Agreement on Cooperation in the Areas of

Foodstuffs, Medicinal Products, Medical Devices and Cosmetics

Between

the Swiss Federal Council

and

the Government of the People's Republic of China

The Swiss Federal Council and the Government of the People's Republic of China, (hereinafter individually referred to as Party or collectively as the Parties);

Considering the close ties that exist between Switzerland and China;

Considering the Free Trade Agreement between the Swiss Confederation and the People's Republic of China signed on 6 July 2013;

Considering the Memorandum of Understanding on Health Cooperation between the Swiss Federal Council and the Government of the People's Republic of China signed on 17 May 2005;

Bearing in mind Switzerland's and China's shared commitment to improving the protection of health in both countries;

Recognising that while there are differences between Switzerland's and China's health systems, Switzerland and China share a commitment to promoting the development of and facilitating access to high-quality foodstuffs, medicinal products, medical devices and cosmetics, as a means of continuing to improve the health of their populations;

Reaffirming the importance of international standards;

With a view to facilitating patient and consumer access to products within the scope of this Agreement;

Desiring to establish a cooperation framework and promote direct channels of communication between the competent authorities involved;

Have concluded the following Agreement:

ARTICLE 1

Definitions

1.1 "Foodstuffs" means:

(a) food and health food as defined respectively in Articles 99 and 51 of the Food Safety Law of the People's Republic of China;

(b) foodstuffs as defined in Article 3 of the Swiss Federal Act on Foodstuffs and Utility Articles;

1.2 "Medicinal products and medical devices" means:

(a) drugs as defined in Article 102 of the Drug Administration Law of the People's Republic of China and medical devices as defined in Article 76 of the Chinese Regulations for the Supervision and Administration of Medical Devices;

(b) medicinal products and medical devices as defined in Article 4 (a) and (b) of the Swiss Federal Act on Medicinal Products and Medical Devices;

1.3 "Cosmetics" means:

(a) chemical products as defined in Article 2 of the Chinese Regulations Concerning the Hygiene Supervision over Cosmetics;

(b) utility articles as defined in Article 5 (b) of the Swiss Federal Act of Foodstuffs and Utility Articles.

ARTICLE 2

Scope

2.1 This Agreement covers bilateral cooperation in the areas of:

(a) Foodstuffs, in particular food safety;

(b) Medicinal products and medical devices; and

(c) Cosmetics.

2.2 For bilateral cooperation related to inspection and quarantine in the area of imported and exported foodstuffs and cosmetics, Chapter 6 (Technical Barriers to Trade), Chapter 7 (Sanitary and Phytosanitary Measures) of the Free Trade Agreement between the Swiss Confederation and the People's Republic of China signed on 6 July 2013 and other relevant agreements between the Parties or their authorities apply.

ARTICLE 3

Purpose

3.1 Through bilateral cooperation the Parties shall strengthen their efforts to improve the protection of health in both countries.

3.2 The Parties shall strengthen their cooperation and mutual understanding in the areas covered by this Agreement.

In particular, the Parties shall facilitate the exchange of views and knowledge about relevant regulations in both countries. Areas and means of cooperation are set out in Article 4, in Annexes to this Agreement or may be agreed otherwise.

3.3 In order to avoid duplications of procedures the Parties will cooperate and consider the requests by either Party to accept reports, certificates and authorisations issued

by their relevant conformity assessment bodies. Specific obligations may be set out in Annexes to this Agreement or may be agreed otherwise.

3.4 The Parties recognise the importance of international standards, provisions, practices and guidelines as a basis for technical regulations and conformity assessment procedures for foodstuffs, medicinal products, medical devices and cosmetics, including those developed by the International Organization for Standardization (ISO), the World Health Organization (WHO), the World Organisation for Animal Health (OIE), the Organisation for Economic Co-operation and Development (OECD), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF), Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and Codex Alimentarius.

