



**FUNDAMENTAL RULE OF HUNGARIAN REGULATORY AFFAIRS SOCIETY**

Developed on 28<sup>th</sup> of January, 2000

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Revised on 22<sup>nd</sup> of May, 2006.



## FOREWORD

We, the undersigned, namely the members of the Hungarian Regulatory Affairs Society (hereinafter referred to as Association) registered into the court registry of social organizations under reference number 9013 by Decision No. 14.Pk.60160/2000/2 of the Budapest Court (Fővárosi Bíróság), have decided to accept the new, revised fundamental rules of the Association dated year 2000, on the basis of the minutes taken during the General Meeting held on 22 February, 2006, and by maintaining legal continuity.

## I. GENERAL PROVISIONS

- (1) Hungarian Name of Association: **Magyarországi Gyógyszertörzskönyvezők Társasága**
- (2) The Hungarian abbreviation of Association: **MAGYOTT**
- (3) English Name of Association: **Hungarian Regulatory Affairs Society**
- (4) English abbreviation of Association: **HURAS**
- The Head Office of Association: H-1112 Péterhegyi lejtő 8. I.em. 3 sz.
- Telephone number: (+36) 30-3435052
- Working language of Association: Hungarian

## II. AIM AND FUNCTION OF ASSOCIATION

The function of Association is extended to entire territory of the Republic of Hungary.

The Association is the first, voluntarily established, self-governing organization set up in Hungary for regulatory professionals involved in the registration of human medicinal products. It is established for the purposes defined in the Statutes, has a registered membership, and organises and co-ordinates the activities of its members in order to achieve the declared purposes.

The Association is a legal entity.

The Association strives to achieve the following aims:

- To establish and maintain – in observance of applicable law – the first non-profit, non-political organization in Hungary as a professional forum competent in issues related to the registration and regulation of medicinal products for human use.
- To foster the recognition of drug registration as an independent professional discipline of applied sciences in Hungary; as well as to advance and support the integration of the science of drug registration into graduate and postgraduate education.
- Furthermore to provide a framework of continuous education and training for adequately qualified professionals working in the pharmaceutical industry or drug registration field.
- As a result of foregoing to increase the appreciation and professional prestige for the members of Association and to guarantee the highest professional standards in course of their professional activities.



- To establish and maintain professional contacts with other European Drug Regulatory Authorities for a better recognition and understanding of the European Regulatory System and requirements

*Regular functions:*

- Organization of meetings and professional conferences for specialists dealing with questions of drug registration and regulation (establishment of expert panels, organization and support of further training courses).
- Organization of an annual HURAS Congress.
- Regular publication of the newsletter "HURAS Híradó" (HURAS News), creation and maintain of a "HURAS web site" on the Internet.
- Maintenance of regular relationships with foreign drug regulatory Associations (e.g. TOPRA, MEGRA, etc.).
- The establishment of operational, constructive working relationships and contacts network with the competent Hungarian drug regulatory and legislative Authorities (e.g. National Institute of Pharmacy, Ministry of Health, National Center for Epidemiology).
- Upon request or own initiative and following a consultation with members, providing opinions and proposals related to the establishment and amendments of decisions, concepts, legal regulations, standpoints, etc. related to its field of specialty.

The Association does not represent any company interests.

Being a voluntary, non-profit organization, enterprising is not considered among the primary functions of the Association.

The descriptions of internal procedures, purchasing and accounting protocols are set out in the „*Standard Operating Regulations*” compiled by the Association’s Governing Body and adopted by the Association’s General Assembly.

### III. MEMBERSHIP IN THE ASSOCIATION

The ordinary members of the Association are all those Hungarian or foreign natural persons who accept the Association's objectives, meet the requirements of membership, and gain admittance to the Association.

The member list of HURAS is the property of the Association. It cannot be transferred to third parties or sold.

Membership requirements:

1. Working in the area of pharmaceutical regulatory affairs or being a professional related to or interested in regulatory affairs
2. Payment of annual membership fees.

Supporting member status is open to all those natural or legal persons who contribute to the realisation of the Association's objectives, principally through financial assistance.

Honorary member status may be awarded to persons with outstanding achievements in the field of drug registration who can promote the aims of the Association by their contribution to professional values.



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Supporting member or honorary member status may only be awarded on the recommendation of the Governing Body.

Admittance of ordinary members — upon written application — is within the jurisdiction of the Governing Body, whereas admittance of supporting and honorary members — upon recommendation from the Governing Body — is within the jurisdiction of the General Assembly.

