Switzerland No. 1 (2026)

Agreement

between the United Kingdom of Great Britain and Northern Ireland and the Swiss Confederation on Mutual Recognition in relation to Conformity Assessment

Bern, 11 December 2025

[The Agreement is not in force]

Presented to Parliament
by the Secretary of State for Foreign, Commonwealth and Development Affairs
by Command of His Majesty
September 2026

CP 1678

Switzerland No. 1 (2026)

Agreement

between the United Kingdom of Great Britain and Northern Ireland and the Swiss Confederation on Mutual Recognition in relation to Conformity Assessment

Bern, 11 December 2025

[The Agreement is not in force]

Presented to Parliament
by the Secretary of State for Foreign, Commonwealth and Development Affairs
by Command of His Majesty
September 2026

CP 1678

This publication is available at www.gov.uk/official-documents

Any enquiries regarding this publication should be sent to us at Treaty Unit, Foreign, Commonwealth and Development Office, King Charles Street, London, SW1A 2AH

ISBN 978-1-5286-6815-6
E03684030 09/26

Printed on paper containing 40% recycled fibre content minimum

Printed in the UK by HH Global on behalf of the Controller of His Majesty's Stationery Office

AGREEMENT BETWEEN THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND AND THE SWISS CONFEDERATION ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

The United Kingdom of Great Britain and Northern Ireland ("the United Kingdom") and the Swiss Confederation ("Switzerland"), together referred to as "the Parties".

CONSIDERING the close ties that exist between the Parties;

CONSIDERING the Trade Agreement between the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland of 11 February 2019;

DESIRING to combine the provisions on mutual recognition of conformity assessment of the Trade Agreement between the United Kingdom of Great Britain and Northern Ireland and the Swiss Confederation from 11 February 2019 on Mutual Recognition of Conformity Assessments and the Agreement between the United Kingdom of Great Britain and Northern Ireland and the Swiss Confederation on Mutual Recognition in relation to Conformity Assessment of 17 November 2022;

DESIRING to provide for the mutual recognition of the results of conformity assessment procedures required for access to the respective markets of the Parties for certain product sectors;

CONSIDERING that mutual recognition in relation to conformity assessment will facilitate trade between the Parties and ensure protection for health, safety, the environment and consumers; in full respect of regulatory procedures of the Parties as well as of the applicable levels of protection;

CONSIDERING that comparable legal frameworks facilitate mutual recognition;

CONSIDERING their obligations as Contracting Parties to the Agreement establishing the World Trade Organization and, in particular, to the Agreement on Technical Barriers to Trade, which encourages the negotiation of mutual recognition agreements;

CONSIDERING that mutual recognition agreements can contribute to harmonisation at the international level of standards and technical regulations;

CONSIDERING that the close ties between the Parties make the conclusion of further agreements between the Parties appropriate;

HAVE AGREED AS FOLLOWS:

ARTICLE 1

Purpose

1. The Parties hereby grant mutual acceptance of reports, certificates, authorisations and other results of conformity assessment procedures issued by the bodies recognised in accordance with the procedures of this Agreement certifying conformity to the requirements of the other Party in the areas covered by Article 3.

2. In order to avoid duplication of procedures when Swiss and UK requirements are equivalent due to international harmonised rules, the UK and Switzerland shall mutually accept reports, certificates and authorisations issued by recognised conformity assessment bodies and manufacturer's declarations of conformity certifying conformity to their respective requirements in the areas covered by Article 3.

3. The Committee provided for in Article 17 shall specify the sectors to which paragraph 2 shall apply.

4. Conformity marks required by the legislation of one of the Parties must be affixed to products placed on the market of that Party. Alternatively, if permitted by said legislation, digital markings may be used.

5. This Agreement may provide in Annex I for facilitations regarding the obligations of economic operators set out in the relevant legislative, regulatory and administrative provisions of the relevant Section I in Annex I.

6. This Agreement shall not entail mutual acceptance of the standards or technical regulations of the Parties or mutual recognition of the equivalence of standards or technical regulations.

7. This Agreement shall not limit the ability of a Party to prepare, adopt, apply or amend technical regulations, and conformity assessment procedures in accordance with Articles 2 and 5 of the WTO Agreement of 15 April 1994 on Technical Barriers to Trade.

