

Company Number: 01400379

THE COMPANIES ACTS 1985, 1989 and 2006

**COMPANY LIMITED BY GUARANTEE AND
NOT HAVING A SHARE CAPITAL**

ARTICLES OF ASSOCIATION

OF

**THE ORGANISATION FOR PROFESSIONALS IN
REGULATORY AFFAIRS (TOPRA) LIMITED**

Adopted by Special Resolution this 7th day of October 2009

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1. INTERPRETATION

1.1 In these Articles;

“the **Act**” means the Companies Acts 1985, 1989 and 2006 and any statutory modifications or re-enactments thereof for the time being in force;

“**Annual Review**” shall have the meaning given in Article 10;

“the **Articles**” means these Articles of Association;

“the **Board**” means the board of management of the Company;

the “**Council**” shall have the meaning given in Article 9.3;

“the **Directors**” means the directors of the Company appointed pursuant to the Act;

the “**Executive**” shall have the meaning given in Article 6.1.2;

“**Fellow**” shall have the meaning given in Article 3.2.3;

“**Honorary Life Member**” shall have the meaning given in Article 3.2.4;

the “**Immediate Past-President**” shall have the meaning given in Article 6.2;

“**Member**” means the person or persons whose names are for the time being entered on the Register of Members and, prior to such registration, means the persons who subscribed to the Company’s Memorandum and “**Members**” and “**membership**” shall be construed accordingly;

“the **Memorandum**” means the Memorandum of Association;

“**Officers**” means the Immediate Past-President, President and President Elect;

“**Registered Member**” shall have the meaning given in Article 3.2.2;

the “**President**” means the person elected pursuant to Article 6.2;

the “**President Elect**” shall have the meaning given in Article 6.2;

“**Student Member**” means any Member who (i) is in full time education; (ii) has completed full time education no more than one calendar year previously and has not commenced employment in regulatory affairs; or (iii) is unemployed.

1.2 Words expressing the masculine gender only shall include the feminine gender (and vice versa) and words in the singular include the plural (and vice versa).

1.3 Subject as aforesaid or unless the context otherwise requires, words or expressions contained in the Articles shall bear the same meaning as in the Act.

1.4 Expressions referring to writing shall, unless the contrary intention appears, be construed as including references to printing, lithography, photography and other modes of representing or reproducing words in a visible form, including printed copies of communications by facsimile and email.

1.5 Expressions referring to electronic communications shall mean the same as in the Electronic Communications Act 2000.

2. **OBJECTS**

2.1 The Company is established for the purposes expressed in the Memorandum.

2.2 The Company is to be a private company.

3. **MEMBERSHIP**

3.1 The subscribers to the Memorandum and such other persons as shall be admitted to membership shall become Members of the Company.

3.2 Members shall be admitted as Members, Registered Members and Fellows in accordance with the following provisions:

3.2.1 a Member shall be any person who is involved in or has an interest in healthcare regulatory affairs;

3.2.2 a Registered Member shall be any Member who shall certify in writing on an annual basis that he has at least two years’ full-time experience in regulatory affairs, holds a degree or equivalent qualification in a relevant discipline from a recognised educational establishment, is currently engaged in the field of regulatory affairs and is taking reasonable steps to remain up to date in the field of regulatory affairs;

- 3.2.3 a Fellow shall be a Member with at least ten years' experience in regulatory affairs, holding a responsible position in his employing company and who has made a significant contribution to the Company and/or the regulatory affairs profession, as assessed by the Board or those nominated by the Board so to do;
- 3.2.4 the Board may in its absolute discretion admit Honorary Life Members and Student Members, who may or may not be otherwise qualified for admission as Members or Fellows.
- 3.3 The Board shall cause a register to be kept of all Members respectively with their addresses together with such other records of membership as may be deemed necessary or are required by law. Every Member shall either sign a written consent to become a Member or by submission of an electronic application signifying his/her willingness to become a member or sign the Register of Members.
- 3.4 Except as otherwise provided herein, Members shall enjoy such rights and privileges and be under such obligations as the Board shall from time to time determine, in its absolute discretion.

