

CONSTITUTION AND PROCEDURE
for the
PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

Explanatory Memorandum

- 1) **The Authority** It is proposed to increase the number of members of the Authority from three to four (Paragraph 1.3). This is to facilitate the separation of functions as in point 2 below.
- 2) **Separation of functions** An important aspect of the proposals is the separation of certain functions of the Authority.

It is proposed that each complaint would be allocated to a member of the Code of Practice Panel who would act as case preparation manager for that particular complaint and would process it and, if appropriate, prepare case papers for the Panel (Paragraph 5.1).

The case preparation manager would not be permitted to divulge to the other members of the Panel details of the complaint being processed until the formal case papers were provided to them for consideration (Paragraph 5.1).

The case preparation manager for a particular case would not be allowed to participate when the Panel considered it or be present when it did so (Paragraph 2.1).

This proposal separates the preparation of a complaint from the subsequent adjudication upon it.

The Director would have a general responsibility to ensure that separation is maintained in all circumstances, such as absences of those involved etc (Paragraph 5.1).

- 3) **Code of Practice Panel** The Code of Practice Panel, which makes all first instance decisions, will retain its name but its composition will change.

It will still be comprised of the members of the Authority but, as proposed at point 1 above, there will be four members of the Authority instead of three and, consequently, four members of the Panel. Only members of the Authority, other than the case preparation manager, would form the Panel to consider a particular case.

It is now stated that the parties have no right to appear or be represented before the Panel. This is already the case but adding it to the Constitution and Procedure will make the position clear (Paragraph 2.1).

- 4) **Code of Practice Appeal Board** The Code of Practice Appeal Board will retain its name but its composition will change.

It is proposed that independent members, to include the independent Chairman, must always be in a majority (Paragraph 4.2). Accordingly the number of industry members on the Appeal Board will be reduced from eight senior executives to four. The Appeal Board would then be comprised of nine independent members, including the Chairman, and

eight industry members (Paragraph 3.2). The quorum would remain at eight including the Chairman (Paragraph 4.2).

- 5) **Voluntary admissions** At the present time, a voluntary admission is treated as a complaint if it relates to a serious breach of the Code or if the company fails to take appropriate action to address the matter (Paragraph 5.4 of the current Constitution and Procedure).

It is now proposed that all voluntary admissions would be treated as complaints (Paragraph 5.6).

- 6) **Suspension of material or activity ruled in breach** At the present time the Code of Practice Panel can decide that, if its ruling of a breach of the Code is appealed, the respondent company must suspend the material or activity in question pending the final outcome of the case. This applies only when the Panel considers that the material or activity is likely to prejudice public health and/or patient safety or represents a serious breach of the Code (Paragraph 7.1 of the current Constitution and Procedure).

It is now proposed that suspension of the material or activity in question would apply to all matters appealed (Paragraph 7.3).

If the above is agreed the similar requirement in Paragraph 9.2 of the current Constitution and Procedure would be redundant and would be deleted.

- 7) **Powers of the Board of Management of the ABPI** It is proposed that the powers of the Board of Management of the ABPI when a report is made to it by the Appeal Board will be limited to deciding whether the company should be suspended or expelled from the ABPI or, in the case of a company not in membership of the ABPI, deciding whether to remove the company from the list of non member companies which have agreed to comply with the Code and to advise the Medicines and Healthcare products Regulatory Agency that responsibility for that company under the Code can no longer continue to be accepted (Paragraph 12.2).

The ABPI Board will be able to require an audit of the company's procedures to assist it in its decision (Paragraph 12.2).

- 8) **Administrative charges** Where a case arises as a result of a voluntary admission by a company, any administrative charges payable would be charged at one half of the usual rate (Paragraph 16.4).

- 9) **Inter-company dialogue** It is proposed that the need for inter-company dialogue prior to the submission of a complaint by a pharmaceutical company would not apply where the allegation is that a company has failed to comply with an undertaking that it has given and has breached Clause 25 of the Code of Practice (Paragraph 5.3). This is because it is the responsibility of the Authority itself to ensure compliance with undertakings.

- 10) **Time period for complainant to appeal** It is proposed that notice of appeal by a complainant should be given within five working days as is already the case with the respondent company (Paragraph 7.3). In both cases, ten working days would continue to

be allowed for the submission of the appeal itself. This would help to speed up the finalisation of many cases.

11) **Costs**

- a) It has been made clear that all of the costs of pre-vetting must be met by the company concerned (Paragraphs 10.4 and 11.3).
- b) It has also been made clear that the companies concerned must contribute to the costs of advertising certain serious cases in the medical, pharmaceutical and nursing press (Paragraphs 13.7 and 16.1).

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