ARTICLE 2

Definitions

For the purposes of this Agreement:

> «Economic operator» shall mean the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant legislative, regulatory and administrative provisions in the relevant Section I in Annex I.

«National accreditation body» shall mean the sole body in a Party that performs accreditation with authority derived from the Party where it is established to verify and confirm the technical competence of bodies to assess the conformity with the other Party's designated standards and technical regulations for the relevant product sector laid down in the legislative, regulatory and administrative provisions referred to in the relevant Section I in Annex I.

«Accreditation» shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by international standards and, where applicable, any additional requirements including those set out in the legislative, regulatory and administrative provisions referred to in the relevant Sections I and II in Annex I, to carry out a specific conformity assessment activity.

«European co-operation for Accreditation» shall mean the body who supports and enables National Accreditation Body Members to share and build within Europe and among the Mediterranean States a common body of knowledge to develop a sound and harmonised approach to accreditation which is required to ensure that conformity assessment bodies have the technical capacity to perform their task.

«Conformity assessment» shall mean systematic examination to determine the extent to which a product, process or service fulfils specified requirements.

«Conformity assessment body» shall mean a body established in the territory of either Party that independently performs conformity assessment activities, including calibration, testing, certification, inspection or authorisations.

«Joint Committee» (hereinafter referred to as the « Committee») shall mean the Committee composed of representatives of the Parties and responsible for the management and monitoring of the smooth functioning of this Agreement.

«Designating authority» shall mean an authority responsible for the designation, suspension and withdrawal of conformity assessment bodies under its jurisdiction in accordance with Annex II.

«Market surveillance authority» shall mean an authority responsible for carrying out market surveillance in the Parties.

«Notifying authority» shall mean the single authority of a Party responsible for the notification of designated conformity assessment bodies to be recognised under this Agreement by the other Party.

«Technical regulation» shall mean a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging,

marking or labelling requirements as they apply to a product, process or production method.

8. The definitions laid down by ISO and IEC may be used to establish the meaning of the general terms relating to conformity assessment contained in this Agreement. In the event of an inconsistency between the definitions laid down by ISO and IEC, and definitions in this Agreement, the definitions in this Agreement shall prevail.

ARTICLE 3

Scope, Structure and Exceptions

1. This Agreement covers the mandatory conformity assessment procedures ensuing from the legislative, regulatory and administrative provisions listed in Annex I.

2. Annex I defines the product sectors covered by this Agreement. The Annex is divided up into sectoral chapters and these are subdivided as follows:

Section I: legislative, regulatory and administrative provisions;

Section II: conformity assessment bodies;

Section III: designating authorities and authorities responsible for market surveillance information sharing;

Section IV: special rules relating to the designation of conformity assessment bodies;

Section V: supplementary provisions.

3. Annex II sets out general rules applicable to the designation and the notification of conformity assessment bodies.

4. Annex III sets out general rules applicable to accreditation bodies.

ARTICLE 4

Origin

The provisions of this Agreement shall apply to products covered by this Agreement irrespective of their origin.

ARTICLE 5

Recognised Conformity Assessment Bodies

The Parties hereby agree that conformity assessment bodies recognised in accordance with Article 6 fulfil the conditions of eligibility to assess conformity.

ARTICLE 6

Recognition of Conformity Assessment Bodies

1. The following procedure shall apply for the recognition of conformity assessment bodies in relation to the requirements set out in the relevant Chapters of Annex I:

   a. A Party wishing to have a designated conformity assessment body recognised shall notify the other Party in writing of its proposal to that effect, adding the information according to Annex II to its request.

   b. If the other Party agrees to the proposal or does not contest it within 60 days following the notification of the proposal, the conformity assessment body shall be considered a recognised conformity assessment body.

   c. If the other Party contests the proposal within 60 days following the notification of the proposal, or the designated conformity assessment body does not meet the conditions described in Annex II, the conformity assessment body shall not be considered a recognised conformity assessment body and the procedure set out in paragraphs 2 to 6 of Article 7 shall be followed. After the completion of verification, the proposal to list the conformity assessment body may be resubmitted to the other Party.

