ISO/TC 215
ISO/TC 215 - Health informatics
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N946 EFPIA ISO Liaison A Application Letter

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efpia
European Federation of Pharmaceutical Industries and Associations

Dr M.-L. PELAPRAT
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P.O. Box 56
CH – 1211 GENEVA 20

4th January 2012

Dear Dr Pelaprat,

In accordance with the ISO/IEC Directives, the European Federation of Pharmaceutical Industries and Associations (EFPIA) would like to apply for the liaison status category A within the ISO Technical Committee 215 on Health Informatics.

Following our analysis of the relevant admission clauses and requirements, EFPIA could be fully eligible for the liaison status category A.

EFPIA represents, as an international non-profit organization under Belgian law (aisbl), the pharmaceutical industry operating in Europe. Through its direct membership of 31 national associations and 38 leading pharmaceutical companies, EFPIA is the voice of 2,000 research-based pharmaceutical companies committed to support a vision of modern, sustainable healthcare systems in Europe. Particularly systems providing patients with equal and early access to the best and safest medicines, also by ensuring the highest security of the medicines supply chain.

EFPIA is actively engaged in the implementation of the Falsified Medicines Directive (Directive 2011/62/EU), which was published in the EU Official Journal on 1st July 2011. The Directive requires that all prescription-only medicines will have to bear safety features (i.e. a unique serial number placed on each pack together with tamper evident packaging), subject to possible exclusions based on risk assessment. Tamper-evidence feature together with unique serial number on each medicine pack will allow pharmacists to check whether a pack has been tampered with and previously dispensed, alerting them to any risk of counterfeiting. However, to ensure maximum effectiveness it is vital that all medicine packs are verified systematically at pharmacy level. The European Commission will define the mechanics of how this system will work in Delegated Acts that are to be adopted in the coming months. The Delegated Acts will define the specifications of the serial number allowing identification/ authentication of individual packs and the accessibility of national product databases that allow verification of each dispensed pack.

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On this ground, EFPIA is working with the European Commission, together with the European Pharmacists and Wholesalers (PGEU & GIRP), on the implementing rules of the point of dispense product verification system.

With respect to identification of products, EFPIA is supportive of the use of a 2D Data Matrix as data carrier of choice, encoded with a product code, serial number, batch number and expiry date. This information should be encoded using the relevant application identifiers. EFPIA's

The choice of standards is driven by a broad number of factors including but not limited to:

- Patient safety - globally unique codes and certainty of product identification;
- Interoperability – ability for the proposal to work across markets, stakeholders and sectors;
- Complexity reduction – one solution which can be leveraged for all levels of packaging while allowing to chose the appropriate symbols;
- Technical suitability – factors such as robustness of data carrier, ability to print on line, etc.;
- Cost effectiveness of solutions – appropriate for needs of users;
- Flexible and future compatibility – part of an ongoing standard which will not be superseded;
- Proven solution - used in the retail sector worldwide.

Product identification must ensure that an item, e.g. a pack, can be globally identified through a unique identifier, so to prevent different products having the same identifier which would ultimately lead to harm to patients and costs for the healthcare provider. One of the possibilities could be the GS1 product identifier, called GTIN (Global Trade Item Number), which would be used across countries without any restrictions or errors; this means that no trade barriers are created, which would otherwise potentially impact patient care and safety when products cannot be identified. There are many other benefits of a global approach like the possibility to enable traceability within the EU and interoperability within and across other sectors. TC 215 and particularly your activities on "Requirements for International Machine-Readable Coding of Medicinal Products Package Identifiers" (DTS 16791) steer on these issues. Therefore, EFPIA and its members are convinced that the research-based pharmaceutical industry would provide a significant contribution to the work of the Technical Committee through its expertise and practical experience as well as its in-depth knowledge of the EU regulatory framework

Consequently, I would like to ask for admittance of EFPIA as a liaison organisation category A. As representative of our Organisation within the committee, I would like to suggest Mr Andreas M. WALTER, Coding and Serialisation Project Director of EFPIA, who will take care and coordinate our activities within TC215.