The Parties recognise that their full participation in those international bodies will facilitate regulatory convergence between them.

3.5 Each Party supports the affiliation of the other Party's competent authorities to relevant international organisations, in particular those named in paragraph 3.4. The Parties support each other’s effective participation.

3.6 The Parties support and help each other's competent authorities regarding the management of conformity assessment bodies, laboratory testing, inspections of manufacturers, and programmes for market surveillance activities.

ARTICLE 4

Bilateral Cooperation

4.1 The Parties shall within the limits of their resources in particular promote their cooperation on the following:

(a) improving mutual understanding of technical regulations and conformity assessment procedures;

(b) swiftly exchanging information regarding emerging risks;

(c) calling for rapid access to new and innovative products;

(d) facilitating the acceptance of reports, certificates and authorisations issued by the other Party's conformity assessment bodies;

(e) harmonising technical regulations for market access (including market authorisation) or market surveillance with international standards;

(f) discussing trade concerns with the objective of finding mutually acceptable solutions;

(g) assisting economic operators in both countries to understand each other's regulations;

(h) transferring of expertise;

(i) good regulatory practice and the development and implementation of risk management principles including product monitoring, safety, compliance and enforcement practices; and

(j) any other form of cooperation agreed upon by the Parties.

4.2 Bilateral cooperation may be implemented through:

(a) training programmes, study visits and internships for the other Party's staff members;

(b) joint activities such as seminars and workshops; and

(c) any other activities agreed upon by the Parties.

4.3 The Parties may specify cooperation activities for specific areas in Annexes to this Agreement.

ARTICLE 5

Steering Committee

5.1 The Parties hereby establish a Steering Committee comprising representatives of both Parties at senior level.

5.2 The Steering Committee shall:

(a) supervise and review the implementation of this Agreement;

(b) oversee the further elaboration of this Agreement;

(c) supervise the work of all working groups established according to Article 5.3 of this Agreement;

(d) identify sectors for enhanced cooperation, including giving favourable consideration to any sector-specific proposal made by either Party;

(e) initiate arrangements where appropriate;

(f) endeavour to resolve disputes that may arise regarding the interpretation or application of this Agreement; and

(g) consider any other matter that may affect the operation of this Agreement.

5.3 If required, the Steering Committee shall set up working groups to enhance bilateral cooperation in specific areas as listed in article 4. The working groups shall work under a mandate established by the Steering Committee.

5.4 The Steering Committee shall keep up to date a work programme and keep track of its activities.

5.5 The Steering Committee shall take decisions as provided for in this Agreement, or make recommendations.

5.6 The Steering Committee shall meet within one year of the entry into force of this Agreement. Thereafter, it shall meet whenever necessary but normally once every two years. The meetings shall be chaired jointly. The Steering Committee shall establish its rules of procedure.

5.7 Each Party may request, through a notice in writing to the other Party, that a special meeting of the Steering Committee be held.

ARTICLE 6

Financial Arrangements

Each Party shall cover the costs related to its participation in activities under this Agreement.

ARTICLE 7

Confidentiality of Information

The Parties shall treat as confidential information submitted by the other Party which that Party has designated as confidential.

ARTICLE 8

Contact Points

8.1 The Parties shall exchange names and addresses of contact points within the Federal Department of Home Affairs (FDHA) and the China Food and Drug Administration (CFDA) for matters covered by this Agreement. In particular the contact points shall facilitate direct communication between the respective competent authorities.

8.2 The Parties shall notify each other of any significant changes in the structures and responsibilities of the authorities acting as contact points.

ARTICLE 9

Review Clause

9.1 The Parties shall no later than two years after the entry into force of this Agreement and thereafter upon request jointly review this Agreement in the Steering Committee.

9.2 In this review, the Parties shall consider taking into account treatment granted by both Parties to a third Party.

ARTICLE 10

Annexes

The Annexes to this Agreement shall form an integral part thereof.

