



**Associazione Farmaceutici Ticinesi**

## **2019 Annual Report**

*AFTI, the Ticino Pharmaceutical Association, was founded in 1982 with the main goal of grouping the professional and technical staff of the pharmaceutical industry by creating an organization aimed at keeping the industry's operators constantly up to date. AFTI is located in Lugano and is headed by a nine-member Board Committee.*

*AFTI's main mission is to support the continuing education of its affiliates through the organization of courses, congresses, symposia and seminars that help to develop and maintain the professional upgrading of members of society. AFTI is a reference point for the Ticino-based pharmaceutical industry and strives for ever-increasing collaboration among its members, with the aim of promoting the dissemination of innovative technical and scientific information that contributes to the growth of its members and companies to which these belong.*

*AFTI is also open to contacts with other professional associations in the pharmaceutical field to share seminars, scientific meetings and social activities; There is a consolidated and profitable collaboration between AFTI and the AFI (Association of Pharmaceutical Industries) which sees AFTI's active participation at AFI's annual symposium and the joint organization of several events in Italy and Switzerland.*

*AFTI is honored to actively participate as a Delegation to the EIPG, a large group of industrial pharmacists who collaborate at European level to create and develop a technical-scientific culture with common goals.*



*Associazione Farmaceutici Ticinesi*

## *Switzerland – what's news?*

**"The new Swiss regulatory framework"**. The new Swiss regulatory framework TPO IV harmonises many procedures to the one used by EU countries. GMP certificates released by Swissmedic are now available in the Eudra-GMDP database. Simplified procedures for certain categories of products and the revision of dispensing supply categories are among other features of the reform.

The Swiss law governing the marketing authorisation for medicinal products (**Therapeutic Products Ordinance Package IV**, [TPO IV](#)) has been completely renewed at the end of 2018 to **harmonise definitions and procedures to the one used at the European level**. The Package includes different ordinances both of the Federal Council and of the Swissmedic Agency Council, the majority of which have entered into force from **1st January 2019**. Starting from this date, the new legislation is going to be used to process all applications received by the Swiss medicines agency.

For more details please refer to the article published in the EIPG Newsletter issued in April 2019



*Associazione Farmaceutici Ticinesi*

## **Swiss Pharmaceutical market - overview**

Pharmaceuticals is historically one of the main industrial sectors in Switzerland, contributing the **4,5% of national GDP** in 2018 (data [Interpharma](#)). Almost half (49,2%) of the production for export (CHF 83.8 billion in 2017, 38% of total export) went in the EU, mainly to Germany (14,7%); import of pharmaceutical products from the EU reached 79,3% in the same year (CHF 35.3 billion , 19% of total import).

In 2017, the pharmaceuticals market grew 4.1% over the previous year to around CHF 5.8 billion, under the driving force of **innovative anti-cancer therapies** and new products to treat **multiple sclerosis**. The added value for the pharma sector was CHF 28,9 billion (€ 25,3 bln) in 2016. Pharmacies covers half of the market (50,4%), which also comprises self-dispensing doctors (24,8%), hospitals (23,7) and drugstores (1,1%).

**Swissmedic approved 32 medicines with new active ingredients in 2017**, seven under a fast-track procedure. The pharmaceutical industry almost doubled its workforce in the period 1995-2016, reaching **45,500 direct employees** plus 181,000 indirect workers in 2016. Swiss-native pharmaceutical companies, such as Novartis or Roche, are among the main innovators in life sciences of the country. Investments in R&D made in 2017 in Switzerland by the 24 companies members of Interpharma reached CHF 6,8 billion (CHF 114 billion at the global level). Another CHF 500 million were invested in infrastructures (technical apparatus, machines and the equipment and production facilities).

## 2<sup>nd</sup> half of 2018/1<sup>st</sup> half 2019 - Main Activities

In 2018/2019 AFTI organised conferences, courses and presentations for the continuous professional development of the affiliates, in agreement with the main target of the Association.

- GDPR integrated approach: technical, organisational and legal
- Brexit impact on the pharmaceutical sector
- Leader and manager: leadership development in the industry
- Biological medicines and innovative therapies
- Good Manufacturing Practices
- Combination products and differences between Europe and USA
- News foreseen from Swissmedic in 2019
- Human Error
- Clean Room
- New ICH Q13
- General Assembly 2019
- Data Science & Quality by Design
- Drug Supply Chain 2019
- The first months of GDPR: what's happened, specific cases and compliance solutions

## **Special Events and Working Groups**

589h AFI's Symposium, organised by AFI with the participation of AFTI and EIPG, which took place in Rimini in June 2019 (3 days)

### **Five Working Groups are active in AFTI:**

1. *The group of Inspections and Technical Directors*
2. *The working group on GDP*
3. *The working group on Regulatory Aspects*
4. *The working group on Supplier's inspections*
5. *The working group on Quality Risk Management*

## *What AFTI would like to see from EIPG*

*Improve the Special Interest Groups experience in order to have in place Experts Consultation instruments to discuss and prepare position paper expected by the technician working in the industry.*

*Develop, outside of the Newsletter, other independent initiatives of EIPG to promote the European Group all around Switzerland.*

## *AFTI contribution to EIPG during the coming year*

*Being located in Switzerland, outside the EU, we believe that our main contribution to EIPG could be to act as a bridge to the rest of our countries. Switzerland could be a concrete example on how to create a sustainable pharmaceutical environment outside Europe for the current Brexit case.*

*AFTI continuously promote EIPG within its members, both independently and through the pharmaceutical newsletters periodically provided by the EIPG. AFTI website provide also a link to EIPG website for immediate consultation and continuous reminder to all of its members.*

*AFTI strongly support EIPG in the review of the draft of technical documents provided by EMA for a public consultation.*

*AFTI, through the European Affairs VP of EIPG, routinely support the daily work performed by the Group.*