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Additionally and as requested by the ISO/IEC Directives Part I 2011, I accept in behalf of EFPIA:

- The policy based on the ISO/IEC Directives concerning copyright, whether owned by the liaison organization or by other parties;
- The ISO/IEC procedures, including IPR;
- The requirements of ISO/IEC Directives Part I 2011, chapter 2.14 on patent rights.

Finally, for your information and in order to permit you to check the eligibility of our request, I enclose our statutes. EFPIA's membership list can be found on http://www.efpia.eu/Content/Default.asp?PageID=353.

If you have any additional question or in case you need still any other document supporting our application, please do not hesitate to contact us.

In the meantime, I am looking forward to hear from you at your earliest convenience.

Yours sincerely,

Richard BERGSTRÖM
Director General

Encl.

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STATUTES

approved by the Statutory General Assembly of 26 June 1997, and

subsequently amended by Statutory General Assembly decisions of 20 November 1997, 24 June 1999, 22 June 2000, 25 January 2001, 26 May 2004, 29 June 2006, 14 May 2009 and 21 June 2010

Article 1 – Name of the Association

The name of the Association is EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, or, in abbreviated form, EFPIA.

Article 2 – Aim of the Association

The aim of the Association, which has no profit-making purpose, is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.

It operates as the representative organisation of the pharmaceutical industry in Europe. It maintains a permanent contact between its members.

In addition, it pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

The activities of the Association shall extend to all matters of common interest to its members. In particular, it aims to foster an environment that encourages pharmaceutical research and development, manufacture in compliance with high quality standards, intellectual property protection and the introduction of regulatory requirements to allow patients rapid access to medicinal products.

To achieve the above aim, the Association shall:

- represent the pharmaceutical industry operating in Europe with respect to international governmental organizations. In particular, it shall make such bodies aware of the views of the pharmaceutical industry on all matters that are of interest to it and concern public health, especially international legislation and regulations;

- maintain close relations with such governmental bodies and also with non-governmental bodies in order to enhance understanding of problems affecting the pharmaceutical industry;

- study scientific, economic, social and legislative matters of interest to the pharmaceutical industry;

- co-ordinate the policy of member associations, particularly as regards rules of conduct and self-regulatory codes specific to the industry, and organize any exchange of information and views among members;

- co-operate with international organisations having similar objectives and activities. The Association may affiliate with such of these international bodies as the Board may decide;

- represent, in courts of law and to administrative authorities, the general interests of its members.

Article 3 – Seat of the Association

The registered office of the Association is situated in Switzerland, 2 Rue Bellot, CH 1206 Geneva. It may be transferred to any other location by decision of the General Assembly.

The Association has a permanent office in Belgium, 108 Rue du Trône, 1050 Brussels. The permanent office may be transferred elsewhere by decision of the General Assembly.

Article 4 – Membership of the Association

Article 4.1 – Full members of the Association

Full members of the Association include: (i) research-based pharmaceutical companies, developing and manufacturing medicinal products in Europe for human use – *called corporate members*; and (ii) those organisations representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies – *called member associations.*

Member associations shall be divided into four groups, composed as follows:

- group 1: member associations that have their head offices in France, Germany, Italy, Spain, Switzerland or the UK;

- group 2: member associations that have their head offices in Belgium, Denmark, the Netherlands or Sweden;

- group 3: member associations that have their head offices in Austria, Finland, Greece, Ireland, Norway, Poland or Portugal;

- group 4: member associations that have their head offices outside the European Union (EU), European Economic Area (EEA) or European Free Trade Association (EFTA).

Upon admission of an association as a new full member, the General Assembly shall also decide to which of the four groups it belongs.

Article 4.2 – Affiliate members

Any company specialising in particular fields of pharmaceutical research and/or development or in new technologies of particular interest to the pharmaceutical industry may apply to the General Assembly to grant it the title of "*affiliate member company*".

Any organisation representing research-based pharmaceutical companies at national level in Europe can apply to the General Assembly to grant the title of "*affiliate member associations*".

Article 4.3 – Specialised groups

Research-based pharmaceutical companies operating in a particular segment of the pharmaceutical market may apply to form a *specialised group within EFPIA*. Specialised

group members shall conduct their work in line with the Association's general objectives and policy.

Article 4.4 – Admissions – refusals to admit

New full members, affiliate members or specialised groups, including their members, may be admitted by decision of the General Assembly.

