



Appointments to the Board of the Health Products Regulatory Authority

Closing Date: Midnight on 27 October 2015

**State Boards Division
Public Appointments Service
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Stateboards.ie operates under the auspices of the Public Appointments Service and is committed to a policy of equal opportunity.

The Public Appointments Service (PAS), established under statute in 2004, provides an independent shared service in recruitment, assessment and selection to organisations across the Civil and Public Services. On 30 September 2014, the Government decided that the PAS should also be given responsibility for putting in place an open, accessible, rigorous and transparent system to support Ministers in making appointments to State Boards. Our dedicated website, www.stateboards.ie, is the channel through which the PAS advertises vacancies on State Boards. It is also the means through which accomplished, experienced and qualified people, including people who might not previously have been identified as available for appointment, can then apply to be considered for particular vacancies.

Membership of State Boards

High standards of corporate governance in all State Agencies, whether in the commercial or non-commercial sphere, are critical to ensuring a positive contribution to the State's overall social and economic development.

Members of State Boards are appointed to act on behalf of the citizen to oversee the running of the affairs of state bodies. State bodies must serve the interests of the taxpayer, pursue value for money in their endeavours (including managing risk appropriately), and act transparently as public entities. Members of State Boards, and the relevant management team, are accountable for the proper management of the organisation.

Board members should act on a fully informed basis, in good faith, with due diligence and care, and in the best interest of the State body, subject to the objectives set by Government.

The [Code of Practice for the Governance of State Bodies](#) provides a framework for the application of best practice in corporate governance by both commercial and non-commercial State bodies.

In order to be an effective contributor on a State Board it is recommended that members should:

- bring independent and objective scrutiny to the oversight of the organisation;
- be prepared to be challenging when necessary while being supportive to the delivery of organisational strategy and objectives;
- be equipped to offer considered advice on the basis of sound judgement and experience;
- be prepared to make a time commitment to their work commensurate with their role.

Appointments to the Board of the Health Products Regulatory Authority

Location: Meetings will be in the offices of the HPRA, Earlsfort Terrace, Dublin 2

Number of Vacancies: 2 (1 Chairperson and 1 Ordinary Member)

Remuneration: The Chairman is paid an annual allowance of €11,970 and expenses as authorised.

Authority members do not receive any fees or allowances but this is under review.

(It should be noted that in line with the 'One Person One Salary' principle, no public servant will be entitled to receive remuneration in the form of board fees, save for situations that are provided for under statute, e.g., the appointment of Worker Directors).

Time Requirements: The Authority meets at least 6 times per annum with each meeting lasting 3 hours. There may also be occasional extraordinary meetings convened by teleconference or in person. Authority meetings are held in private, with a report of each meeting being published on the HPRA website. Authority members are expected to be in attendance for the entire meeting. Documentation for Authority meetings is provided in advance in electronic format, and members may expect to spend up to one day in preparation for each meeting.

1. Background

The Health Products Regulatory Authority (HPRA) is the regulatory authority for human and veterinary medicines, clinical trials, controlled drugs, medical devices and cosmetics in Ireland. In addition, the HPRA is responsible for the implementation of EU and national legislation relating to Blood and Blood Components and for Tissues and Cells. The HPRA, formerly the Irish Medicines Board (IMB), was established on a statutory basis on 1 July 2014.

The role of the HPRA is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. The HPRA also monitors the safety of cosmetics.

The general functions of the HPRA, as defined by the [IMB Act 1995](#) and subsequent legislation are:

- to ensure the quality, safety and efficacy of medicines available in Ireland and to participate in systems designed to achieve this throughout the European Union
- to review the scientific aspects of the application and reach a conclusion on the likely balance of any benefits versus the risk(s) of a medicine before arriving at a decision.
- following approval and use of a medicine, the HPRA monitors the type and frequency of any reported side-effects.
- to monitor the quality of medicines by conducting inspections at sites of manufacture and sites of distribution of medicines and by random sampling of products both pre and post authorisation
- to authorise the use of medicines for clinical research purposes
- to consider the consequences to human health of the use of medicines in animals
- to regulate the following areas:
 - Human medicines
 - Veterinary medicines
 - Clinical trials
 - Medical devices
 - Controlled drugs
 - Blood and blood components
 - Tissues and cells
 - Cosmetic products
 - The protection of animals used for scientific purposes
 - Organs intended for transplantation

