Press release

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Research-based industries acknowledge the signing of free trade agreement with Mercosur

Interpharma, scienceindustries and Swiss Biotech Association acknowledge the signing of the EFTA free trade agreement between Switzerland and the MERCOSUR countries. We are fundamentally in favor of free trade as a driver of open markets and prosperity. However, effective protection of intellectual property is vital for innovative Swiss companies. Therefore, Switzerland's innovative industries consider it absolutely essential that the Swiss government closely monitors the enforcement of the protection standards in line with the applicable WTO TRIPS regulations.

Interpharma, scienceindustries and Swiss Biotech Association welcome the fact that, with the agreement now signed, the MERCOSUR countries have clearly committed to the standards of the WTO TRIPS agreement on the protection of intellectual property rights.

For Switzerland's innovative industries, it is crucial that intellectual property is protected, regardless of whether products are imported or locally produced. For innovative pharmaceutical, chemical and biotech companies, adequate protection of test data from clinical trials for drug approval is also essential. We would have welcomed to see greater clarity in this area in the new free trade agreement.

We now rely on the Swiss government to proactively address potential challenges in the enforcement of protection standards as well as future improvements in the application and implementation of intellectual property protection with the MERCOSUR countries through the Joint Committee established by the agreement. The agreed review clause provides the Swiss government with the necessary instrument to do so.

In light of international pressure and geopolitical tensions, it is particularly important in the current challenging market environment to strengthen the framework conditions for the life sciences industries by means of viable international agreements, as well as appropriate measures in Switzerland.

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Annex: Importance of intellectual property for the research-based industry

Research-based industries invest large sums of money in the research and development of innovative products. For example, the development of a new medicine usually costs more than CHF 2 billion. Once an innovation has been discovered and developed, it can often be replicated easily and at low cost. In economic terms, the necessary investments can only be made if the protection of intellectual property is guaranteed.

In the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the WTO has defined minimum requirements for the protection of intellectual property that member states must fulfill. The following applies to patents:

> **TRIPS – Article 27 (Patentable Subject Matter)**
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> …patents shall be available 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.
>
> … 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.

Therefore, WTO countries cannot require products to be produced locally in order to obtain effective patent protection. “Forced localization” also contradicts the concept of free trade, especially if countries are members of a free trade agreement.

Clinical trials account for a large proportion of the development costs of new drugs. Data generated in this process not only demonstrates efficacy and improvement with respect to the standard of care, but also serves to clarify any side effects and is therefore essential for patient safety.

In order to facilitate these large investments in clinical trials, the WTO countries have agreed to protect test data:

> **TRIPS – Article 39 (Protection of Undisclosed Information)**
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> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

This agreement ensures that investments in clinical trials made by an innovator cannot simply be used for the authorization of generics.