4. ADMISSION OF MEMBERS

- 4.1 Application for membership shall be made to the Company in the manner prescribed at the time, showing full particulars of the qualification of the applicant for membership together with written undertakings signed on behalf of the applicant (i) to abide by the Articles and other regulations of the Company from time to time in force and (ii) to treat as confidential any documents so marked issued by the Company.
- 4.2 The Board may make such enquiry as it may deem necessary or desirable in order to determine the suitability of the applicant for membership.
- 4.3 The Board shall have full power and authority to refuse an application for membership without giving any reason for its refusal.

5. RESIGNATION, EXCLUSION AND SUSPENSION OF MEMBERS

- 5.1 Membership shall cease:
 - 5.1.1 at the end of a period of two calendar months after the receipt by the Company of written notice from the Member of his intention to resign from membership;
 - 5.1.2 at the end of a period of one calendar month following the issue of a final request for membership subscription if the subscription has not been received or notice of intent to pay has not been received;
 - 5.1.3 if the Member ceases to hold the qualification rendering him eligible for membership under Article 3 above; a Registered Member who fails to complete the annual declaration of education and experience will become a Member for the duration of the next calendar year;
 - 5.1.4 if, at a meeting of the Board, a resolution be passed by not less than two-thirds of the members of the Board present and voting that it is undesirable that such Member shall remain a Member. No such resolution shall become effective

5.2 Membership shall be suspended if at a meeting of the Board a resolution to that effect be passed by not less than two-thirds of the members of the Board present and voting. Such suspension shall be for a period not exceeding two years and be subject to such conditions as to the payment of subscriptions and other matters as the Board shall determine in its absolute discretion. No such resolution shall become effective unless the said Member has had an opportunity of being represented at the meeting in order to state his case and answer any allegation or allegations made against him.

6. **THE BOARD**

6.1 The management board of the Company (the “**Board**”) shall comprise of a maximum of 12 members as follows:

6.1.1 The “**Officers**”, being:

- (a) The President;
- (b) The President-Elect;
- (c) The Immediate Past-President; and

6.1.2 The “**Executive**”, being:

- (a) one member to represent the EU region and one member to represent the North America region
- (b) four other members

6.1.3 Each member of the Board shall be appointed a Director of the Company while holding that position.

6.2 The “**President-Elect**” shall be elected annually from among the Members, Registered Members and Fellows and shall, at the end of his year of office, be eligible to be elected as “**President**” for the following one year term and thereafter as “**Immediate Past-President**” for the next following one year term. He will be eligible for re-election as President-Elect if a period of twelve months has elapsed since he retired from the office of Immediate Past-President.

6.3 Any casual vacancy amongst the Officers shall be filled by the appointment by the Board to that office of any member of the Board or in event of no member of the Board being willing so to act from amongst the Members, Registered Members and Fellows. Such appointment will be held until the end of the term being served.

6.4 The Executive members will be elected for a term of two years from among the Members, Registered Members and Fellows of the Company. At the end of his period of office, a member of the Executive shall be eligible for re-election provided that he has not previously been elected for two successive two-year terms of office in that capacity.

- 6.5 A casual vacancy in the Executive may be filled by appointment by the Board to that office of any Member, Registered Member or Fellow, subject to the criteria laid out below. Such appointment will be held until the end of the term being served.
- 6.6 In order to ensure adequate representation of geographical, sectoral or business interests on the Board, the Board may from time to time appoint up to three additional co-opted members to the Executive, from any Member, Registered Member or Fellow, for a term of one year, and the re-appointment at the end of such term may be renewed by the Board.
- 6.7 The Board may continue to act although its number is reduced below the number of 7 only for the purpose of filling up vacancies until there are at least 7 members of the Board.
- 6.8 Notwithstanding the above, the total number of positions on the Board shall not exceed 12 persons.
- 6.9 A member of the Board shall cease to hold office:
- 6.9.1 if he becomes bankrupt or makes any arrangement or composition with his creditors generally; or
 - 6.9.2 if he becomes incapable by reason of mental disease, illness or injury managing and administering his property and affairs.
 - 6.9.3 if his resignation as a member of the Board is accepted by the Board; or
 - 6.9.4 if at a meeting of the Board which he has had an opportunity of attending in order to state his case and answer any allegation or allegations made against him a resolution be passed by not less than two-thirds of the members of the Board present and voting that it is undesirable that he shall remain a member of the Board.

