### Pharmaceutical Benefits Advisory Committee (PBAC)

### Terms of Reference

### Purpose

The Pharmaceutical Benefits Advisory Committee (PBAC) is a statutory body within the Health Insurance (Jersey) Law 1967 responsible for making recommendations to the Social Security Minister for changes to the Approved List of Pharmaceutical Preparations (the 'Prescribed List').

Under the Law, the Minister is required to consult with the PBAC before exercising his or her powers to approve products as items of pharmaceutical benefit.

### Article 15

- (11) Subject to paragraph (12), the Minister
  - (a) shall approve medicines, drugs, appliances and materials as items of pharmaceutical benefit for the purposes of this Law;
  - (b) in so approving them, may make different provision for the medicines, drugs, appliances and materials that may be prescribed by, respectively, approved medical practitioners, approved dentists and approved prescribing practitioners as items of pharmaceutical benefit; and
  - (c) may at any time alter, revoke or vary any such approval. [45]
- (12) Before exercising his or her powers under paragraph (11) the Minister shall consult with the Pharmaceutical Benefit Advisory Committee.<sup>1</sup>

### Constitution

The membership and terms of service of the Committee are described in the Health Insurance (Pharmaceutical Benefit Advisory Committee) (Jersey) Order 2017 (See Appendix 1).

### Meetings

Meetings will be held quarterly at a time to suit members. Typically, meetings will be face-to-face but other means of consultation may be required at times where the Committee is asked to consider a change to the Prescribed List outside the agreed meeting schedule.

An agenda will be circulated to members, including the application forms and related evidence, no less than 1 week before the date of the meeting. Minutes of each meeting will be distributed within 4 weeks after the date of the meeting.

A total of seven members of the Committee, including at least 2 approved medical practitioners and one pharmacist, constitute a quorum. Members are encouraged to nominate a deputy who can attend in their absence.

In the event that a meeting is not quorate and attempts have been made to secure attendance of appropriate deputies, the meeting may progress. The decisions taken by the Board will be circulated to all board members and members who were not present will be

able challenge the decision, registering their opposition and rationale. Counter views must be submitted within two weeks of receipt of the minutes. Normal voting rules will apply where there is not a unanimous decision.

### Scope

The Committee will primarily consider applications for medicines or medical devices to be added, removed, or otherwise changed in the Prescribed List. These deliberations will be guided by the following considerations;

- evidence of safety and therapeutic effect
- comparison to other medicines available on the List
- potential for improvement to patient care and/or advantages in patient's ability to adhere to medicines regime
- · suitability for prescribing in primary care
- cost and cost effectiveness

The Minister may also consult with the Committee on other issues relating to access to prescription medicines and services under the Health Insurance Fund.

### **Applications**

Applications for changes to the Prescribed List will be submitted on a standard application form (Appendix 2) more than 2 weeks before the date of the meeting. Late submissions may be accepted at discretion of the Chair and Pharmacy Advisor

An application for a new medicine (new chemical entity) must be submitted or endorsed by

- an approved prescriber under the Health Insurance Law (including General Practitioners, dentists and non-medical prescribers), or
- a registered practitioner under the Medical Practitioners (Jersey) Law 1960, or
- a Registered Pharmacist under the Pharmacist and Pharmacy Technicians (Registration) (Jersey) Law 2010

### Recommendations and amendment to the Prescribed List

The Chair of the Committee is responsible for making recommendations to the Minister based on the views of PBAC members. Where the views of the Committee are divided, the Chair may request a vote and the way the members have voted must be recorded alongside the recommendation.

On receiving the Committee's recommendations from the Chair, the Minister may amend the Prescribed List and these amendments will be published as a Ministerial Decision with the Prescribed List updated accordingly and published.

Decisions may be implemented with immediate effect but are typically implemented from a date determined at the time of the PBAC recommendation. There are several considerations including:

 the time taken for NHS Business Services Authority to amend its rules for prescription pricing (changes should be notified by 15<sup>th</sup> of the month for implementation in the following month)

- time for contractors to obtain supplies of new products in to the Island
- the need to deplete existing stocks in the Island when removing a product from the List or changing the basis for reimbursement (for example, restriction to generic products only).
- the development of appropriate services to support the safe and cost-effective use of a new product

### Confidentiality

Members are expected to represent their professional groups and are encouraged to consult with colleagues in advance of meetings. However, some papers contain commercial information that has been provided in confidence and all members should agree to keep such information confidential. Discretion should be used when discussing applications with non-attendees. If in doubt, members should seek advice from the Chair or Pharmacy Advisor, to ensure confidentiality is maintained.