Applications for membership or to form or to join a specialised group shall be addressed to the President. Applications to form a specialised group shall be accompanied by a document setting out the mission of the group.

Decisions of the General Assembly regarding admission or refusal to admit members of the Association or from specialised groups, or to form a specialised group are sovereign. The General Assembly should not be required to give reasons.

Article 4.5 – Membership commitments

By their membership, all members (including members of specialised groups) agree to submit themselves to the Statutes and the Internal Rules of the Association, as well as to the decisions taken in accordance with these Statutes and Internal Rules.

Article 5 – Resignation and exclusion

Article 5.1 – Resignation

Any member may resign at the close of a calendar year subject to six months prior notice.

Article 5.2 – Exclusion

Any member may be excluded by decision of the General Assembly on the following grounds:

- because it no longer fulfils the conditions as defined in Article 3.2 and 3.3 of the Internal Rules at the time of its admission;
- for jeopardising the attainment of the aim pursued by the Association;
- for non-payment of dues after two reminders;
- for any other serious cause.

Specialised group members that impede the Association's general policy may be excluded by decision of the General Assembly on a Board's proposal.

Decisions to exclude will need a three-fourths majority of full members present or represented. Decisions of the General Assembly regarding the exclusion of members of the Association are sovereign.

Article 5.3 – Resignation – exclusion

Excluded or resigning members have no claim to the assets of the Association. In any

event, any dues outstanding, including outstanding subscriptions and / or contributions for the remainder of the year in which exclusion or resignation occurs, remain due.

Article 6 – The bodies of the Association

The bodies of the Association shall be as follows:

- the General Assembly;
- the Board;
- the Executive Committee; and
- the General Management.

Article 7 – The General Assembly

Article 7.1 - Members of the General Assembly

The General Assembly of the Association shall comprise all full members. Each full member shall be represented at meetings of the Assembly by one delegate, appointed for a two year term. Delegates' mandates may be renewed.

If a delegate ceases to belong to the member association or corporate member that appointed him, that delegate's mandate automatically becomes void. The person appointed to replace such a delegate shall complete the original mandate.

Each affiliate member and each specialised group member may be represented at meetings of the General Assembly by one delegate. These delegates may take part in deliberations, but are not entitled to vote.

The General Management shall take part, without voting rights, in the meetings of the General Assembly.

Article 7.2 - Convocation of the General Assembly

The General Assembly shall meet at least once a year and in any case within six months after the end of each financial year, on a date to be fixed by the Board, giving at least one month's prior notice in writing to the members, such notice to be accompanied by the agenda for the meeting. The General Assembly shall be convoked by the General Management of the Association.

The General Assembly may, in addition, meet whenever the Board deems it necessary or at the request of members representing at least one fifth of the votes, such meeting to be convoked in the same way as the annual General Assembly.

A meeting of the General Assembly shall be convoked where a modification of the statutes or the winding up of the Association is proposed.

The General Assembly may deliberate only if there is a quorum representing 75% of full members.

Article 7.3 - Voting rights and majority

At the General Assembly each full member shall have one vote.

The votes of member associations, on the one hand, and of corporate members, on the other, shall be given equal weight (50% each) in calculating the outcomes of votes.

Any absent full member may be represented by one other full member. Each member may nonetheless represent only one other member. Proxies shall be valid only for the specific items on the agenda of the meeting and shall be addressed in writing to the President of the Association.

Unless otherwise stipulated, decisions of the General Assembly shall need not less than a two-thirds majority. Decisions by written consultation may only be taken unanimously by all full members.

Article 7.4 - Powers of the General Assembly

The General Assembly is the sovereign power of the Association. It shall approve the general policy of the Association, as proposed by the Board.

Subject to the provisions of Articles 8.1 to 8.4 of these statutes, the General Assembly shall appoint the members of the Board and confirm the appointment of the President and Vice-Presidents.

The General Assembly shall decide on the admission, the refusal to admit, or the exclusion of any member or specialised group.

The General Assembly shall approve the annual budget and shall approve, within six months after the end of each financial year, the balance sheet and accounts.

The General Assembly agenda shall be determined by the Board. No item other than those set out in the agenda can be deliberated upon by the General Assembly except on a matter of urgency at the request of the President.