7. POWERS AND DUTIES OF THE BOARD

- 7.1 The business of the Company shall be managed by the Board which may exercise all the powers, authorities and discretions of the Company in general meeting subject nevertheless to the provisions of the Act, the Memorandum and the Articles.
- 7.2 The Board may make from time to time and at any time such rules or bye-laws not inconsistent with the Memorandum and Articles as it considers to be in the best interests of the Company, subject always to any extension, modification or repeal thereof resolved to be made by the Members in general meeting, and such rules or bye-laws shall be deemed not to form part of the Articles and shall be construed separately from the Articles except as such rules or by-laws may provide to the contrary but nevertheless shall be binding on the Members and the Board as therein provided.
- 7.3 The Board shall have absolute discretion in the admission, suspension and expulsion of Members.

- 7.4 The Board shall, on behalf of the Members, appoint or authorise the appointment of such staff as it considers appropriate and may determine their duties and conditions of service.
- 7.5 The Board shall cause minutes to be made:
- 7.5.1 of all the appointments of Officers;
 - 7.5.2 of the names of the members of the Board present at each meeting of the Board and any committee thereof; and
 - 7.5.3 of all resolutions, proceedings and business at all meetings of the Company and of the Board and of any committee.

8. **PROCEEDINGS OF THE BOARD**

- 8.1 The Board may meet together for the despatch of business, adjourn, and otherwise regulate its meetings, as it thinks fit. Questions arising at any meeting of the Board shall be decided by a majority of votes. In the case of an equality of votes the President (or, in his absence, the person elected for the purpose in accordance with Article 8.3 below) shall have a second or casting vote. Three members of the Board may at any time summon a meeting of the Board.
- 8.2 The quorum necessary for the transaction of the business of the Board may be fixed by the Board, and unless so fixed shall be, and in any case, shall never be less than the majority of Directors appointed from time to time.
- 8.3 The President shall act as chair at all meetings of the Board at which the President shall be present, but in the absence thereof, the Board shall elect another person to act as chair for that meeting.
- 8.4 All acts bona fide done by any meeting of the Board or of any committee, or by any person acting as a member of the Board shall, notwithstanding it be afterwards discovered that there was some defect in the appointment or continuance in office of any such member or person acting as aforesaid, or that any such member, or any of them, were disqualified, be as valid as if every such person had been duly appointed or had duly continued in office and was qualified to be a member of the Board.
- 8.5 A resolution in writing signed by all the members for the time being of the Board or of any committee of the Board who are entitled to receive notice of a meeting of the Board or of such committee shall be as valid and effectual as if it had been passed at a meeting of the Board or of such committee duly convened and constituted.
- 8.6 A meeting of the Board or any committee of the Board may consist of a conference between members of the Board who are not all in one place but at which each is able (directly or by telephonic communication) to speak to each of the others and to be heard by each of the others simultaneously. A member of the Board taking part in such conference shall be deemed to be present in person at the meeting and shall be entitled to vote or be counted in the quorum accordingly and entitled to vote on matters whilst in such communication. Such a meeting shall be deemed to take place where the largest group of those participating in the conference is assembled, or if

9. COMMITTEES

- 9.1 The Board may appoint committees, task forces and other groups for such objects or purposes and with such powers and duties as it may prescribe.
- 9.2 All committees shall go out of office at the expiration of 60 days after the Annual Review meeting in each calendar year but any or all of the committees may be reconstituted or re-appointed in the absolute discretion of the Board.
- 9.3 The Board will consider nominations from the Members and Fellows for members of an advisory Council of no more than 25 persons including the Officers. Appointments to the Council will be at the absolute discretion of the Board. Members of the Council, other than the Officers, will not be Directors of the Company.

