HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Terms of Reference and Rules of Procedure
Health Products Regulatory Authority

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CONTENTS

1 ESTABLISHMENT

1.1 The Health Products Regulatory Authority (hereafter for the purposes of referring to the nine members appointed by the Minister referred to as 'the Authority') is established by Section 3 of the Irish Medicines Board Act, 1995 ('the Act').[1]

1.2 The seal of the Authority is authenticated by the signature of the Chairperson or another member of the Authority authorised by it to act in that behalf, and by the signature of an officer of the Authority authorised by it to act in that behalf.

2 MANDATE

(Statutory)

2.1 The Authority is responsible for the discharge of the functions specified in Section 4 of the Act (see Appendix 1) and any other obligations or responsibilities laid down in primary and secondary legislation.

(Strategic)

2.2 The Authority approves the strategic plan and reviews performance against the plan.

(Reserved functions)

2.3 The Authority takes decisions relating to very significant and serious public and/or animal health matters except in circumstances where a meeting of the Authority cannot be convened, in which case the HPRA Leadership Team takes the decision and informs the Chairperson at the earliest opportunity and the Authority as soon as practical.

2.4 The Authority refuses applications, or suspends, revokes or terminates authorisations as set out in legislation except in circumstances where:

(a) the urgency is such that a meeting of the Authority cannot be convened, or

(b) the application or authorisation is subject to a binding European decision, or

(c) the application or authorisation is for a clinical trial or clinical investigation;

[1] The body was originally established as the Irish Medicines Board ('the Board'); the name was changed to Health Products Regulatory Authority by the Health (Pricing and Supply of Medical Goods) Act 2013.

in which case the HPRA Leadership Team takes the decision and informs the Authority.

2.5 Taking into consideration the recommendations of its Audit and Risk Committee, the Authority approves the internal financial controls and the financial audit function and satisfies itself that the financial controls and systems of risk management are robust and defensible. The Authority appoints the internal auditor.

2.6 The Authority approves the investment policy, major investments, capital projects and the terms of major contracts.

2.7 Significant acquisitions and the disposal or retirement of assets above a threshold set by the Authority are subject to Authority approval.

2.8 The Authority approves treasury policy and risk management policies.

2.9 The Authority approves corporate plans as required.

2.10 The Authority approves significant amendments to the pension benefits of the Chief Executive and staff.

2.11 The Authority approves the annual budget, monitors expenditure and supervises the preparation and submission of the annual statutory accounts.

2.12 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.

2.13 The Authority selects and appoints the Chief Executive, with the consent of the Minister for Health. The terms of office and the remuneration of the Chief Executive are determined by the Minister for Health, after consultation with the Authority and with the consent of the Minister for Finance. The Authority, through its Performance Review Committee, conducts a process of annual performance appraisal of the Chief Executive. Succession planning for the role of Chief Executive is also undertaken by the Authority.

(General)

2.14 The Authority advises and supports the Chairperson, Chief Executive and management.

2.15 The Authority ensures that the procurement rules include competitive tendering for purchases above an approved threshold and ensures compliance with national guidelines and EU directives.

2.16 The Authority approves the Code of Conduct applicable to employees, Authority and committee members and nominated experts.

2.17 The Authority receives assurances from the Chief Executive of compliance with statutory and administrative requirements in relation to the approval of the appointment, number, grading, and conditions of all staff including remuneration and superannuation.

2.18 The Authority ensures that the principles and provisions set out in the Code of Practice for the Governance of State Bodies are adhered to.

2.19 The Authority keeps itself up to date and fully informed about strategic issues and changes affecting the State body and the environment in which it operates.

2.20 The Authority reviews the results of the Authority performance evaluation process that relate to the composition of the Authority and corporate governance generally.

2.21 The Authority keeps under review corporate governance developments (including ethics-related matters) that might affect the State body, with the aim of ensuring that the State body's corporate governance policies and practices continue to be in line with best practice.

2.22 At least once a year, the Authority reviews its own performance, constitution and terms of reference to ensure it is operating at maximum effectiveness and implements any changes it considers necessary.

3 COMPOSITION

3.1 The Authority consists of nine members appointed by the Minister for Health for a period not exceeding five years, which may be extended for up to one further five-year period at the discretion of the Minister.

3.2 If a member resigns, the resignation takes effect from the date on the letter of resignation or the date of receipt by the Minister for Health of the letter, whichever is the later.

3.3 Members of the Authority are paid remuneration and allowances for expenses as approved by the Minister for Health, with the consent of the Minister for Public Expenditure and Reform.