With the acceptance of the application, the members agree and promise to support the aims of the Association and to pay the membership fees fixed by the General Assembly.

The General Assembly determines the membership fees annually. For the year 2008, membership fee shall amount to HUF 7,500. The obligation to pay the membership fee may be waived by the Governing Body for considerations of fairness upon written application not more than once for each member.

**Rights of members:**

- a) All ordinary members are entitled to participate in the General Assembly of the Association and to vote there. Each ordinary member has one vote.
- b) Only ordinary members may participate in and are eligible for elections.
- c) They are entitled to participate and vote in the General Assembly and other events organised by the Association,
- d) elect the Association's officials directly,
- e) make proposals or suggestions to any of the Association's organs,
- f) receive certain privileges at the Association's events.
- g) Supporting and honorary members have no right to vote, may not participate in or be eligible for elections.
- h) Honorary members may participate in the activities of the Association in a consultative capacity.
- i) Supporting members may attend the annual General Assembly as observers.

**Obligations of members:**

Obligations of ordinary members:

- a) Respect of the Statutes of the Association;
- b) Active participation in the activities of the Association;
- c) Payment of membership fees by April 30 each year with the exception of retired individuals or members on child-nursing leave who will be granted an exemption from the payment of their membership fees upon submitting a request for exemption.

**Membership is terminated as follows:**

- a) upon member's death;
- b) by resignation, which may only take effect as of the end of a given month/year upon written notice to the Governing Body;
- c) by exclusion upon a resolution of the General Assembly if the member acts in violation of the interests of the Association, or fails to pay his membership fees for a whole year — following notice and in the absence of any application for the waiver of such fees.



#### IV. THE ORGANIZATION OF THE ASSOCIATION

The Association's organs are as follows:

- the General Assembly;
- the Governing Body;
- the Auditors; and
- the Committees.

##### **The General Assembly:**

The Association's supreme organ is the General Assembly.

The General Assembly consists of the totality of the membership, and has jurisdiction over all matters concerning the Association.

The General Assembly has exclusive **jurisdiction** over the following:

- drafting, adoption, or amendment of the Statutes;
- election of the Governing Body;
- election of the Chairpersons of the Committees;
- election of the two Auditors;
- determination of the budget, and acceptance of the report on the use of the Association's assets;
- acceptance of the report on the work of the Governing Body, and determination of the tasks and objectives for the following period;
- determination of the membership fee;
- admittance of supporting and honorary members; exclusion of members — subject to consent from the Governing Body;
- acceptance or modification of the "*Standard Operating Regulations*" of the Association;
- decisions on the termination of the Association or its fusion with another civil organisation, and decisions on assets.

##### **Convocation** of the General Assembly:

- the regular General Assembly shall be convened not less than once a year;
- an extraordinary General Assembly shall be called if not less than one third of the members request such in writing, including the reasons therefore, if the Governing Body considers it necessary, or if the State Attorney's Office exercising legal supervision proposes so in writing.

The Governing Body shall announce the time, venue, and agenda of the General Assembly.

The quorum of the General Assembly consists in 50 percent of the members with voting rights plus one member. In the absence of a quorum, a new General Assembly shall be called with the same



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agenda within 30 days. The latter General Assembly shall be deemed to constitute a quorum regardless of the number of members attending.

Resolutions of the General Assembly shall be made in public ballot by simple majority vote. Decisions on matters within the exclusive jurisdiction of the General Assembly require a qualified majority vote of two thirds of the ballot.

**The Governing Body:**

The Governing Body is the administrative and representative organ of the Association.

It manages and organises the activities of the Association between General Assemblies.

The Governing Body prepares the General Assembly, manages the Association's assets in accord with the accepted budget, and organises the work of the Association.

The Governing Body consists of five persons, elected from among the Association's members by the General Assembly.

The mandate of the Governing Body is three years for the first management cycle and two years thereafter.

The members of the Governing Body: the President, the Vice President, the Secretary-General, the Treasurer and the Head of Education and Organising Committee are nominee and elected by the General Assembly.

The head of the Governing Body is the President. If he is unavailable, the Vice President acts in his place with the same jurisdiction. The Association is represented with full authorization by the President or the Vice President.

Decisions on elections to the post of President and Vice President are made in public ballot by simple majority vote.

The President shall be in charge of the activities of the Governing Body and set its work schedule and order. In the case of a tie vote, the President's vote prevails.

