ASOCIACION ESPAÑOLA
DE FARMACEUTICOS DE LA INDUSTRIA

COUNTRY REPORT 2018

✵ AEFI Mission and goals

Promotion of the technical, scientific and social advancement of the members and safeguard the strict observance of the ethical standards.

To achieve said ends, AEFI can organize and convene courses, congresses, seminars, meetings and other activities, as well as to promulgate publications, within the field of pharmacy and of other professionals in the Industry, with freedom of time, place and persons.

AEFI will have as specific ends:

a) To assume the representation of the associates in their relations with the different organisms or entities of a technical or scientific nature, be they national or international.

b) To defend the rights of the Association as a body and of the Associates as its members.

c) When appropriate, to propose to the General Council of Official Colleges of Pharmacists or any other relevant body, the drafting of as many dispositions it deems opportune for the technical and professional advancement of the members it represents.

d) To foment and promulgate with all the means at its disposal, all kinds of scientific work, and request the support that is necessary for them.

e) To institute prizes, awards and distinctions in the form and measure are established.

f) To collaborate with the competent organisms insofar as this concerns the benefit of the service to/for the associates and to the Health Authorities.

g) To establish relations and contacts with as many Commissions, Organisms, Associations, etc., both national and foreign, that can benefit the professional, scientific, technical and/or social advancement of the associates or of the Association itself.

h) To inform the members of AEFI on all kinds of technical and legal questions affecting their professional sphere into the pharmaceutical industry and related markets and it is judged of interest for the same.

i) To achieve the ends of AEFI, the following may be established, in accordance with the legislation and standards in force, i.a) specialized groups according to the type of industries or areas of work in which the associates exercise their profession, i.b) sections as established in article 2.

j) To promote and to foment the continuous vocational training of the associates.

✵ AEFI KPI 2018

INDICATORS	2018
Nº active members	1.908
Nº collaborative partners	3
Nº specialised courses	55
Nº participants (courses)	1965
Nº participants (Symposium)	380
Nº working groups	37
Nº job vacancies	95
Nº Website sessions	45.902
Nº relevant institucional acts	23
Nº signed agreements	13

✵ News 2018

- AEFI ORDINARY GENERAL ASSEMBLY (Madrid, 9th May 2018)
- SECTIONS ASSEMBLIES:
  - Barcelona, 26th April 2018
  - Madrid, 24st April 2018

- Principal Goals of the present Governing Board (2016-2020)

  - Revision of the Statutes and Internal Rules: New texts approved by the Extraordinary General Assembly in June 2017.

  - External Media Communications evaluation and improvement: New Web design. Community Manager Representative (Twitter, Linkedin).

  - Internal Communication improved between the boards and members of the Association. Number of working groups increased.

  - Increase the visibility of the Association: Welcome Plan for new associates, new promotional materials. Promotion of best relationships with other entities and scientific societies: participation in external events.

  - New steps on Corporate Social Responsibility Policy.

✵ Relevant activities

- Participation in the 5th Pharmaceutical, Biopharmaceutical, Cosmetics and Laboratory Technology Forum, FARMAFORUM 2018 (Madrid, 7st-8th March 2018): AEFI Seminar "Entorno de las líneas de fabricación y fabricación en continuo y en campaña".

- 38th Symposium AEFI: "Conectados" (Madrid, 9th-10th May 2018).

✵ AEFI Awards

- XII Best Publication Awards (2017): "Guía Práctica de los requerimientos de las buenas prácticas de la distribución de la UE" and "Fármacos proteicos. Estrategias de administración".

- Best Poster Award Symposium 2018: "Impacto de los cambios de legislación europea en la unidad de farmacovigilancia".

- Best Oral Communication Symposium 2018: "Auditoría a fabricantes de material de acondicionamiento: estuches".

✵ Public Consultations

- Comments to the following National Legislative Projects:

  - Proyecto de Real Decreto por el que se modifica el Real Decreto 177/2014, de 21 de marzo, por el que se regula el sistema de precios de referencia y agrupaciones homogéneas de medicamentos en el Sistema Nacional de Salud, y determinados sistemas de información en materia de financiación y precios de los medicamentos y productos sanitarios. (Reference prices)

  - Proyecto de Real Decreto por el que se modifica el Real Decreto 824/2010, de 25 de junio, por el que se regulan los laboratorios farmacéuticos, los fabricantes de principios activos de uso farmacéutico y el comercio exterior de medicamentos y medicamentos en investigación. (Marketing Authorization Holders and Manufacturers)

  - Proyecto de Real Decreto por el que se modifica el Real Decreto 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente. (Adaptation of the regulation of Marketing Authorization of medicinal products and falsified medicines).

  - Proyecto de Real Decreto por el que regulan los estudios observacionales con Medicamentos. (Clinical observational studies)

  - Proyecto de Real Decreto por el que se regula el procedimiento de financiación selectiva de los productos sanitarios con cargo a la prestación farmacéutica del Sistema Nacional de Salud para pacientes no hospitalizados y se determinan los márgenes correspondientes a su distribución y dispensación. (Reimbursement of medical devices)

- Proyecto de Orden Ministerial por la que se regulan determinados aspectos de la autorización de los medicamentos alérgenos de producción industrial y de los alérgenos de uso humano y veterinario. (Public consultation to regulate allergen products)

- Comments to the following European Legislative Projects and other documents:

-Reflection paper on the pharmaceutical development of medicines for use in the older population.

-Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development.

-Volume 4 ANNEX 1 on the full review of Manufacturing of Sterile Medicinal Products.

- Comments on Audit (EMA- GMP/GDP IWG and QWG).

-Questionnaire *Ordre des Pharmaciens*: Company Responsibilities and the Chief Pharmaceutical Officer (Pharmacien Responsable).

- Industry Stakeholder meeting on Brexit and operation of the centralised procedure for human and veterinary medicinal products.

✵ Other relevant issues

- Board Meeting (Zaragoza, 28th-29th September 2018).
- Active Working Group on Corporate Penal Compliance and General Data Protection Regulation (GDPR).