3.4 The Chairperson/members of the Authority are appointed by the Minister for Health, following assessment of their application under a transparent system that is implemented on an independent basis by the Public Appointments Service. Successful candidates must meet the specific and detailed criteria determined by the Minister as necessary for a member of the Authority.

All appointments to the Authority are subject to the arrangements as outlined in the Guidelines on Appointments to State Boards, other than those where vacancies must be filled through a particular process or where a Minister is reappointing an Authority member and where that member has already demonstrated his/her capacity to perform effectively.

4 CHAIRPERSON

4.1 The Chairperson is appointed by the Minister for Health. The term expires upon expiration of the Chairperson's period of membership of the Authority but, if he or she is re-appointed as a member of the Authority, he or she shall be eligible for re-appointment as Chairperson of the Authority.

4.2 If the Chairperson resigns, the resignation takes effect at the start of the next meeting of the Authority after it is informed by the Minister of the resignation.

4.3 The Chairperson is responsible for the efficient conduct of the business of the Authority, in particular by:

- providing an effective leadership to the Authority and giving a strategic direction to the HPRA,
- planning the work of the Authority with the Chief Executive and the Secretary to the Authority,
- monitoring, together with the Secretary to the Authority, that the rules of procedure are respected,
- ensuring that at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the Authority,
- aiming to achieve consensus on issues discussed by the Authority, and
- reporting on the activities of the Authority, as appropriate.

4.4 The Chairperson of the Authority is paid remuneration and allowances for expenses as approved by the Minister for Health, with the consent of the Minister for Public Expenditure and Reform.

5 SECRETARY TO THE AUTHORITY

5.1 The Secretary to the Authority ensures that the Authority receives information and papers in a timely manner to enable full and proper consideration to be given to the issues.

5.2 The Secretary to the Authority is also responsible for the formal induction of new members of the Authority and organising mentoring for Authority members where required.

5.3 The Secretary to the Authority, on behalf of the Authority, ensures that on appointment to the Authority, non-executive Authority members receive a formal letter of appointment setting out clearly what is expected of them in terms of time commitment, committee service and involvement outside Authority meetings.

6 MEETINGS

6.1 Meetings of the Authority are held at least six times a year. Meetings are normally held every two months. The dates of the meetings are agreed on an annual basis by the Authority.

6.2 Meetings of the Authority are organised by the Secretary to the Authority at the request of the Chairperson of the Authority.

6.3 Unless otherwise agreed, confirmation of each meeting outlining the venue, time and date together with an agenda of items to be discussed, is forwarded to each member of the Authority and any other person required to attend a week before the date of the meeting. Supporting papers are sent to Authority members and to other attendees as appropriate, at the same time.

6.4 Only members of the Authority have the right to attend Authority meetings. The Chief Executive attends the meetings of the Authority but is not entitled to vote. Other individuals may be invited to attend for all or part of any meeting, as and when appropriate as necessary.

6.5 Members may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting.

6.6 Meetings are chaired by the Chairperson. In his/her absence, or if the office of the Chairperson is vacant, the members present at the meeting choose a Chairperson from among themselves.

6.7 The Authority may act in the absence of one or more members. Members who cannot attend all or part of a meeting should notify the Secretary to the Authority in advance of the meeting.

6.8 The quorum for meetings is one half of the appointed Authority membership plus one. A duly convened meeting of the Authority at which a quorum is present is competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the Authority.

6.9 Members are expected to attend as near to 100% of meetings as possible. Where a member does not attend Authority meetings for a period of six consecutive months, and following a failure to satisfactorily resolve the matter, the Chairperson will write to the Minister for Health about the member's non-attendance.

6.10 The agenda for the Authority meeting is established by the Chairperson in consultation with the Chief Executive and the Secretary to the Authority and is circulated with related papers in advance of the meeting.

6.11 Each member of the Authority present has one vote. Authority decisions are made by consensus or by a majority of votes of the members present. If there is an equal division of votes, the Chairperson has a casting vote.

6.12 Any other employee of the HPRA or any other person may be invited to attend for particular items of business or sessions of an Authority meeting at the discretion of the Chairperson but they are not entitled to vote.

6.13 The Authority meets at least twice a year without the Chief Executive or management present to discuss any matters deemed relevant.

7 MINUTES OF MEETINGS

7.1 Minutes of each meeting are prepared by the Secretary to the Authority.

7.2 The minutes indicate the names of attendees and in respect of each item on the agenda:

- a summary record of the proceedings,
- the decisions taken or the conclusions reached by the Authority.

7.3 Draft minutes are sent to members before the next meeting. They are adopted at the following meeting and signed by the Chairperson.