### Freedom of Information

Amendments to the Prescribed List and the report on which such recommendations are based will be published as a Ministerial Decision. On occasion these may be redacted to protect commercial information or may classified as entirely exempt from publication according to the provisions of the Freedom of Information Law.

Minutes of the PBAC will not be routinely published or released as they are deemed to be policy under development. (See below). Minutes will be retained by the committee for 10 years and thereafter archived.

Freedom of Information (Jersey) Law 2011

Part 5 – Qualified Exemption Information

### 35 Formulation and development of policies

Information is qualified exempt information if it relates to the formulation or development of any proposed policy by a public authority.

### Conflicts of interest

All members of the Committee must submit a declaration of interests which will be retained by the committee for the duration of the members service and for two years following the end of their term of service or resignation. (Appendix 3).

The conflict of interest should be updated as soon as practically possible whenever there is a new or changed interest. One-off interests will be considered to have lapsed 12 months after declaration.

Appendix 1: Health Insurance (Pharmaceutical Benefit Advisory Committee) (Jersey)
Order 2017

# HEALTH INSURANCE (PHARMACEUTICAL BENEFIT ADVISORY COMMITTEE) (JERSEY) ORDER 2017

THE MINISTER FOR SOCIAL SECURITY, in pursuance of Articles 15A and 36 of the Health Insurance (Jersey) Law 1967<sup>[1]</sup>, orders as follows –

Commencement [see endnotes]

### 1 Interpretation

In this Order –

"Committee" means the Pharmaceutical Benefit Advisory Committee established under Article 2;

"Department" followed by a description means the administration of the States for which the Minister of that description is responsible;

"Medical Officer of Health" means the person appointed as such under Article 10 of the Loi (1934) sur la Santé Publique<sup>[2]</sup>;

"non-medical prescribing practitioner" means an approved prescribing practitioner who is not a doctor or a dentist:

"nurse" means a person registered as a nurse under the Health Care (Registration) (Jersey) Law 1995[3];

"States' employee" has the same meaning as in Article 2 of the Employment of States of Jersey Employees (Jersey) Law 2005[4].

### 2 Establishment and membership of Committee

- (1) The Pharmaceutical Benefit Advisory Committee is established.
- (2) The Committee consists of
  - (a) a chairperson appointed by the Minister;
  - (b) a States employee, appointed by the Minister, who is working in the Department of Social Security;
  - (c) a pharmacist or medical practitioner, appointed by the Minister, who is working in an administration of the States in that capacity;
  - (d) 3 approved medical practitioners nominated by a body of persons that appears to the Minister to be representative of general medical practitioners in Jersey;
  - (e) 2 pharmacists, one of whom being nominated by the Jersey branch of the Royal Pharmaceutical Society and the other being nominated by a body of persons that appears to the Minister to be representative of approved suppliers in Jersey;
  - (f) an approved dentist nominated by a body of persons that appears to the Minister to be representative of dentists in Jersey;
  - (g) 2 States' employees working in the Department of Health and Social Services, one of whom being a representative of the committee or other body responsible for

- advising that Department on the use of medicines and the other being a person nominated by the Chief Nurse of the Health and Social Services Department to represent non-medical prescribing practitioners and nurses;
- (h) the Medical Officer of Health; and
- (i) the Chief Pharmacist at the General Hospital.
- (3) The following persons are ineligible for appointment as chairperson under paragraph (2)(a)
  - (a) members of the States;
  - (b) any medical practitioner, dentist, optician, pharmacist or non-medical prescribing practitioner; and
  - (c) any States' employee working in the Department of Social Security or the Department of Health and Social Services;
  - (d) any other person who might reasonably be regarded as having a conflict of interest in undertaking the role of chairperson.
- (4) A person appointed to fill a casual vacancy in the office of chairperson or member of the Committee holds office until the date on which the person in whose place the person is appointed would have ceased to hold office.
- (5) The Committee must appoint either of the members appointed under paragraph (2)(b) or (c) to be vice-chairperson of the Committee, and in the absence of the chairperson the vice-chairperson is to preside at meetings of the Committee.
- (6) A member of the Committee may appoint a deputy to act on the member's behalf at any meeting of the Committee and if that appointment is notified in advance to the secretary of the Committee the deputy is entitled to act in the place of that member.
- (7) However
  - (a) an approved medical practitioner, pharmacist, dentist, non-medical prescribing practitioner or nurse may appoint only a person of like qualifications to act on his or her behalf;
  - (b) the Chief Pharmacist may appoint only the Deputy Chief Pharmacist at the General Hospital to act on his or her behalf; and
  - (c) no person appointed under paragraph (6) may act as vice-chairperson.

