scienceINDUSTRIES
SWITZERLAND

Position paper

Free Trade Agreements (FTA)
Objectives of scienceindustries

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The Swiss chemical, pharmaceutical and biotechnological industry has a significant interest in trade liberalization and strong intellectual property rights protection at the global, regional, and national level. Needless to say that scienceindustries, the association of the Swiss chemical and pharmaceutical companies, prefers all her interests to be addressed in multilateral trade agreements, as they will bring the largest welfare gains for all parties involved and the broadest protection against any national discrimination.

However, if bilateral FTAs are negotiated, we would like our preferences listed in this paper to be included as far as possible by the authorities negotiating the FTAs. Additionally, we take it as given that any new FTA to be negotiated will comply fully with all the existing WTO agreements and will go beyond the minimum standards and obligations established in these agreements.

1. Market Access

1.1 Tariffs and Quotas

Eliminate all customs tariffs and quotas for products classified in the HS chapters 28 to 39.14. If an immediate elimination of all tariffs is not feasible, adequate transition periods should be defined.

Strive at eliminating tariffs and quotas in the following additional HS classifications:

1206 Sunflower seeds, whether or not broken

1209 Seeds, fruit and spores, of a kind used for sowing

1504 Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified

2106.90 Food preparations not elsewhere specified or included

2309.90 Preparations of a kind used in animal feeding

8436 other machinery (for tailored agro solutions)

9001 Contact lenses

9018 Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electromedical apparatus and sight-testing instruments

Eliminate specific levies on products if they exist.

1.2 Preferential Rules of Origin

With the increasing number of regional and bilateral FTAs the variety and complexity of the rules of origin has also grown, sometimes with rules as detailed as per customs tariff line. Handling these differences of rules in a worldwide supply chain setup has become a tremendous administrative burden to internationally operating companies. Therefore, rules of origin are today a key element in determining the magnitude of the economic benefits that accrue from preferential trade agreements.

Use FTA negotiations to strive at **worldwide harmonized and easy to handle rules of origin** in all FTAs. The rules should include the concept of choosing the alternative, change of tariff heading and/or added value rule. In HS chapters 28 and 29 the change of the CAS number could be an additional concept. In HS chapter 30 unequal rules of origin have to be avoided (e.g. 3002 and 3004). Provide within the FTA for a mechanism to adapt rules of origin later.

scienceindustries considers an early **access to the list of rules of origin and to the corresponding introductory** notes as a prerequisite for industry support of the Swiss negotiators.

Rules for wholly obtained goods. The cultivation of human, animal and plant cells under controlled conditions (such as defined temperature, growth medium, gaz mixture, pH) outside of a living organism is known as cell culture. Nowadays, an important part of modern manufacturing technology in the production of pharmaceutical active ingredients is cell culture-based. The products from cell cultures shall be considered as wholly obtained materials and therefore, to allow for new production technologies, existing rules for “wholly obtained goods” shall be adapted as follows:

- Products obtained by using human cell cultures in that country;
- Products obtained from live animals in that country or obtained by using animal cell cultures in that country;
- Plants and plant products harvested, picked or gathered in that country or obtained by the use of plant cell cultures in that country;

Exemptions from the Principle of Territoriality shall be included in every FTA in order to account for modern supply chains. The permitted added-value of outward-processing shall be harmonized in all FTAs at a level of 20% of the ex-works prize of the final product for which originating status is claimed.

The **verification** of the applied prove of origin shall be conducted by the **customs authority or the designated responsible authority of the exporting Party only**. The presence of a representative of the importing Party as an observer during such a course has to be avoided due to the handling of sensitive data (name of suppliers, prizes, calculations, proprietary production processes etc.) during the verification process. Negotiations should be lead in a manner which enables the partners to build up confidence and trust in the verification activities of each other.

Use the new set of **non-preferential rules of origin** - once accepted internationally - that is currently being negotiated in WTO and WCO.

1.3 Direct Shipment Rule

Avoid rules requiring **direct shipments** between FTA partners as a prerequisite to get preferential treatment. Storage and shipment of goods of preferential origin is to be allowed from any country in the world, as long as these activities do not change the preferential origin of the goods. The origin of the goods has to be accessible for checks (e.g. through a declaration of origin at the time the goods

have been imported into the country from which they are shipped; the unique requirement should be the traceability of goods.).

1.4 Customs Procedures/Trade Facilitation

Make customs procedures more efficient. **Facilitate documentation requirements** by using internationally recognized documentation sets. Ease customs procedures by the introduction of government **approved authorized traders.** Increase transparency and efficiency by the **use of modern information technologies**.

1.5 Technical Barriers to Trade (TBT/SPS)

FTA partner countries must comply with the specific **WTO agreements** on TBT (technical barriers to trade) and SPS (sanitary and phytosanitary measures).

Refer in the FTA to **relevant international standards**, where such standards exist (e.g. Codex Alimentarius).

Include provisions for the **Mutual Recognition** of technical standards, conformity assessment procedures and certifications in the FTA. The scope should include at least GLP and GMP regulations.

1.6 Government Procurement

Comply with the **plurilateral WTO Government Procurement Agreement**. FTA partners not currently parties to the Agreement should be required to ratify it and bring their procurement policies into accordance with the Agreement.

Use FTA negotiations to pursue an **enlargement of the scope** of the WTO Government Procurement Agreement. At present, many of the public sector entities responsible for the direct and indirect procurement of and/or payment for pharmaceutical or agrochemical products are not covered by the WTO Government Procurement Agreement.

1.7 Transparency in Government Actions

Use FTA negotiations as a vehicle to introduce principles of **transparency, objectivity and administrative efficiency**, including precise deadlines for decisions and obligation to provide objective justification for decisions on market access, product registration, reimbursement of pharmaceutical products, patent filing, etc.

These provisions could be similar to the EU Transparency Directive in the pharmaceutical area which requires member states to follow a certain number of procedures in order to set prices for reimbursement or adopt any other pricing arrangements. These procedural safeguards are designed to ensure transparency, objectivity and administrative efficiency in decision making. They also provide pharmaceutical companies with predictability; and ensure decisions are neither arbitrary nor abusive

2. Intellectual Property Rights (IPR)

2.1 General Obligations

Include **all types of intellectual property protection instruments** in the FTA: patents, regulatory data protection, trademarks, confidential business data, copyrights, designation of origin (AOC).

Require of FTA partners to access and adhere to all relevant **international intellectual property protection agreements**, in particular to the Patent Cooperation Treaty (PCT), to WTO TRIPS and to the Plant Variety Protection Act (UPOV 1991).

2.2 Patents

Provide **mandatory protection for all inventions**, in all fields of technology. The only permitted exceptions must be aligned with the provisions of TRIPS (Art. 27), e.g. for inventions which commercial exploitation would violate ordre public or be against morality. No exception shall be made for inventions meeting the provisions of TRIPS, including patents on plant species and improvements for active molecules, such as new mixtures, uses or formulations.

Establish **patentability standards** which are in line with EPO practice. Assert that only the responsible IP-authorities examine patent applications and decide on its issuance.

Require **national exhaustion** of patent rights for products subject to public price regulation as a rule and prevent reimportation of patented goods into the country of the patent owner or into countries of an agent of the patent owner. Include the possibility for the patent holder to restrict parallel imports within contractual arrangements.

Require that **compulsory licensing** is used in good faith and in accordance with the procedures as laid down in TRIPS. It shall not be used as an instrument to pursue industrial or commercial objectives, butonly in exceptional circumstances and as a last resort. Include mechanisms for fair compensation to the patent holder. Assert that importation of a patented product satisfies any working requirements (according to Art. 27.1 TRIPS).

Encourage the trading partner to issue patents diligently. Require **patent term extensions** to compensate patent owners for effective patent time lost due to long regulatory review periods (Patent Term Restoration/Supplementary Protection Certificate). Provide means to expedite patent applications. Prohibit pre-grant oppositions.

2.3 Data Exclusivity (Regulatory Data Protection)

Ensure a **term of protection** of preferably ten years but no less than 6 years for an originator's data related to safety and efficacy used for marketing approval of products containing new molecular entities. The protection must cover both, undisclosed data as well as direct or indirect reliance on results of the data. Assert that new molecular entities encompass small chemical molecules as well as biologics (large molecules).

Extend the protection to **new indication approvals**.

Prohibit any **link between data exclusivity protection period and patent term**.

Require that any application for a marketing authorization of a generic, biosimilar or intended copy relying on regulatory data of the originator is made known in order to achieve a **transparent process**.

2.4 Trademark Provisions

Do not allow FTA partners to unreasonably interfere in the **use of trademarks** (e.g. through restrictions on the use of trademarks relative to the use of generic name of pharmaceuticals or agrochemical products in marketing or on label).

Provide means for customs authorities to assist trademark owners in **preventing third parties** from placing their goods on the market, without authorization.

2.5 Counterfeiting

Confront illegal import, production, placing on the market and use of counterfeit products (counterfeits, trademark violations, goods obtained by piracy and goods that infringe a patent or another IP-right) by means of a **market surveillance** system as well as by **deterrent penalties** to counterfeiters.

Provide for mechanisms allowing customs authorities to **effectively combat counterfeit** products whether they are imported, exported or transiting. Allow for preliminary injunctions and evidence preservation.

Establish **criminal sanctions** against IP infringement which harm public interest and establish a risk on health or environment.

When applying anti-counterfeit enforcement measures, **prevent discrimination** of foreign entities by requiring notarization and legalization of documents beyond what is required of national parties.

3. Investment Protection

Negotiate a specific Investment Protection Agreement that complies with the relevant framework of the OECD.

Implement the WTO-concepts of non-discrimination (MFN) and national treatment of investors.

Include an investor-state dispute settlement procedure.