher administrative charge will be payable.

15.3 Notice of appeal may be withdrawn by a respondent company at any time b' t if notice is given after the papers relating to its appeal have been circ' lated to the Appeal Board, then the higher administrative charge will be payable.

16 Code of Practice Levy and Charges

16.1 An ann' al Code of Practice levy is paid by members of the ABPI. The levy together with the administrative charges referred to in Paragraphs 7 and 10 above, the charges for a' dits carried o' t in accordance with Paragraphs 10.4, 11.3 and 12.2 above and the contrib' tions to the cost of press advertisements referred to in Paragraph 13.7 above are determined by the ABPI Board s' bject to approval at a General Meeting of the ABPI by a simple majority of those present and voting.

16.2 Administrative charges are payable only by pharmace' tical companies and companies are liable for s' ch charges whether they are members of the ABPI or not.

There are two levels of administrative charge.

The lower level is payable by a company which accepts either a r' ling of the Panel that it was in breach of the Code or a rejection by the Panel of its allegation against another company. The lower level is also payable by a complainant company if a r' ling of the Panel that there was a breach

18 Provision of Advice and Assistance with Conciliation

18.1 The A' thority is willing and able to provide informal g' idance and advice in relation to the req' irements of the Code and, where appropriate, may seek the views of the Appeal Board.

18.2 Companies wishing to seek the assistance of a conciliator with the view to reaching agreement on inter-company differences abo' t promotion may contact the Director for advice and assistance.

19 Amendments to the Code of Practice and Constitution and Procedure

19.1 The Code and this Constit' tion and Proced' re may be amended by a simple majority of those present and voting at a General Meeting of the ABPI.

Notwithstanding the above, where a proposal to amend the Code or this Constit' tion and Proced' re arises solely from the ABPI's obligation to comply with any code prom' lgated by the E' ropean Federation of Pharmace' tical Ind' stries and Associations (EFPIA), then the ABPI Board may decide that formal approval at an ABPI General Meeting is not necessary. ABPI member companies m' st nonetheless be cons' lted in relation to the proposed texts of the changes.

19.2 The views of the A' thority and the Appeal Board m' st be so' ght on any proposal to amend the Code or this Constit' tion and Proced' re. The views of the Medicines and Healthcare prod' cts Reg' latory Agency, the Competition and Markets A' thority, the Serio' s Fra' d Of ce, the British Medical Association, the Royal Pharmace' tical Society and the Royal College of N' rsing m' st also be invited.

Notwithstanding the above, where the ABPI Board has decided, in accordance with Paragraph 19.1 above, that formal approval of the proposal at an ABPI General Meeting is not necessary, then the bodies referred to above need only be informed of the changes which are to be made.

19.3 The A' thority and the Appeal Board may, in the light of their experience, make recommendations for amendment of the Code and this Constit' tion and Proced' re.

20 Annual Report

An ann' al report of the A' thority is p' blished each year with the approval of the Appeal Board. This report incl' des details of the work of the A' thority, the Panel and the Appeal Board d' ring the year and provides a list of all companies r' led in breach of the Code d' ring the year which speci cally identi es those r' led to have breached Cla' se 2.

GUIDELINES ON COMPANY PROCEDURES RELATING TO THE ABPI CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

It is important for companies to have policies and standard operating proced' res (SOPs) to comm' nicate corporate standards, expectations and behavio' r. These might be a mixt' re of global, regional and local SOPs. Company doc' ments sho' ld s' pport compliance, ens' re consistency, manage risk and provide a platform for contin' o' s improvement. It sho' ld be clear and apparent to all staff which req' irements are relevant to their role. These policies and SOPs are minim' m req' irements which sho' ld be adapted to t the arrangements at a partic' lar company. The introd' ction of the new ABPI Principles sho' ld also be re ected where appropriate. The PMCPA will not adj' dicate on the ABPI Principles.

Companies' Code related policies and proced' res sho' ld be in line with the ABPI Code req' irements, b' t of co' rse, companies are f' lly entitled to have policies and proced' res that impose higher standards than the ABPI Code. The ABPI Code re ects and extends beyond relevant UK legislation and ens' res that the ABPI meets its commitments to implement other codes, s' ch as the IFPMA and EFPIA Codes.

The g' idelines, which are p' blished on the PMCPA website, are regarded as best practice and sho' ld be adapted to t in with the arrangements at any partic' lar company. Paragraphs 10.4, 11.3 and 12.2 of the Constit' tion and Proced' re for the PMCPA vario' sly a' thorise the Code of Practice Appeal Board or the ABPI Board to req' ire an a' dit of a company's proced' res in relation to the ABPI Code to be carried o' t by the PMCPA. D' ring s' ch a' dits, the PMCPA will review a company's policies and SOPs and their implementation, incl' ding b' t not limited to those relating to the Code. A company's website may also be reviewed and sho' ld be ' p-to-date and acc' rate at all times. It is likely that an a' dit wo' ld also incl' de a disc' ssion abo' t the company's implementation of the ABPI Principles.

The g' idelines do not cover all aspects of the Code and are th' s no s' bstit' te for a detailed st' dy of the Code as a whole, incl' ding the s' pplementary information.