The General Assembly shall approve the Internal Rules. These rules are intended for the purpose of implementing the statutes and to clarify internal governance. Any subsequent change in the Internal Rules must be approved by the General Assembly.

Article 8 – The Board

Article 8.1 – Members of the Board

The Board shall comprise up to 25 members, and no less than 6 members.

The President may invite other delegates to meetings of the Board. These delegates shall take part in the discussions in accordance with arrangements to be decided by the President, without voting rights.

The Chairperson (who will be a corporate member delegate) and the two Vice-Chairs (one corporate member delegate and one member association delegate) of the Executive Committee will be invited to attend meetings of the Board, without voting rights. A second member association delegate will attend meetings of the Board, without voting rights.

Members of the General Management shall attend meetings of the Board, without voting rights.

Article 8.2 – Capacity of members of the Board

Delegates to the Board shall be the highest-ranking person in charge of the corporate member's pharmaceutical operations or a person in charge of the corporate member's pharmaceutical operations at global / international level, empowered to act on behalf of the corporate member that he / she represents.

Delegates to the Board shall be proposed to the General Assembly by common accord among corporate members. They shall ensure an appropriate and effective allocation of seats.

Article 8.3 – Mandate of members of the Board

Members of the Board shall be appointed by the General Assembly for a period of two years. Their mandate may be renewed.

If their appointment has to be interrupted before completion of the full term of office, a replacement may be appointed, on the conditions laid down in Article 8.2 of these statutes, to complete the original mandate.

Mandates shall not be transferable.

Article 8.4 – Powers of the Board

The Board has the largest administration powers and duties. The Board shall carry out all tasks and duties determined by the General Assembly, and has the power of decision for all matters not specifically falling within the competence of the General Assembly. It shall administer and manage the assets of the Association and ask the General Assembly to approve the discharge of its responsibilities. The Board is also called to set out the strategy, priorities and governance of the Association.

No acquisition or disposal of immovable of the Association shall be made without the assent of the General Assembly.

The Board shall confirm the mandates of the Executive Committee.

The Board shall put forward proposals for decisions to be taken by the General Assembly and shall ensure their implementation by the General Management. The Board shall appoint members of the General Management.

Article 8.5 – The President

The Board shall nominate among its members a President and two Vice-Presidents. The Vice-Presidents shall be chosen in such a way as to ensure the continuity of the activities of the Association. The appointment of the President and the Vice-Presidents shall be confirmed by the General Assembly.

The President and Vice-Presidents shall serve for a period of two years.

The President shall represent the Association in all matters in respect to third parties and governments.

The President shall preside over meetings of the General Assembly and the Board. In the event of a tied vote in the Board, the President shall have the casting vote.

The Vice-Presidents shall assist and act as the substitutes of the President. If the President is absent, the immediate Past President shall take precedence.

Legal suits shall be followed up by the Board, represented by its President. In the event of appearance in a court of law, the President may be represented by substitute acting with a special power of attorney.

The President may delegate his responsibilities according to the rules decided by the Board.

Article 9 – The Executive Committee

Article 9.1 – Members of the Executive Committee

The Executive Committee shall comprise up to 30 corporate member delegates and 11 member associations' delegates. The Board shall confirm the mandates of the Executive Committee.

The Executive Committee Chairperson may invite other delegates to meetings of the Executive Committee. These delegates shall take part in the discussions in accordance with arrangements to be decided by the Chairperson, without voting rights.

Members of the General Management shall attend meetings of the Executive Committee, without voting rights.

Article 9.2 – Corporate member delegates

Corporate member delegates to the Executive Committee shall be nominated by common accord among corporate members. Corporate members shall ensure an appropriate and effective allocation of seats.

Each corporate member delegate shall be the highest-ranking person in charge of that member company's pharmaceutical operations in Europe.

Mandates shall not be transferable.

Article 9.3 – Member Associations' delegates

Member associations' delegates to the Executive Committee shall be nominated by common accord among member associations. Member associations belonging to group 1, as defined in Article 4.1 of these statutes, shall be permanently represented. Other member associations shall be represented in turns, by three members of those belonging to group 2 and two members of those belonging to group 3, as defined in Article 4.1 of these statutes.