8 URGENT DECISIONS

8.1 Between meetings, it may be necessary for the Authority to take urgent decisions for the proper functioning of the HPRA. Urgent decisions may be taken by convening an extraordinary meeting, by telephone, teleconference or videoconference. In each case, the quorum must be reached.

8.2 A full report on the outcome of the urgent business and the decisions taken are presented at the next general meeting of the Authority.

9 COMMITTEES

9.1 The structure of the Authority and the committees is shown in Appendix 2.

9.2 Under Section 9 of the Act, the Minister is empowered to appoint an Advisory Committee on Human Medicines, an Advisory Committee on Veterinary Medicines and an Advisory Committee on Medical Devices to advise the Authority.

9.3 The Authority has established the following committees: Audit and Risk Committee, HPRA Leadership Team and Performance Review Committee.

9.4 The Authority may, from time to time, establish such committees of the Authority as are necessary to assist it in the performance of its duties. They may include members who are not members of the Authority if specialist skills are required. Where a committee is put in place:

- the terms of reference will be specified in writing and approved by the Authority;
- the Authority, on the nomination of the Chairperson, will appoint its members;
- all governance procedures concerning the operation of the Authority will be applied to a committee.

9.5 The Authority may appoint to a committee, other than to an Advisory Committee or to a subcommittee appointed under Section 9 of the Act, persons who have a special knowledge and experience related to the purpose of the committee. The appointment of a person to a committee is subject to such terms and conditions as the committee may determine.

9.6 The Authority may at any time dissolve a committee, other than an Advisory Committee or a subcommittee appointed under Section 9 of the Act.

9.7 The decisions of a committee, other than an Advisory Committee or subcommittee appointed under Section 9 of the Act, are subject to confirmation by the Authority unless the Authority dispenses with the necessity for confirmation.

9.8 The Authority may regulate the procedure of committees other than an Advisory Committee or subcommittee appointed under Section 9 of the Act, but, subject to any such regulation, committees may regulate their own procedure.

9.9 Reports on the proceedings of the committees are submitted to the Authority.

10 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

10.1 The names of the Authority members and their professional qualifications are made public.

10.2 Members of the Authority will make an annual declaration of financial or other beneficiary interest in any industry regulated by the HPRA, and will make a declaration under the Ethics in Public Office Act.

10.3 At each meeting, members will declare any financial or other beneficiary interest in any agenda item. When a member is unable to participate in a meeting due to a conflict of interest, he or she must inform the Secretary to the Authority in advance of the meeting in writing. The member will withdraw from the meeting while the item is considered and will not vote or act as a member in relation to it.

10.4 Members of the Authority will abide by the HPRA's Code of Conduct.

10.5 Members of the Authority are required not to disclose information received by them while performing their duties, even after their duties have ceased.

11 DEVOLVED FUNCTIONS

(Chief Executive)

11.1 The Chief Executive is appointed by the Authority to manage and control the administration and business of the Authority. The Authority acts through, and certain of its functions are performed in its name by, the Chief Executive or other officer of the Authority duly authorised by the Chief Executive.

11.2 The Chief Executive is appointed by the Authority:

a) to appoint persons to be authorised officers, and
b) to furnish each authorised officer so appointed with a warrant of authorisation;

in accordance with the requirements of regulations made under the Irish Medicines Board Act, 1995, the European Communities Act, 1972 or the Misuse of Drugs Act 1977.

(HPRA Leadership Team)

11.3 The HPRA Leadership Team is responsible for carrying out the competent authority functions for the regulation of medicinal products for human use, clinical trials on medicinal products for human and veterinary use, clinical investigations, medicinal products for veterinary use, medical devices, blood and blood components, tissues and cells, human organs, cosmetics, controlled drugs, drug precursors and protection of animals used for scientific purposes as set out in the legislation listed at http://www.hpra.ie/homepage/about-us/legislation, other than functions reserved by the Authority.

11.4 Subject to 11.5 below, save for clinical trials on human medicines, clinical investigations on medical devices, and cases relating to scientific animal protection, the HPRA Leadership Team, on proposals to refuse, requests the advice of the Advisory Committee for Human Medicines, the Advisory Committee for Veterinary Medicines or the Advisory Committee for Medical Devices, as appropriate.

11.5 In cases of an urgent public and/or animal health matter of a serious or significant nature, the HPRA Leadership Team takes decisions, including suspensions and urgent suspensions, on public and/or animal health matters where the urgency is such that the Authority cannot be convened. The Chairperson is informed of the decisions at the earliest opportunity and the Authority as soon as practical.

11.6 The HPRA Leadership Team approves decisions to prosecute an offence through the courts or to refer it to the Director of Public Prosecutions.