ARTICLE 11

Consultations

Each Party may refer any matter relating to the interpretation or application of this Agreement to the Steering Committee. The Committee shall endeavour to settle the matter, and must be supplied with any information which may facilitate a thorough examination of the situation with a view to finding an acceptable solution.

ARTICLE 12

Final Provisions

This Agreement enters into force upon signature and is intended to remain effective for a long-term period. Either Party may terminate this Agreement at any time upon six months' written notice to the other Party.

The Steering Committee shall consider proposals for amendments to this Agreement submitted by a Party, and recommend amendments to this Agreement to the Parties. This Agreement may be revised by the Parties upon mutual consent.

Done in duplicate in Davos on 21 January 2015, in the French, Chinese and English languages, each text being equally authentic. In case of divergence between the language versions, the English text shall prevail.

For the Swiss Federal Council	For the Government of the People's Republic of China
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Annex 1

Good Manufacturing Practices (GMP)

For medicinal products, the Parties acknowledge to facing similar challenges to assess and ensure the quality of production as well as the integrity in a globalised supply chain. A key instrument in this regard is the establishment and enforcement of internationally recognised Good Manufacturing Practices ("GMP") on manufacturing sites.

1. Scope

The provisions of this Annex shall apply to all medicinal products which are industrially manufactured in Switzerland or in China , and to which GMP requirements apply.

2. Definitions

2.1 GMP standards means internationally recognised standards reflecting the state of the art of quality assurance which ensures that medicinal products are consistently produced and controlled.

2.2 GMP inspection report means a report, drawn up by the inspectors responsible for the inspection of a site where medicinal products are manufactured. GMP inspection reports are drawn up in accordance with GMP standards and contain in particular the inspectors' observations, a brief summary of the findings and recommendations (where applicable) and their conclusions regarding the GMP status of the inspected site.

3. Exchange of GMP Inspection Reports

3.1 Upon request and for use exclusively within the scope of this Annex, the participating authorities shall exchange GMP inspection reports, unless the concerned manufacturer disagrees.

4. Confidence Building Measures

4.1 In addition to supporting the affiliation of the other Party's competent authorities to relevant international organisations as set out in Articles 3.5 and 3.6 of the Agreement, the Parties agree to:

4.1.1 cooperate to improve the mutual understanding of their GMP systems in particular regarding organisation, standards and approach;

4.1.2 strengthen confidence in the other Party's system by inter alia sharing inspection reports, performing observed inspections or specific training of experts.

4.2 Additional confidence building measures shall be defined if necessary.

4.3 Following successful conclusion of the confidence building measures and based on criteria agreed by the Parties, the Parties consider relying on:

4.3.1 the GMP inspection reports on manufacturers by the participating authority of the other Party; and

4.3.2 the relevant manufacturing authorisations granted by the participating authorities of the other Party.

5. Safeguard Clause for Inspections

The Parties reserve the right to conduct their own inspections. Inspections shall be notified to each other in advance and in compliance with the processes to obtain relevant authorisations. The inspections shall be carried out by one Party and may be observed by the other Party.

Annex 2

Good Laboratory Practices (GLP)

For medicinal products, the Parties acknowledge to facing similar challenges to assess and ensure the high quality of non-clinical testing of chemicals as well as the integrity in a globalised supply chain. A key instrument in this regard is the establishment and enforcement of internationally recognised Good Laboratory Practices ("GLP") on manufacturing sites.

1. Scope

The provisions of this Annex shall apply to medicinal products, which are industrially manufactured in Switzerland or in China, and to which GLP requirements apply.

2. Definition

2.1 GLP system means a system based on internationally recognised standards reflecting the state of the art of quality assurance which ensures that medicinal products are consistently produced and controlled.

3. Compliance of the GLP System

3.1 The Parties recognise the importance of internationally recognised GLP standards and compliance monitoring to ensure the generation of high quality and reliable test data for the non-clinical safety testing to support the conformity assessment procedures of medical products.