The Governing Body shall meet as necessary, but in all events, not less than six times a year, including the extended Governing Body meetings.

The Governing Body shall see to the proper keeping of records for the Association and its representation as required by the applicable regulations in force. The Governing Body shall decide on matters related to the Association's legal status, and on ethics disputes arising between members of the Association.

The President is entitled to make decisions concerning the Association's affairs at his own discretion and responsibility — subject to the obligation to report to the Governing Body and to the General Assembly afterwards.

**The Auditors:**

The two Auditors are elected by the General Assembly.

The Auditors are responsible for monitoring current affairs and auditing the Balance Sheet.

They shall report to the Governing Body and to the General Assembly on the results of their investigations.

They confirm the minutes of the General Assembly meeting.



### **Committees:**

The Association sets up two constant Committees. The Association may create ad hoc Committees for the execution of any of its tasks. The Committees direct the organisation, co-ordination, and execution of particular sub-tasks in order to achieve the objectives set by the Association. The Chairpersons of the Committees shall report to the Governing Body and — during their operation — shall participate in the extended meetings of the Governing Body. The operation of the ad hoc Committees shall terminate with the completion of their particular task.

The Chairperson or a member of a Committee may concurrently fill any other office, as well.

Constant Committees:

Education and Organising Committee.

Pharmacovigilance Committee

Information management Committee

### **The nominating committee and the order of election:**

Prior to the elections, the Governing Body selects a nominating committee.

The nominating committee draws up a nomination list for the members of the Governing Body, the Chairpersons of the Committees, the Auditors, and the members of the Ethics Committee

Any additional persons may be included in the nominating list if they are supported by two thirds of the General Assembly in a public vote.

The General Assembly elects the officers of the Association from the nominating list by a two-third-majority vote.

The mandate of the previous officers ceases when the General Assembly has elected the new officers for the posts.

In the event of the vacation of an office due to causes of death, resignation, termination of membership, or any other reason, an extraordinary General Assembly shall be called for the election of the Governing Body member. The mandate of the new Governing Body member elected in the above manner shall last as long as the mandate of the member in whose place he is elected.

## **V. THE ASSETS OF THE ASSOCIATION**

The Association's own assets may primarily come from membership fees, contributions from legal or natural person members, and other revenues.

The Association may only use the assets available to it for the purposes of the Association.

Disposition over bank account requires signatures (endorsement) from two members of the Governing Body. The members of Governing Body are: the President, the Vice-President, the Secretary-General, the Treasurer and the Head of Education and Organising Committee. In case of disposition over the bank account one of the signer is the President or if unable to attend, the Treasurer, the second signer may be any other member of Governing Body.

The Association operates in accord with the business and asset management provisions of the law applicable to social organisations, on the basis of an annual financial plan.



**Business management of the Association:**

Decisions on the utilisation of the Association's assets and its business management in the periods between General Assemblies are made by the Governing Body in accord with the previous resolutions of the General Assembly.

The Association may engage in business activities in order to finance its operations, but it is not the primary object of the Association to act as a commercial organisation. Thus, in particular, the Association is entitled to undertake as part of its commercial activities the organisation of conferences and professional meetings including non-commercial hospitality, the publication of printed matter, newsletters, and books, the organisation of public lectures, the creation and maintenance of internet web sites as well as the publishing of paid advertisements (related to job advertisements, events, publications, services, etc.) on the HURAS homepage and its publications.

## VI. THE TERMINATION OF THE ASSOCIATION

The Association shall be terminated by:

- winding up;
- fusion with another social organisation;
- winding up, or announcing its termination.

In the event that the Association is terminated, its assets — following the satisfaction of its creditors — shall be disposed of in accord with the provisions of the Statutes.

Any remaining assets shall be placed in a so-called "closed foundation" and applied to support future activities, associations, or foundations of a similar nature. The relevant measures to be taken in that respect shall be the responsibility of the executors.

All questions not specifically regulated in the Statutes shall be governed by the relevant provisions of the Hungarian Civil Code and Act No. II of 1989 on associations.

## VII. FINAL DISPOSALS

- (1) The operation of the Association is subject to enforcement control by prosecution according to the rules governing its activities.
- (2) In case of any issues not regulated by the fundamental rules of the Association, the laws governing social organizations will be applied.
- (3) The text of the present fundamental rules is a consolidated version that comprises the amendments of 22 May, 2006.

Budapest, 22<sup>nd</sup> of May 2006.



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Signature: \_\_\_\_\_

Ilia Slavov

President of Association