



Appointment to the Board of the Health Products Regulatory Authority

Closing Date: 3pm on Tuesday 8th January 2019.

**State Boards Division
Public Appointments Service
Chapter House, 26 – 30 Abbey Street Upper, Dublin 1**

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State Boards.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. In that regard and in accordance with 13.2 of the Guidelines on Appointments to State Boards, "it is advisable that no member of a State Board should serve more than two full terms of appointment or should hold appointments to more than two State Boards."

The [Code of Practice for the Governance of State Bodies 2016](#) (the Code) 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.

Appointment to the Board of the Health Products Regulatory Authority

Location:	HPRA, Earlsfort Terrace, Dublin 2
Number of Vacancies:	1
Remuneration:	€7,695, (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 statutorily provided for e.g. Worker Directors). Travel and subsistence is payable at appropriate Civil Service rates.
Time Requirements:	6 half day meetings per annum. Up to one day may be needed for preparatory work in advance of each meeting.

Authority members are required to devote as much time to duties on the Authority as is necessary for the proper and efficient discharge of those duties, and to comply with the relevant provisions of the Code of Practice for the Governance of State Bodies. Induction training is provided for new Authority members. The Authority is supported in its work by the Executive of the Health Products Regulatory Authority, acting under the Chief Executive.

Authority members may be appointed by the Minister for Health to the position of Chair of one of the HPRA's Scientific Advisory Committees which meet up to 4 times per annum with each meeting lasting between 1 and 2 hours.

1. Background

The Health Products Regulatory Authority (HPRA) is the regulatory authority responsible for the protection and enhancement of public and animal health by regulating 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 was formerly known as Irish Medicines Board (IMB). In July 2014 the IMB became the HPRA, the new name reflecting the agency's broader remit and expanded regulatory functions.

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 enforce the regulations for which it has responsibility.

2. Functions of the Board

The Authority 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 and Risk 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 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 Authority selects and appoints the Chief Executive, with the consent of the Minister for Health and, through its Performance Review Committee, conducts a process of annual performance appraisal of the Chief Executive.

Further information on the HPRA can be found at www.hpra.ie.

The current membership of the Authority is: -

Name	First Appointed	Reappointed	Expiry Date	Position type	Basis of appointment
Ann Horan	01/01/2011	01/01/2016	31/12/2020	Chair	Nominated and appointed by the Minister for Health following PAS Process
Brian Jones	27/01/2016		26/01/2021	Board Member	Nominated and appointed by the Minister for Health following PAS Process
Catriona O'Driscoll	01/01/2011	01/01/2016	31/12/2020	Board Member	Nominated and appointed by the Minister for Health
David Holohan	27/01/2016		26/01/2021	Board Member	Nominated and appointed by the Minister for Health following PAS Process
Diarmuid Quinlan	22/05/2014		21/05/2019	Board Member	Nominated and appointed by the Minister for Health
Elizabeth Keane	22/05/2014		21/05/2019	Board Member	Nominated and appointed by the Minister for Health
Patrick M. Brangan	22/05/2014	22/05/2017	31/12/2019	Board Member	Nominated and appointed by the Minister for Health
Wilf Higgins	22/05/2014	22/05/2017	31/12/2019	Board Member	Nominated and appointed by the Minister for Health

3. Person Specification

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

Candidates **must** possess:

A third level professional qualification in medicine and significant post qualification clinical medicine experience relating to Clinical Pharmacology and Therapeutics.

In addition, candidates must demonstrate in their application evidence at an appropriately senior level of ideally 2 or more of the following:

- Legislative and/or regulatory experience of pharmaceuticals including requirements for authorisation to access the market and on-going monitoring.
- Experience in clinical trials or pre-clinical studies, quality control, stability, manufacturing or prescribing of pharmaceuticals.
- Experience in a private or public organisation preferably with relevance to delivery of public health related service or role.
- Previous relevant Board or Committee membership
- Experience of commercial decisions and financial oversight

It is desirable that all candidates have experience in the following areas:

- Experience in corporate governance and compliance
- Experience in a regulatory environment
- A demonstrated commitment to public service values and regulation in the public interest;

Candidate's attention is drawn to the provisions of the Code in relation to the role of a Board member, where the principle states:

- Each State body should be headed by an effective Board which is collectively responsible for the long-term sustainability of the body.
- Non-executive Board members should bring an independent judgement to bear on issues of strategy, performance resources, key appointments and standard of conduct.

Details on the role of Board Members can be found in Section 3 of the Code which can be found [here](#).

In order to qualify for appointment a person must not have any conflicts of interest likely to interfere with his/her ability to assume the role of a member of the Board. Please give careful consideration to the possibility of any potential conflict of interest that may exist and address this in your cover letter. The Assessment Panel may decide, based on the perceived level of conflict, not to forward your name for consideration.

NOTE: The HPRA adheres stringently to the Ethics in Public Office Acts, 1995 and 2011. In addition, the IMB Acts 1995 and 2006 have specific provisions which require an annual disclosure of interests by HPRA Authority members, employees and members of advisory committees.

4. 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 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 Authority may at any time be removed from membership 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 Authority of its functions.

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

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

The roles and responsibilities of Authority Members are described in the Code of Practice for the Governance of State Bodies 2016 which is available on the website of the Department of Finance ([Code of Practice for the Governance of State Bodies](#)).

An Authority member shall cease to be a member 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.

5. Submitting your Application

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 exist and address this in your cover letter. The Assessment Panel may decide, based on the perceived level of conflict, not to forward your name for consideration.

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 Authority 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. **Please only include information that is directly relevant to the particular role for which you are applying.**

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

6. Assessment Process

An Assessment Panel (the "Panel") will be convened by PAS to consider and assess the applications 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
 - Meeting¹/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.

Please note that the Public Appointments Service will not be responsible for any expenses incurred by candidates as part of our selection process.

7. 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.

¹ The Public Appointments Service will not be responsible for refunding any expenses incurred by candidates.

8. Data Protection

The Data Protection Act 2018 provides that the processing of personal data shall be lawful where such processing is necessary for the performance of a statutory function of a controller. PAS is mandated by statute under the Public Service Management (Recruitment and Appointments) Act, 2004 to act as the centralised assessment and selection body for the civil service and to carry out all the procedures necessary to undertake the recruitment, assessment and selection of suitable candidates for appointment. By submitting your personal data (including your name, address, contact details and details of your education and work history contained in your curriculum vitae and cover letter) via publicjobs.ie, you acknowledge that such data may be used by the Public Appointments Service and disclosed to and used by client departments, in connection with its statutory roles to assist and advise relevant Ministers in relation to appointments to the boards of State bodies. The information contained in your publicjobs profile is yours to manage, amend, update or delete as appropriate. For more detailed information on our Data Protection Policy, please see our [Code of Practice for the Protection of Personal Data in the Public Appointments Service](#).

If your application is assessed and you are considered to be suitable for appointment your c.v. and cover letter (and any additional supplementary information requested as part of the application process), will be forwarded to the State Board Liaison Officer in the relevant Department. Once it obtains your personal data, the Department will act as data controller of such data and will retain it for up to one year following the appointment/s. Unless you request the withdrawal of your application such data may be used in considering your suitability for other similar vacancies/roles that arise for a period of up to one year for this Board.

APPENDIX 1

Submitting your application:

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.
8. If there is a supplementary question, ensure that your response complies with the word limit and that it does not contain any special characters (i.e. %, & etc) or you may receive an error message and will be unable to submit your application.
9. Click on "continue".
10. 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.
11. 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.