10. GENERAL MEETINGS

- 10.1 The Company shall hold at least one general meeting in each calendar year, which shall be the “**Annual Review**”. Not more than 15 months shall elapse between the date of one Annual Review and that of the next but otherwise it shall be held at such time and place as the Board shall appoint.
- 10.2 The business of the Annual Review shall be the presentation of the Company’s financial results for the previous financial year and the presentation of the new Board to the Members.
- 10.3 In addition, an extraordinary general meeting may at any time be called by direction of (i) the President or (ii) the Board or (iii) the Executive members, and shall be called upon a request in writing to the Board signed on behalf of at least 25 Members for the discussion of any special subject or subjects (including the removal of any member(s) from the Board) of which notice shall be given by those who desire that the meeting shall be called. No business shall be transacted at an extraordinary general meeting save such as is specified in the notice of it given to Members.
- 10.4 At all extraordinary general meetings 30 Members and/or Registered Members and/or Fellows (attending in person or by proxy) shall form a quorum.

11. NOTICES OF GENERAL MEETINGS

- 11.1 The Company shall give all Members and Fellows not less than 14 clear days’ notice of all general meetings and each such notice shall be accompanied by an agenda of the business to be transacted at such general meeting. If necessary, a supplementary agenda may be sent not less than three days before the general meeting. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given.
- 11.2 The notice shall be given, in manner hereinafter mentioned or in such other manner, if any, as may be prescribed by the Company in general meeting, to all the Members, to the members of the Board provided always that any general meeting of the Company shall, notwithstanding that it is called by shorter notice than that specified in this

the general meeting of the Company to be held on the _____ day of
20____, and at any adjournment thereof.

Signed this _____ day of _____ 20____.”

This form is to be used in [favour of]* [against]* the resolution.

Unless otherwise instructed, the proxy will vote as he thinks fit.

*Strike out whichever is not desired.”

- 12.5 The instrument appointing a proxy shall be deemed to confer authority to demand or join in demanding a poll.
- 12.6 A vote given in accordance with the terms of an instrument of proxy shall be valid notwithstanding the previous death or insanity of the principal or revocation of the proxy or of the authority under which the proxy was executed, provided that no intimation in writing of such death, insanity or revocation as aforesaid shall have been received by the Secretary before the commencement of the meeting or adjourned meeting at which the proxy is used.
- 12.7 Voting at all meetings shall be by show of hands or ballot in the absolute discretion of the President (or chairman elected for the purpose in the absence of the President), and all motions shall, subject to any exceptions set out in these Articles and any requirements of the Act, be determined by a majority of those present who are qualified to vote except that any change to the Company’s memorandum or articles of association must be determined by no less than three quarters of those who are present and qualified to vote. The President (or the chairman elected for the purpose in the absence of the President) shall have an original and also a casting vote.
- 12.8 Upon any question being declared carried by a majority of those present, any three of the Members in the minority may demand a secret ballot of all Members qualified to vote on the said question. If a secret ballot is demanded as aforesaid, it shall be taken in such manner and at such time within 14 days and at such place as the President (or the President elected for the purpose in the absence of the President) directs and either at once or after any interval or adjournment or otherwise and the result of the secret ballot shall be deemed to be the resolution of the meeting at which the secret ballot was demanded.
- 12.9 The Board may from time to time by a simple majority resolve that its decisions relating to matters of business specified in such resolution shall require to be passed by the special majority thereby specified and any such resolution of the Board shall not be amended, modified, suspended or rescinded by the Board save by the like special majority.
- 12.10 Any decision that is required to be taken in an extraordinary general meeting may be passed by a written resolution in accordance with the Act and that decision will be as valid and effectual as if passed by the Company in an extraordinary general meeting.