2. Functions of the Board of the Authority

The Board of the Health Products Regulatory Authority is responsible for the discharge of the functions specified in [Section 4 of the IMB Act](#) and any other obligations or responsibilities laid down in primary and secondary legislation. This includes:

- Approving the strategic plan and reviewing performance against the plan.
- Taking decisions relating to the withdrawal of a product or authorisation from the market in circumstances where the matter is only national (i.e. not mandated by EU processes)
- Through its Audit Committee, approving the internal financial controls and the financial audit function. The Authority appoints the internal financial auditor.
- Approving the investment policy, major investments, capital projects and the terms of major contracts.
- Approving the annual budget, monitoring expenditure and supervising the preparation and submission of the annual statutory accounts.

- The Board of the Authority makes an annual report on the activities of the Health Products Regulatory Authority (HPRA), including a financial statement, to the Minister for Health. The report is published.
- The Board of the Authority selects and appoints the Chief Executive, with the consent of the Minister for Health and, through its Remuneration Committee, conducts a process of annual performance appraisal of the Chief Executive.

3. Structure of the Board of the Authority

The current Board of the Authority comprises a Chairperson and 8 members. Two vacancies, that of Chairperson and Board Member fall to be filled on 31st December 2015.

The current composition is:

Name	Appointed	Position type
Ann Horan	Jan. 1, 2011	Member
Catriona O'Driscoll	Jan. 1, 2011	Member
Diarmuid Quinlan	May 22, 2014	Member
Elizabeth Keane	May 22, 2014	Member
Mary Horgan	Oct. 19, 2011	Member
Michael Hayes	Jan. 1, 2011	Chairperson
Noel O'Donoghue	Jan. 1, 2011	Member
Patrick M. Brangan	May 22, 2014	Member
Wilf Higgins	May 22, 2014	Member

4. Person Specification

The Minister for Health invites expressions of interest from suitably qualified persons in any of the areas listed below to sit on the Authority of the Health Products Regulatory Authority.

Chairperson

Candidates must have two or more of the following:

- Significant prior Board membership experience;
- Significant experience at a senior executive level in a private or public organisation;
- Understanding and experience of regulatory oversight;
- Experience of commercial decisions and financial oversight.

In addition to the essential requirements, it is desirable that candidates have:

- Third level and/or a professional qualification ideally in business, law, life sciences, science, engineering, veterinary or agricultural science with significant experience since qualifying.

Authority Member

Candidates must have:

- Significant experience at a senior executive level in a private or public organisation with a specific focus on corporate governance, finance and/or strategy;
- Experience of commercial decisions and financial oversight.

In addition to the essential requirements, it is desirable that candidates have:

- Significant experience of being on (a) Board(s);
- Experience of a regulatory environment;
- Third level and/or a professional qualification ideally in business, law, or accounting.

For all candidates, it is desirable that they can demonstrate:

- A commitment to public service values and regulation in the public interest;
- A strong sense of ethics, integrity and impartiality.

5. Terms of Appointment

In accordance with Section 7 of the Irish Medicines Board Act, 1995, the Minister, when making an appointment shall fix the length of that appointment at no more than five years. Membership shall be on such terms as the Minister determines.

A member of the Board of the Authority may at any time resign his or her membership by letter addressed to the Minister and the resignation shall take effect from the date specified therein or upon receipt of the letter by the Minister, whichever is the later.

A member of the Board of the Authority may at any time be removed from membership of the Board of the Authority by the Minister if, in the Minister's opinion, the member has become incapable through ill-health of performing his or her functions, or has committed stated misbehaviour, or his or her removal appears to the Minister to be necessary for the effective performance by the Board of the Authority of its functions.

If a member of the Board of the Authority dies, resigns, becomes disqualified or is removed from office, the Minister may appoint a person to be a member of the Board of the Authority to fill the casual vacancy so occasioned.

A member of the Board of the Authority whose period of membership expires by the effluxion of time shall be eligible for re-appointment as a member of the Board of the Authority.