12 AUTHORISATION

12.1 The Authority is authorised to obtain, at the HPRA's expense, outside legal or other professional advice where they judge it necessary to discharge their responsibilities as Authority members.

12.2 The Authority is authorised to seek the information it requires from the HPRA to perform its duties.

13 REPORTING RESPONSIBILITIES

13.1 The Authority keeps the Minister of the parent Department informed of matters arising within the State body.

14 GENERAL PROVISIONS

14.1 These terms of reference and rules of procedure are adopted by the Authority and are made public.

14.2 These terms of reference and rules of procedure are to be read as standing orders in accordance with Section 8(8) of the Act.

APPENDIX 1 PRINCIPAL FUNCTIONS OF THE AUTHORITY

Section 4 of the Irish Medicines Board Act 1995, as amended.

a) The licensing of the manufacture, preparation, importation, distribution and sale of medicinal products,

b) To exercise the powers conferred on the competent authority by Directive No. 2001/83/EC of 6 November 2001[2], other than the powers conferred by Article 5.3 of the said Directive,

c) To exercise the powers conferred on the supervisory authority by Regulation (EC) No. 726/2004 of 31 March 2004[3],

d) To exercise the powers conferred on the competent authority by Directive 2001/82/EC of 6 November 2001[4],

e) To exercise the powers specified in the Control of Clinical Trials Acts, 1987 and 1990, and conferred on the Board[5] by section 35 of the Act,

f) To establish and administer a service for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products,

g) To establish and administer a service for obtaining and assessing reports on any adverse effects of medicinal products in use in the State,

h) To advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which medicinal products may be marketed or continued in use in the State,

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[2] Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use.

[3] Regulation (EC) No. 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[4] Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products.

[5] Renamed as the Health Products Regulatory Authority by the Health (Pricing and Supply of Medical Goods) Act 2013.

i) To arrange for the collection and dissemination of information relating to medicinal products including, in particular, information concerning the pharmacological classification and the therapeutic efficacy of such products,

j) To furnish, whenever it is so requested by the Minister, advice to the Minister in relation to the licensing of the manufacture, importation, distribution and sale of medicinal products and in relation to the standards of manufacturing practice (including quality control) of medicinal products,

k) To establish and administer a service:

- for the receipt of applications from persons proposing to export any description of medicinal products, cosmetic products, veterinary medicinal products or medical devices

- for the issue to such persons of certificates containing any statement relating to such description of such products or devices as the Board considers appropriate after having regard to:

    - the law (whether under any enactment or rule of law or otherwise) in the State which is for the time being applicable to such description of such products or devices, and
    - the law (whether under any enactment or rule of law or otherwise) in the place to which such description of such products or devices is to be exported which is for the time being applicable to such description of such products or devices,

l) To establish and administer a service for the inspection of any service for the collection, screening, processing and quality control facilities and procedures in respect of human blood, blood components, blood products and plasma derivatives for the purpose of ensuring the safety and quality of blood, blood components, blood products and plasma derivatives and to advise the Minister in relation to such general or particular matters arising out of the administration of such a service as the Minister may refer to the Board,

m) If so requested, to advise the Minister or others concerned on such matters relating to medical devices as may be referred to it and are connected with the functions or activities of, or the services provided by the Board,

n) To furnish, whenever it so thinks fit or is so requested by the Minister, advice to the Minister in relation to any matter connected with the functions or activities of, or the services provided by, the Board,

o) To exercise the powers conferred on the competent authority by Council Directive 98/79/EC of the 27th October, 1998[6] and the European Communities (*In Vitro* Diagnostic Medical Devices) Regulations, 2001,

p) To exercise the powers conferred on the competent authority by Council Directive 90/385/EEC of 20 June 1990[7] and the European Communities (Active Implantable Medical Devices) Regulations, 1994 (S.I. No. 253 of 1994) and Council Directive 93/42/EEC of 14 June 1993[8] and the European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252 of 1994),

q) To exercise, subject to subsection (5), the powers specified in section 14(1) of the Misuse of Drugs Act 1977 (as amended by section 7 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006)[9],

r) The authorisation of persons under section 24 of the Misuse of Drugs Act 1977 (as amended by section 9 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006),

s) To exercise the powers conferred on the competent authority by Directive 2001/20/EC of 4 April 2001[10],

t) To exercise the powers conferred on the competent authority by Council Directive 76/768/EEC[11] of 27 July 1976, Commission Directive 95/17/EC of 19 June 1995 and the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004),

u) To exercise the powers conferred on the competent authority by Directive 2004/23/EC of 31 March 2004[12],

v) To exercise the powers conferred on the competent authority and the authority responsible for notified bodies by Regulation (EU) 2017/745 of the European Parliament