Each member associations delegate shall be a person responsible for the day-to-day direction of the member association.

Mandates shall not be transferable.

Article 9.4 – Mandate of the members of the Executive Committee

Members of the Executive Committee shall be confirmed by the Board, for a period of two years. Their mandate may be renewed.

If their appointment has to be interrupted before completion of the full term of office, a replacement may be appointed, on the conditions laid down in Article 9.2 or 9.3 of these statutes, as applicable. The new delegate shall complete the original mandate.

Article 9.5 – The powers of the Executive Committee

The Executive Committee gets its powers from the Board and shall carry out the tasks and duties determined by the Board.

The role of the Executive Committee is the implementation and operation of the priorities set by the Board to which it is accountable. It has the power to take decisions needed to achieve that role and to prepare budget proposals.

The Executive Committee may put forward proposals for consideration by the Board.

The Executive Committee shall ensure implementation of their decisions by the General Management.

Article 9.5 – The Chair and Vice-Chairs

The Executive Committee shall nominate among its members a Chairperson and two Vice-Chairs.

The Chairperson and one Vice-Chair shall be chosen among corporate member delegates. The other Vice-Chair shall be chosen among member associations. Corporate members and member associations shall each nominate their representatives.

The Executive Committee Chairperson shall not be from the same company as the EFPIA President.

The Chairperson and Vice-Chairs shall serve for a period of two years.

The Chairperson and Vice-Chairs shall represent the Executive Committee in the Board.

The Chairperson shall preside over meetings of the Executive Committee. In the event of a tied vote in the Executive Committee, the Chairperson shall have a casting vote.

Article 10 - The General Management

The General Management consists of a Director General and, as applicable, a Deputy Director General, appointed by the Board. It shall manage the secretariat of the bodies of

the Association and co-ordinate the activities of the Association. In accordance with the authority and responsibilities delegated to it by the General Assembly, the Board or the Executive Committee, the General Management shall be responsible for the implementation of the decisions made by the General Assembly, the Board and the Executive Committee.

Article 11 – Financial arrangements

The financial year shall correspond with the calendar year.

On the recommendation of the Board, upon advice of the Executive Committee, the General Assembly shall, within six months of the end of each financial year, approve the accounts of the previous year and the budget of the Association for the following year. Account being taken of budget forecasts, the annual subscription payable by full members shall be determined by the General Assembly, as follows:

a. the combined subscriptions payable by member associations, on the one hand, and the combined subscriptions payable by corporate members, on the other, shall each be equal to 50% of the amount approved as a basis for calculating subscriptions;

b. the burden of subscriptions payable by full member associations in groups 1, 2 and 3 as defined in Article 4.1 of these statutes shall be shared as follows:

   - 72%, in equal shares, by group 1 member associations as defined in Article 4.1 of these statutes;

   - 19%, in equal shares, by group 2 member associations as defined in Article 4.1 of these statutes;

   - 9%, in equal shares, by group 3 member associations as defined in Article 4.1 of these statutes.

   Member associations in group 4 as defined in Article 4.1 of these statutes shall not exceed that payable by a member association in group 3 as defined in Article 4.1 of these statutes.

c. the burden of subscriptions payable by full corporate members shall be shared amongst them in equal shares.

Furthermore, companies that become corporate full or affiliate members shall make an additional one-off payment to EFPIA of € 15,000, as a contribution towards its cash reserves.

The subscription of an affiliate member company shall be equal to no less than one-third of the subscription paid by a full corporate member. The subscription of an affiliate member association shall not exceed that payable by a member associations in group 3 as defined in Article 4.1 of the statutes.

The General Assembly, upon Board proposal, may decide of specific rules for collection of contributions to fund specific projects, including project funding and funding of specialised groups dedicated activities.

The contribution of specialised group members shall be fixed in accordance with a financial agreement approved by the General Assembly, upon Board proposal.

Article 12 – Entering into force

This consolidated version of the statutes, approved by the Statutory General Assembly of 21 June 2010, enters into force with immediate effect.

Article 13 – Working languages

The working languages of the Association are French and English.

Article 14 - Winding up

In the event of a winding up of the Association its net assets shall be distributed among the members in proportion to the dues paid by each of them in the course of the three preceding financial years.