13. ACCOUNTS

- 13.1 The Company shall cause accounting records to be kept in accordance with the Act. Such records shall be kept at the registered office or, subject to the provisions of the Act, at such other place or places as the Board thinks fit and shall always be open to the inspection of the Officers and the Board.
- 13.2 The Board shall from time to time determine whether and to what extent and at what times and places and under what conditions or regulations the accounts and books of the Company or any of them shall be open to the inspection of Members and no such Member shall have any right to inspect any accounts or book or document of the Company except as conferred by the Act or authorised by the Board or the Company in general meeting.
- 13.3 The Board shall, from time to time, cause to be prepared and laid before the Company in general meeting such statements of accounts and reports as are required by the Act.
- 13.4 A copy of every statement of accounts (including every document required by law to be annexed to it) which is to be laid before the Company in general meeting and the report of the Board shall, not less than 21 days before the date of the meeting, be sent to every Member and every person entitled to receive notice of general meetings or made available for every member to view e.g. on the web site.
- 13.5 The Company shall comply with all obligations for the examination or audit of accounts and the appointment of auditors (where required) pursuant to the provisions of the Act.

14. NOTICES

- 14.1 Any notice to be given to or by any person pursuant to these Articles (other than a notice calling a meeting of the Board) shall be in writing or shall be given using electronic communications to an address for the time being notified for that purpose to the person giving the notice. In this Article, “address” in relation to electronic communications, includes any number or address used for the purposes of such communications.
- 14.2 A Member present, either in person or by proxy, at any meeting of the Company shall be deemed to have received notice of the meeting and of the purposes for which it was called.
- 14.3 Proof that an envelope containing a notice was properly addressed to the last address provided to the Company, prepaid and posted shall be conclusive evidence that the notice was given. Proof that a notice contained in an electronic communication was sent in accordance with guidance issued by the Institute of Chartered Secretaries and Administrators shall be conclusive evidence that the notice was given. A notice shall be deemed to be given at the expiration of 48 hours after the envelope containing it was posted or in the case of a notice contained in an electronic communication, at the expiration of 48 hours after the time it was sent.

15. **DISSOLUTION**

- 15.1 Clauses 7 and 8 of the Memorandum relating to the winding up and dissolution of the Company shall have effect as if the provisions thereof were repeated in these Articles.

16. **INTERESTS OF MEMBERS OF THE BOARD**

- 16.1 Subject to the provisions of the Act, and provided that he has disclosed to the Board the nature and extent of any material interest of his, a member of the Board notwithstanding his office:

16.1.1 may be a party to, or otherwise interested in, any transaction or arrangement with the Company or in which the Company is otherwise interested;

16.1.2 may be a director or other officer of, or employed by, or a party to any transaction or arrangement with, or otherwise interested in, any body corporate promoted by the Company or in which the Company is otherwise interested; and

16.1.3 shall not, by reason of his office, be accountable to the Company for any benefit which he derives from any such office or employment or from any such transaction or arrangement or from any interest in any such body corporate and no such transaction or arrangement shall be liable to be avoided on the ground of any such interest or benefit.

- 16.2 For the purposes of Article 16.1 above:

16.2.1 a general notice given to the Board that a member of the Board is to be regarded as having an interest of the nature and extent specified in the notice in any transaction or arrangement in which a specified person or class of persons is interested shall be deemed to be a disclosure that the member of the Board has an interest in any such transaction of the nature and extent so specified; and

16.2.2 an interest of which a member of the Board has no knowledge and of which it is unreasonable to expect him to have knowledge shall not be treated as an interest of his.

17. **AFFILIATED BODIES**

- 17.1 The Board shall have power to affiliate with any other organised body or bodies having objects which are in the interests of the Company upon such terms and conditions as may be agreed upon by the Board and the governing authority of the other body or bodies.

18. **INDEMNIFICATION**

- 18.1 The Company shall indemnify out of the assets of the Company all members of the Board all members of any committee or task force, employees of the Company and all others acting on behalf of the Company whether paid or unpaid in respect of all actions, claims and damages whatsoever made against them either alone or jointly with others in respect of any act, thing or matter lawfully done or omitted to be done

18.2 Article 18 shall only have effect in so far as its provisions are not avoided by Section 232 of the Companies Act 2006.

19. **COMMUNICATIONS BY MEANS OF WEBSITE**

19.1 Subject to the provisions of the Act, a document or information may be sent or supplied by the Company to a person by being made available on the Company's website.