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[6] Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices.
[7] Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.
[8] Directive 93/42/EEC of 14 June 1993 concerning medical devices.
[9] To be commenced
[10] Directive 2001/20/EC of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
[11] Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.
[12] Directive 2004/23/EC of 31 March 2004 on setting the standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

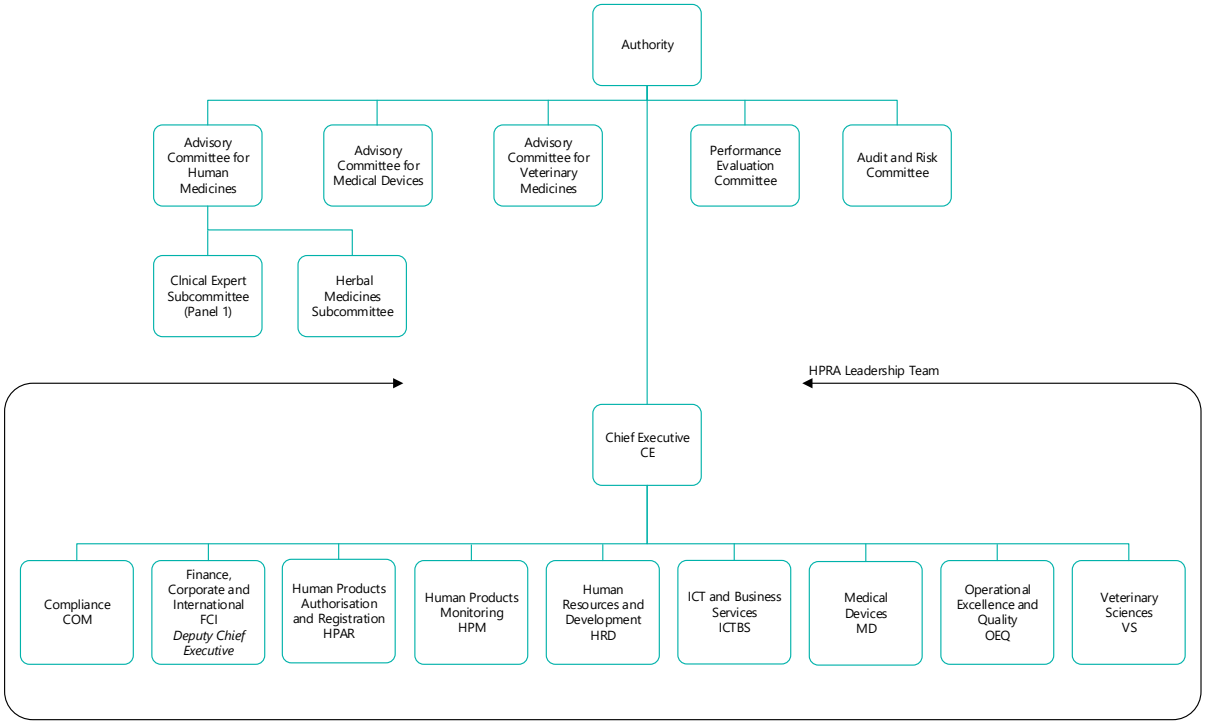
and of the Council of 5 April 2017[13] and carry out the functions conferred on the Authority under Regulation 3(3)(a) of the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017),

w) To exercise the powers conferred on the competent authority and the authority responsible for notified bodies by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[14] and carry out the functions conferred on the Authority under Regulation 3(3)(b) of the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017),

x) To perform such other functions as are conferred on the Board by this or any other enactment (including any statutory instrument made thereunder).

[13] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
[14] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

APPENDIX 2 STRUCTURE OF THE AUTHORITY, COMMITTEES AND DEPARTMENTS



APPENDIX 3 ACQUISITION OF LAND, BUILDINGS OR OTHER MATERIAL ASSETS

In addition to the requirements set out in Department of Public Expenditure and Reform circulars, as amended from time to time, the following procedures will apply:

(i) Independent valuation: Where land or property is being considered for acquisition an independent valuation will be obtained. These valuations will be obtained before any decision is taken by the Authority to purchase or sell lands. The valuations will be obtained from professional property valuation surveyors.

(ii) Listing of parties to transaction: All parties to land and property transactions will be clearly reported to the Authority when transactions are being considered. Any Authority resolution related to the purchase of land or property will state the party or parties the asset is being purchased from.

(iii) Options by others to purchase: Where a third party developer has obtained an option to purchase land and is selling this option to the HPRA, any profit margin, where it can be determined, being charged by the developer will be reported to the Authority.