

Some links to relevant information on APIC:

APIC website - <http://www.apic.cefic.org>

Summaries of API Conferences - http://www.api-conference.org/pa4.cgi?src=api_conf_reports.htm&id=S136108115044594

Safemedicines.org website - http://www.safemedicines.org/latin_america/counterfeit.php

Budapest presentation 2008 - <http://www.apic.cefic.org/pub/API%20LPF%20Budapest%20Feb%202008.ppt>

Alensa website - <http://www.alensa.com/docs/qsupply.pdf>

See also: API Compliance Institute : <http://www.gmp-compliance.org>

EFCG website - <http://efcg.cefic.org>

APIC Position Papers - <http://www.apic.cefic.org/position/position.html>

List of APIC Position Papers:

- APIC Position Paper Bulk Post-Approval Change Authorization Procedures (PACAPs)
- APIC Position Paper CEP vs. DMF
- APIC Position Paper on Counterfeiting of APIs
- APIC Position Paper on Requests for Statements
- APIC Position Paper - Need for GMP for API production
- APIC Position Paper - No Safe Medicines Without Safe Ingredients
- APIC Position Paper on Variation Regulations
- CEFIC/APIC comments on the Consultation regarding "The Future of Pharmaceuticals for Human Use in Europe"
- EFCG /APIC comments on the Consultation Paper in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use

APIC's relationship with EFCG

Since 2004, APIC has acquired the membership of the CEFIC sector group EFCG (European Fine Chemicals Group). The EFCG brings in executive awareness and influence on certain major legislative and regulatory issues.

Within joint efforts the two sector groups bundle their complementary fields of expertise and experience to strengthen their voice. A major topic for their joint focus is the current regulatory non-level playing field in the European API market that is threatening patient safety as well as the continuity of the European API industry.

Contact

For joining APIC, for requesting more information and for ordering additional copies of this brochure please contact:

APIC Secretariat General

Tel : +32 2 676 72 02 and +32 2 676 72 44
Fax : + 32 2 676 73 59
apic@cefic.be
www.apic.cefic.org



APIC is a Sector Group of Cefic



“Compliant APIs for Patient Safety”



APIC represents producers of APIs and API intermediates in Europe. Its membership consists of more than 60 companies, located all over Europe, and of several national industry associations.

Who is APIC?

The CEFIC* Sector Group **APIC** (the Active Pharmaceutical Ingredients Committee) was founded in 1992 as a direct consequence of the rapidly increasing European regulatory requirements affecting the manufacture of Active Pharmaceutical Ingredients (APIs).

APIC represents producers of APIs and API intermediates in Europe. Its membership consists of more than 60 companies, located all over Europe, and of several national industry associations.

For around 2/3 of its members, selling APIs and intermediates is their major business while ca. 1/3 of the members are primarily marketing final medicinal products. APIC's focus is on worldwide Quality, Good Manufacturing Practice (GMP) and Regulatory matters relating to APIs and intermediates.

Through the years APIC has developed into a high-profile industry association with an excellent, worldwide reputation.

APIC's mission

- **To promote the use of compliant APIs in medicinal products to ensure patient safety**
- **To represent the interests of pharmaceutical and chemical companies producing APIs and intermediates in Europe by being recognised experts who advance and influence the global GMP and Regulatory environment**

APIC's major strategic objectives are:

- **Level Playing Field:** To strongly advocate regulatory compliance in all global markets and its enforcement through inspection.
- **Post approval change authorisation:** To put the responsibility to manage change into the hands of industry.
- **Harmonisation:** To support global harmonisation in the fields of quality and regulatory affairs.
- **Networking/ Advocacy:** To continually improve contacts and to increase the profile of APIC with all relevant stakeholders

* *CEFIC (the European Chemical Industry Council): The Brussels-based organisation that represents the European Chemical Industry*

APIC's major strengths are:

- Its continuous awareness of and communication on new quality and regulatory developments affecting APIs
- Its large network of contacts with health authorities worldwide as well as with other industry stakeholders
- Its very active and pro-active role in defending the interests of APIs manufacturers from a perspective in which the safety of patients is taking the central position
- Its high integrity

