**CONSTITUTION AND PROCEDURE**

**FOR THE**

**PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY**

**AMENDMENT NUMBER 1**

**Paragraph 1.3 Prescription Medicines Code of Practice Authority**

**Current text (extract)**

‘The Authority is appointed by and reports to the Board of Management of the Association of the British Pharmaceutical Industry (ABPI) (the “ABPI Board”) and consists of the Director, Deputy Director, Secretary and Deputy Secretary.’

**Proposal**

To replace all references to the ABPI Board of Management with ABPI Board.

To read:

‘The Authority is appointed by and reports to the Board of the Association of the British Pharmaceutical Industry (ABPI) (the ‘ABPI Board’) and ….’

**Reason**

To reflect the status of the ABPI as a company limited by guarantee since 1 January 2016. It was not possible to make these changes before the change to the ABPI status.

\* \* \* \* \*

Similar changes to other parts of the Constitution and Procedure for example, the diagram on page 43 of the current booklet and Paragraph 12.

\* \* \* \* \*

**AMENDMENT NUMBER 2**

**Paragraph 1.3 Prescription Medicines Code of Practice Authority**

**Current text (extract)**

‘Notwithstanding the above, the Director reports to the Appeal Board for guidance on the interpretation of the Code and the operation of the complaints procedure and to the President of the ABPI for administrative purposes.’

**Proposal**

To add a reference to the ABPI Vice President.

To read:

‘Notwithstanding the above, the Director reports to the Appeal Board for guidance on the interpretation of the Code and the operation of the complaints procedure and to the President of the ABPI (or, at the President’s discretion, the Vice President of the ABPI) for administrative purposes.’

**Reason**

To reflect recent changes at the ABPI to appoint a Vice President.

\* \* \* \* \*

**AMENDMENT NUMBER 3**

**Paragraph 1.3 Prescription Medicines Code of Practice Authority**

**Current text (extracts)**

‘The Authority is appointed by and reports to the Board of Management of the Association of the British Pharmaceutical Industry (ABPI) (the ‘ABPI Board’) and consists of the Director, Deputy Director, Secretary and Deputy Secretary ….

In the absence of the Director, the Deputy Director is authorized to act on his behalf. In the absence of the Director and Deputy Director, the Secretary is authorized to act on the Director’s behalf.’

**Proposal**

To replace ‘Secretary and Deputy Secretary’ with ‘two Managers’ and to permit one of them to act in the absence of the Director and Deputy Director.

To read:

‘The Authority is appointed by and reports to the Board of the Association of the British Pharmaceutical Industry (ABPI) (the “ABPI Board”) and consists of the Director, Deputy Director and two Managers ….

In the absence of the Director, the Deputy Director is authorized to act on his behalf. In the absence of the Director and Deputy Director, one of the Managers is authorized to act on the Director’s behalf.’

**Reason**

To update job titles.

\* \* \* \* \*

Similar changes will be needed in Paragraphs 2.2 and 3.4.

\* \* \* \* \*

**AMENDMENT NUMBER 4**

**Paragraph 2.2 current text**

Two members of the Authority form a quorum for a meeting of the Panel. Decisions are made by majority voting. The Director or, in his absence the Deputy Director or, in his absence, the Secretary acts as Chairman of the Panel and has both an original and casting vote.

**Proposal**

To introduce the concept of co-opting a person to join the Panel to allow for more flexible resources. This is similar to current arrangements for the Code of Practice Appeal Board (Paragraph 4.2 of the current Constitution and Procedure).

To read:

If necessary the Director or in his/her absence the Deputy Director, may co-opt an appropriate person to be a member of the Panel. The Director should seek the agreement of the Chairman of the Appeal Board prior to any co-option.

**Reason**

The purpose of such co-option is to ensure that the consideration of cases is not delayed due to the unavailability of members of the Authority and will provide more flexibility. The recent vacancy at the PMCPA meant that for over a year there were only two potential members of the Panel rather than three. This has substantially increased pressure on staff including limiting meetings of the Panel and meant cases have taken longer to complete. It is also a recommendation of the recent review of the process.

Possible candidates to be a co-opted member of the Panel include a previous member of the Authority or the Appeal Board. Clearly conflicts of interest will have to be taken into account.

\* \* \* \* \*

**AMENDMENT NUMBER 5**

**Paragraph 5.5 current text**

‘When the respondent company’s response is received the case is referred to the Panel to determine whether or not there has been a breach of the Code.’

**Proposal**

To reintroduce the concept that following receipt of the response from the company a decision is made that there is a *prima facie* case to answer before referring the papers to the Code of Practice Panel.

To read:

‘When the respondent company’s response is received the case preparation manager must determine whether there is a *prima facie* case to answer under the Code. If, in the view of the case preparation manager, no *prima facie* 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 submits further evidence, then the respondent company shall be invited to comment on that further evidence before the matter is referred to the Panel.’

**Reason**

The determination of a *prima facie* case following receipt of the response was part of the 2006 Code and was removed in 2008. Following the introduction of the case preparation manager role in 2011 and the separation of the preparation of the case from those that consider the case, the reintroduction of a judgement following the response from the company is possible again. The ability of the case preparation manager to rule no *prima facie* case should decrease the number of Panel rulings of no breach of the Code as the matter is outside the scope of the Code.

There should be a means of appealing a decision of no *prima facie* case to answer and this is covered by referring the matter to the Panel as currently.

\* \* \* \* \*

**AMENDMENT NUMBER 6**

**Paragraph 12.3 current text (extract) Reports to the ABPI Board**

‘The company concerned is advised in advance of the membership of the ABPI Board and asked if it has any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the ABPI Board during consideration of the report. The President (or Chairman in the absence of the President) determines whether objections are valid.

Members of the ABPI Board must declare any other interest in a report prior to its consideration. Having consulted the company representative(s) (if present), the President (or Chairman in the absence of the President) determines whether it is appropriate for a particular member to remain for the consideration of the report.’

**Proposal**

To amend to use Chair instead of Chairman and make it clear that it is the Chair of the ABPI Board who acts in the absence of the ABPI President.

To read:

‘The company concerned is advised in advance of the membership of the ABPI Board and asked if it has any objections to particular members and the grounds for such objections. Any member in respect of whom there are valid objections must withdraw from the ABPI Board during 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 must declare any other interest in a report prior to its consideration. Having consulted 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 particular member to remain for the consideration of the report.’

**Reason**

To add clarity and update language.

\* \* \* \* \*

**AMENDMENT NUMBER 7**

To change all references to the Chairman of the Appeal Board to the Chair and his to his/her. To change references to the Director and Deputy Director from his to his/her.

29 August 2018