### **3** Terms of service

- (1) The chairperson of the Committee and the members mentioned in Article 2(2)(d), (e) or (f) hold office in accordance with their terms of appointment.
- (2) However they shall cease to hold office
  - (a) if they tender their resignation in writing to the Minister;
  - (b) if a curator is appointed to their person or property; or
  - (c) if, without reasonable excuse, they fail to attend 3 consecutive meetings of the Committee.
- (3) The persons mentioned in paragraph (1) may be appointed for a maximum term of 5 years but such appointment is renewable.
- (4) However, the aggregate of the terms served must not exceed 9 years.
- (5) The members of the Committee not mentioned in paragraph (1) hold office by virtue of the employment or engagement that qualifies them for appointment but cease to be members of the Committee if and when that employment or engagement ceases.

### 4 Secretary

The Minister must appoint a secretary of the Committee who is to be paid such remuneration and allowances as the Minister thinks fit.

### 5 Proceedings

- (1) 7 members of the Committee, including at least 2 approved medical practitioners and one pharmacist, constitute a quorum.
- (2) On any matter on which the votes of the Committee are divided, the manner in which the members have voted must be recorded.

### 6 Transitional provision

- (1) A person appointed to the Pharmaceutical Benefit Advisory Committee constituted under Schedule 1 to the Health Insurance (Jersey) Law 1967 is treated as having been appointed under this Order save that his or her appointment expires in accordance with that Schedule.
- (2) Article 3 does not apply to an appointment mentioned in paragraph (1) but applies following the expiry of that appointment.

### 7 Citation

This Order may be cited as the Health Insurance (Pharmaceutical Benefit Advisory Committee) (Jersey) Order 2017.

## Appendix 2: Application for change to the Prescribed List

# **Application for amendment to the Prescribed List**

What sort of change is proposed? (Please tick as appropriate)						
Add new medicine	Add new formulation of a medicine on the List					
Remove a medicine	Remove a formulation	Change to generic only				
OTHER (please state)						
2. Name of medicine (including brand name if known)						
3. Indication						
4. Is the product licensed for this indication			Yes	No		
5. Recommended dose						
6. Cost per patient at recommended dose (annual cost if appropriate)						
7. What alternatives are on the List?						
8. Why is this change needed?						

9. How many patients are likely to be affected by this change?  (for a new product, what is the expected uptake; if a product is to be removed or made generic only, how many patients are currently prescribed this product)
10. Estimated cost impact of this change
11. What published evidence is there to support this change? Is there a published assessment of the effectiveness/cost-effectiveness of this product? (If so, please give details)

Please send the completed form to Paul McManus (<a href="mailto:paul@inpax.co.uk">paul@inpax.co.uk</a>), Pharmacist Adviser to the Government of Jersey

## Appendix 3: Declaration of interests

Personal details	
Print Name:	
Position:	
Employing organisation	
Category of interest Details	
Direct pecuniary interests	
Personal Family Interests (Iqndirect pecuniary interests)	
Non-pecuniary interests	
Non-pecuniary personal benefits	
Any other relevant area(s) of interest	
Chair will take account of the relevand agreed and recorded. It is the respons as practically possible. All declarations interests.	
Signed:	
This information will be held by the Ph	narmaceutical Benefit Advisory Committee and retained for the for two years following the end of the members term or their
allow free and full debate to inform u	pers and attendees agree to keep detailed discussions confidential to mencumbered decision making. Discretion should be used when ses and papers should not be shared without agreement of the chair or stiality is maintained.
I declare that I agreed to abide by the	se principles of confidentiality.
Signed:	Date: