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

1517.90 Margarine; edible mixtures or preparations of animal or vegetable fats or oils or of fractions of different fats or oils of this Chapter, other than edible fats or oils or their fractions of heading 1516:
- other

2106.90 Food preparations not elsewhere specified or included

2309.90 Preparations of a kind used in animal feeding

2710.19 Other preparations, containing by weight 70% or more of petroleum oils

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 all specific levies on products.

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.

Rules of origin are 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.

The appendice contains modern, easy to handle rules of origin which shall be the standard rules for new Free Trade Agreements as well as for Free Trade Agreements which need to be modernized.

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 the verification process has to be avoided due to the handling of sensitive data (name of suppliers, prizes, calculations, proprietary production processes etc.). 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, splitting of consignments and shipment of goods of preferential origin is to be allowed from any non-party country in the world, as long as these activities do not change the preferential origin of the goods and the activities are done under Customs control.
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 requirements should be the identity (e.g. Batch-#) and traceability of goods.).

Refer in the FTA to **relevant international standards:**

1.4 Customs Procedures/Trade Facilitation

According to the **WTO Trade Facilitation Agreement** make customs procedures more efficient. E.g. f**acilitate 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).

1.6 Mutual Recognition (MRA)

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.

1.7 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.

1.8 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 transpar-

ency, 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 including, but not limited to, patents, trademarks, copyrights, industrial designs, geographical indications, protection of submitted data for obtaining marketing authorization (regulatory data protection), plant breeders' rights (plant variety protection), and trade secrets (confidential business information).

Require of FTA partners to access and adhere to all relevant **international intellectual property protection agreements**, in particular to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) the Patent Cooperation Treaty (PCT), to the Patent Law Treaty, to the Paris Convention, to the Berne Convention, to the Madrid System for the international registration of trademarks, The Hague agreement concerning the international deposit of industrial designs and to the Plant Variety Protection Act (UPOV 1991).

2.2 Patents

Provide the availability of patents for any **inventions whether products or processes**, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

The only permitted exceptions must be aligned with the provisions of TRIPS (Art. 27), e.g. for inventions which commercial exploitation would violate public policy 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, e.g. polymorphs and salts of active ingredients.

Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Importation and offering on the market of a product shall be deemed to be “working of the patent” in the country of importation.

Oppositions should only be possible post-grant.

Establish **patentability standards** which are in line with the European Patent Convention as well as the EPO practice.[1] Assert that only the responsible IP-authorities examine patent applications and decide on its issuance.

Require that **national exhaustion** regimes on patent rights for products subject to public price regulation are applied as a rule to prevent non-authorized re-importation of patented goods, meaning that the effect of a patent in a particular country is exhausted only if the patented product which is subject to public price regulation has been put on the market by the patentee in the respective country. Include the possibility for the patent holder to restrict or allow 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, but only 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).

[1] European Patent Convention: https://www.epo.org/law-practice/legal-texts/epc.html; Case Law of the EPO’s Boards of Appeal: https://www.epo.org/law-practice/case-law-appeals/case-law.html; Guidelines of Examination at the EPO: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/index.htm

Encourage the trading partner to issue patents diligently. Require **patent term extensions** or similar instruments for pharmaceutical and agrochemical products 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.

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

Provide a judicial system in which IP rights can be enforced effectively and ensure that courts with respective legal and technical knowledge are available. Provide preliminary measures to stop imminent IP infringements.

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). Data Exclusivity shall not depend on first launch or market approval in the respective country.

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

Patent term and data exclusivity protection period should be treated as independent protection rights.

Require that any application for a marketing authorization of a generic, biosimilar or intended copy relying on regulatory data of the originator is made public 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 pharmaceutical 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 Industrial Designs

The requirements for the deposit of designs should be similar as under the Hague Agreement[2].

2.6 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.

[2] The Hague Agreement concerning the international deposit of industrial designs:https://www.wipo.int/treaties/en/registration/hague/

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.

2.7 Enforcement

Acquisition and maintenance of an intellectual property right is meaningless if that right cannot be enforced in the marketplace. Therefore, the existence of an effective enforcement regime is a central aspect of a well-functioning IP system. Appropriate provisions for the enforcement of IP rights should at least refer to the corresponding articles in TRIPS (Art. 41-61 TRIPS).

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.

Appendice

Standard for preferential rules of origin (in an non-hierarchical order) for Free Trade Agreements which need to be modernized or which are currently in the negotiation process.

NOTE REFERRING TO CHAPTERS 28 TO 39.14

1. The fundamental principle is that if a substantial transformation of a molecule has occurred, then the origin of the product is the country where the transformation took place.
One of the methods for determining origin should be the rule of Change in Tariff Classification (Tariff Shift) on a heading (4-digit HS Code) or sub-heading level (6-digit HS Code). For Chapter 30 as in some important headings the CTSH criteria does not work, the rule should be “manufacture from any heading”.

2. Goods that do not undergo a change in tariff classification are nonetheless originating goods if the value of all non-originating materials that have been used in the production of the good, and do not undergo the applicable change in tariff classification, does not exceed 20 % of the adjusted value of the good.

3. If Goods do not undergo a change of tariff classification and the value of all non-originating materials that have been used in the production of the goods is above 20%, they are nonetheless originating goods if the value of all the non-originating materials used does not exceed at least 60% of the ex-works price of the product.

4. For the purpose of this note, a product shall be considered as wholly obtained, thereby considered as originating in a Party if:

(a) products of Chapter 30 are obtained by using cell cultures;

(b) products falling within Chapters 28 to 39.14 are obtained by fermentation.

5. The approaches referred to in paragraph 2 shall be interpreted as follows:

(a) “Cell culture” is defined as the cultivation of human cells, animal cells and plant cells under controlled conditions (such as defined temperatures, growth medium, gas mixture, ph) outside a living organism.
(b) "Fermentation" is a biotechnological process in which bacteria, yeasts, fungi or enzymes are used to produce products falling within Chapters 28 to 39.14.

6. The main method for determining origin should be the rule of Change in Tariff Classification. If “Change in Tariff Classification” is not feasible, the alternative approaches shall be applied in sequence as follows:

(a) chemical reaction;

(b) mixtures and blends;

(c) purification;

(d) change in particle size;

(e) standards materials;

(f) isomer separation.

7. The alternative approaches referred to in paragraph 4 shall be interpreted as follows:

(a) Chemical reaction: A “chemical reaction” is a process (including a biochemical process) which results in a molecule with a new structure by breaking intramolecular bonds and by forming new intramolecular bonds, or by altering the spatial arrangement of the molecule. A chemical reaction may be expressed by

a change of the “CAS number”. The following are not considered to be chemical reactions for the purposes of determining whether a product is an originating good:

(i) dissolving in water or other solvents;
(ii) the elimination of solvents including solvent water; or
(iii) the addition or elimination of water of crystallization.

(b) Mixtures and blends: the deliberate and proportionally controlled mixing or blending (including dispersing) of materials to conform to predetermined specifications which results in the production of a good having physical or chemical characteristics which are relevant to the purposes or uses of the good and are different from the input materials is considered to be origin conferring.

(c) Purification: Purification is considered to be origin conferring provided that one of the following criteria is satisfied:

(i) purification of a good resulting in the elimination of 80 per cent of the content of existing impurities; or
(ii) the reduction or elimination of impurities resulting in a good suitable for one or more of the following applications:
(aa) pharmaceutical, medicinal, cosmetic, veterinary, or food grade substances;
(bb)chemical products and reagents for analytical, diagnostic or laboratory uses;
(cc) elements and components for use in micro-elements;
(dd) specialised optical uses;
(ee) non toxic uses for health and safety;
(ff) biotechnical use;
(gg) carriers used in a separation process; or
(hh)nuclear grade uses.

(d) Change in particle size: The deliberate and controlled modification in particle size of a good, other than by merely crushing or pressing, resulting in a good having a defined particle size, defined particle size distribution or defined surface area, which are relevant to the purposes of the resulting good and have different physical or chemical characteristics from the input materials is considered to be origin conferring.

(e) Standards materials: The production of standards materials is considered to be origin conferring. Standards materials (including standard solutions) are preparations suitable for analytical, calibrating or referencing uses having precise degrees of purity or proportions which are certified by the manufacturer. The production of standard materials is to be considered as origin conferring.

(f) Isomer Separation: The isolation or separation of isomers from a mixture of isomers is to be considered origin conferring.