3.2 The Parties recognise that international harmonisation of testing procedures facilitates the acceptance of non-clinical test data.

4. Exchange of GLP Inspection Reports

4.1 Upon request and for use exclusively within the scope of this Annex, the participating authorities shall exchange GLP inspection reports, unless the concerned manufacturer disagrees.

5. Confidence Building Measures

5.1 In addition to supporting the affiliation of the other Party's competent authorities to relevant international organisations as set out in Articles 3.5 and 3.6, the Parties agree to:

5.1.1 cooperate to improve the mutual understanding of their GLP systems in particular regarding organisation, standards and approach;

5.1.2 strengthen confidence in the other Party's system by inter alia sharing inspection reports, performing observed inspections or specific training of experts.

5.2 Additional confidence building measures shall be defined if necessary.

5.3 Following successful conclusion of the confidence building measures and based on criteria agreed by the Parties, the Parties consider relying on testing data generated in full compliance with the GLP system of the other Party.

6. Internal Procedures

6.1 The Parties shall set up a GLP compliance monitoring programme.

6.2 The authorities shall keep up-to-date a register of test facilities in their territories that comply with the GLP system.

7. Safeguard Clause for Inspections

The Parties reserve the right to conduct their own inspections. Inspections shall be notified to each other in advance and in compliance with the processes to obtain relevant authorisations. The inspections shall be carried out by one Party and may be observed by the other Party.

Annex 3

Medicinal Products

In addition to means and areas of cooperation set out in Article 4, Annex 1 and Annex 2 of the Agreement, the Parties will in the area of medicinal products in particular cooperate on the following:

(a) supporting the affiliation of the other Party's competent authorities to international initiatives, such as ICH and PIC/S;

(b) supporting the use of international standards for the content of technical dossiers;

(c) building confidence to rely on inspection reports and test data; and

(d) establishing and strengthening the exchange of information on medicinal products (both pre- and post-authorisation).

Annex 4

Medical Devices

In addition to means and areas of cooperation set out in Article 4 of the Agreement, the Parties will in the area of medical devices in particular cooperate on the following:

(a) building confidence to rely on inspection reports and test data;

(b) improving mutual understanding regarding post-marketing surveillance;

(c) registration and extension procedures; and

(d) establishing and strengthening the exchange of information on medical devices;

(e) sharing relevant information and taking necessary action, at administrative level, regarding violations in the field of medical devices.

Annex 5

Food Safety

In addition to means and areas of cooperation set out in Article 4 of the Agreement, the Parties will in the area of food safety in particular cooperate on the following:

(a) enhancing the exchange of information and cooperation concerning laws, regulations and policies;
(b) enhancing the exchange of information and sharing experiences in the field of supervision systems and mechanisms; establishing, if considered necessary, a coordination or response mechanism to address common food safety issues; and
(c) enhancing cooperation on technical training and information exchange inter alia in the field of food safety risk monitoring and early warning systems, risk assessment, risk communication and risk management mechanisms, laboratory administration and capacity development, including testing standards and methodologies, data statistics and analysis.

Annex 6

Cosmetics

In addition to means and areas of cooperation set out in Article 4 of the Agreement, the Parties will in the area of cosmetics in particular cooperate on the following:

(a) facilitating the registration and notification of cosmetic products and ingredients;

(b) strengthening the exchange on alternative test methodologies to animal testing and the registration of new ingredients;

(c) establishing mutual confidence regarding national technical regulations and in-market controls through information exchange between competent authorities;

(d) working towards global harmonisation of technical regulations respecting the fulfilment of legitimate national objectives in particular regarding the protection of health;

(e) sharing best practice experience to strengthen market surveillance and alert systems in light of the risks of cosmetic products for human health and the environment; and

(f) organising joint workshops with industry representatives to discuss new technical regulations.