The roles and responsibilities of Board Members are described in the Code of Practice for the Governance of State Bodies 2009 which is available on the website of the Department of Finance ([Code of Practice for the Governance of State Bodies](#)).

A member of the Board of the Authority shall cease to be a member of the Board of the Authority if he or she is nominated as a member of Seanad Éireann, is elected as a member of either House of the Oireachtas or as a representative in the European Parliament, elected to the European Parliament, or becomes a member of a local authority.

6. Submitting your expression of interest

Before submitting your expression of interest, please review the self-assessment questionnaire which can be found [here](#). This questionnaire is designed to help you in considering whether to submit an expression of interest - you are not required to submit the questionnaire as part of the application process.

Having considered the general suitability criteria for membership of a State Board, you should consider carefully how your background and experience fits with the specific appointment criteria set out in the Person Specification section in this booklet. Please give careful consideration to the possibility of any potential conflict of interest that may arise if appointed to this board.

Your submission should be made via the following link www.stateboards.ie together with your **Curriculum Vitae** and a **Cover Letter** (see Appendix 1 of this booklet for help with the online process).

IMPORTANT NOTE

Please take care when submitting your expression of interest. As the Assessment Panel will generally make its recommendation(s) based on consideration of the documentation which you submit, it is most important that you do the following:

1. *Ensure your Cover Letter (and supporting CV) clearly specifies how your particular background and experience meets the requirements of the Board position(s) specified in this booklet, and*
2. *That you fully answer any supplementary questions which are presented to you as part of our online application process.*

This will help ensure that the Assessment Panel is as informed as possible as to the basis for your candidature and why you believe you are a person who could potentially be appointed to this State Board.

If you have any questions regarding the application process please email info@stateboards.ie.

7. Assessment Process

An Assessment Panel (the "Panel") will be convened by PAS to consider and assess the expressions of interest received by PAS. The Panel will:

- review and discuss the expressions of interest received against the specific appointment criteria for the role, as advertised in this Information Booklet;
- assess potential candidates further once they meet the specified appointment criteria by undertaking any or all of the following steps:
 - Consideration of the written applications; and/or
 - Meeting/conference call; and/or
 - Referee checks; and/or
 - Any other selection or verification method deemed appropriate (this may include PAS requiring statutory declarations from shortlisted applicants as to the bona fides of the qualifications and experience contained in their applications).
- arrive at a shortlist of suitable candidates to be sent forward for consideration by the Minister.

8. Confidentiality

Subject to the provisions of the Freedom of Information Acts, 2014, applications will be treated in strict confidence. All enquires, applications and all aspects of the proceedings are treated as strictly confidential and are not disclosed to anyone, outside those directly involved in that aspect of the process.

Certain items of information, not specific to any individual, are extracted from computer records for general statistical purposes.

9. Data Protection Acts 1988 & 2003

For further information on Data Protection please follow the [link](#)

APPENDIX 1

Submitting your expression of interest

In order to submit your application, you should take the following steps:

1. Go to www.stateboards.ie.
2. On the bar at the top of the page click on "Available Appointments".
3. This brings you to a page with all our advertised vacancies. Select whichever position you would like to apply for (you are welcome to apply for more than one position if you wish).
4. On the relevant page please click on the "apply for position" button at the bottom of the page
5. This will bring you to a page on www.publicjobs.ie and, if you already have a publicjobs.ie account, will prompt you for your username and password. If you do not have an account you will be asked to create one.
6. Once you input your details you will be brought to a page where there is a prompt in the middle of the page which says "apply here". Click on the link to the online application form beside it.
7. A form will appear on your screen, some of the text boxes will be populated with information from your publicjobs.ie profile (Name, address etc.). You will need to complete the rest of the fields and enter your name and the date at the bottom of the form. Click on "continue".
8. You will then be brought to a screen where you should upload your CV and Cover Letter. These are required documents and your application cannot be processed without them. Once you have selected these and uploaded them, please click on the "submit" button at the bottom of the page.
9. You will receive an e-mail confirmation (to the address listed in your publicjobs.ie profile) to confirm that your application has been submitted.

You must confirm that you do not have any conflicts of interest or legal impediment which would be likely to interfere with your ability to play a full part on the Board. You must also confirm that you can make yourself available to attend meetings and to carry out the duties of a Board member.