APIC's major achievements

APIC has played and is playing an important - and in a number of cases a leading - role in improving the regulatory environment for the API manufacturing industry, to the benefit of patient safety, the benefit of society as a whole and for the sake of its own continuity. Examples of major achievements are:

- Development and adoption by the respective health authorities of a harmonised GMP standard for APIs (**"ICH/Q7"**) for the US-, EU- and Japanese markets
- Issuance of a globally recognized APIC document on the interpretation of the ICH/Q7 guideline (**"ICH Q7 How-to-do Document"**)
- Initiation of the fight against unsafe, often low-priced **Rogue- & Counterfeit APIs**. APIC is still playing a leading role in this fight together with the European Fine Chemicals Group (EFCG), another sector group of CEFIC
- Complete removal of the disproportionately high regulatory barriers that obstructed the use of genetically modified organisms (**GMOs**) in the fermentative and enzymatic manufacture of (non-protein) APIs
- Organisation of the annual **European API Conference**. This has become the number one API event in Europe on GMP- and Regulatory aspects
- Development and launch of the **"APIC Audit Program"**: a third party API audit program aimed at reducing costs and resources for API auditing, made available to the worldwide pharmaceutical industry
- Initiation of new thinking within the US/FDA on breaking down regulatory barriers against improvements in API manufacture and in pharmaceutical manufacture in

general, which contributed in first instance to the launch of the "BACPAC I guideline" and ultimately to the launch of the current **FDA 21st Century Initiative** that aims to foster innovation and continuous improvement in manufacture

- Promotion of similar new thinking within EU health authority circles which contributed to the currently running revision of the **EU Variations Regulations**
- Provision of crucial input during the development of a European authorities guidance on **API fermentation** requirements, which resulted in realistic requirements and an optimal workability of the guidance
- Strong and continual contribution to improvements to the **Certification of Suitability** (CEP or "COS") system and -procedures through intensive cooperation and communication with EDQM
- Issuance of an Industry Guidance on **Cleaning Validation** of API facilities
- Development of an internal industry guidance on **how to safeguard confidential information** within global API registration procedures

APIC structure:

Reporting to APIC's Executive Committee are its two main working groups:

- **Working Group on Regulatory Affairs**
- **Working Group on Quality / GMP**

Within each Working Group a number of Task Forces are operational but also "joint RA & Q/GMP task forces" are active. Each Task Force concentrates its efforts on one major issue. The APIC organisation is a dynamic one: it is frequently adapted to accommodate the necessary work on new topics and issues. New Task Forces are regularly established while others cease to exist as soon as their objective has been reached.

In addition to the work of the Task Forces the Working Groups themselves have a number of important ongoing tasks such as:

- Providing input to health authorities on API-related draft legislation, regulations and guidelines
- Issuing position papers and publications on major Regulatory- and Q/GMP topics

- Developing and implementing tools to achieve and maintain regulatory compliance
- Interpreting existing regulations and guidelines
- Participating in "interested parties meetings" and other meetings with health authorities such as EMEA, European Commission, EDQM, US/FDA
- Discussing topics not covered by APIC task forces and taking actions on these
- Giving presentations at international conferences

Networking

In order to achieve its mission APIC is in regular contact with national- and intergovernmental bodies, such as:

European Commission (EC)
European Medicines Agency (EMA)
European Directorate for the Quality of Medicines (EDQM)
US Food and Drug Administration (FDA)
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
World Health Organization (WHO)
Council of Europe (CoE)
Pharmaceutical Inspection Cooperation Scheme (PIC/S)
and - mostly through the EFCG – the European Parliament (EP)

In addition APIC seeks to coordinate the representation of the interests of its members with other related industry associations, such as:

European Federation of Pharmaceutical Industries and Associations (EFPIA)
US Synthetic Organic Chemical Manufacturers Association (SOCMA)
European Generic Medicines Association (EGA)
International Pharmaceutical Excipients Council (IPEC)
International Federation for Animal Health (IFAH)
Pharmaceutical Research and Manufacturers of America (PhRMA)
US Generic Pharmaceutical Association (GPhA)
Association of the European Self-Medication Industry (AESGP)