2. A Party can propose that the scope of activity of a recognised conformity assessment body under its jurisdiction be amended. The procedure provided for in paragraph 1 shall apply.

ARTICLE 7

Challenge and suspension of conformity assessment bodies

1. Each Party shall have the right to contest the technical competence of a recognised conformity assessment body under the jurisdiction of the other Party.

2. Any contestation shall be exercised in an objective and reasoned manner in writing to the other Party.

3. Upon receipt of a written complaint by the contesting Party pursuant to paragraph 2, the other Party shall promptly:

a. seek additional information from the conformity assessment body, market surveillance authorities, national accreditation body and economic operators, as relevant;

b. investigate the complaint; and

c. provide the other Party with a written reply to the complaint in order to refute the challenge or to correct the deficiencies which form the basis of the contestation.

4. In the event of the challenge not being resolved following the procedure in paragraph 3, the disagreement shall be referred by the contesting Party to the Committee. Where the Committee decides that a verification of the technical competence of the conformity assessment body in question is required, this shall be undertaken jointly by the Parties in accordance with Annex II paragraph 6.

5. Each Party shall ensure that conformity assessment bodies under its jurisdiction are available for verification of their technical competence as required.

6. The result of that verification shall be discussed in the Committee with a view to resolving the issue as soon as possible.

7. Unless otherwise decided by the Committee, the disputed recognised conformity assessment body shall be suspended by the competent designating authority from the time disagreement has been established until agreement has been reached in the Committee. Suspension shall be indicated in the list of recognised conformity assessment bodies referred to in Article 14 paragraph 5.

8. The suspension shall remain in effect until agreement has been reached by the Committee with respect to the future status of that conformity assessment body.

ARTICLE 8

Withdrawal of Recognised Conformity Assessment Bodies

1. The designating authority of a Party shall withdraw designation of a recognised conformity assessment body where:

a. the Committee, pursuant to Article 7 paragraph 8, agrees that the disputed body should be withdrawn;

b. the challenge has not been resolved within 120 days after suspension under Article 7 paragraph 7;

c. the conformity assessment body’s accreditation lapses;

d. the conformity assessment body ceases to qualify as a conformity assessment body because it is no longer established in the territory of the Party; or

e. a Party has established that a conformity assessment body under its jurisdiction no longer meets the requirements laid down in Annex II, or that it is failing to fulfil its obligations according to the legislation in the relevant Section I in Annex I.

2. The designating authority shall notify the other Party of the withdrawal immediately.

ARTICLE 9

Recognition of Conformity Assessment as well as Treatment of Files of a Suspended or Withdrawn Conformity Assessment Body

1. Reports, certificates, authorisations and other results of conformity assessment procedures issued by a conformity assessment body after the date at which its designation has been withdrawn or suspended need not be recognised by the Parties. Reports, certificates, authorisations and other results of conformity assessment procedures issued by a conformity assessment body before the date its designation has been suspended or withdrawn shall continue to be recognised by the Parties unless the responsible designating authority has limited or cancelled their validity. The Party under whose jurisdiction the responsible designating authority is operating shall notify the other Party in writing of any changes relating to a limitation or cancellation of validity.

2. In the event of suspension or withdrawal of a conformity assessment body, or where the conformity assessment body has ceased its activity, the designating Party shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible designating and market surveillance authorities at their request.

ARTICLE 10

Information Exchange

1. The Parties shall exchange all relevant information regarding implementation and application of the legislative, regulatory and administrative provisions listed in Annex I.

2. Each Party shall notify changes to its designating, notifying and market surveillance authorities to the other Party in writing within 60 days after their implementation.

ARTICLE 11

Notification of Regulatory Change

1. The Parties shall notify each other of any change to the legislative, regulatory and administrative provisions listed in Annex I at least 60 days before its entry into force. Any change shall be indicated and the Party making the change shall provide additional information identifying the reasons for the change. The Party making the change shall provide reasonable assistance to the other Party's designating authorities in identifying differences with its own legislative, regulatory and administrative provisions.

2. The designating authorities of the Parties shall assess where necessary the impact of the differences on the functioning of this Agreement, taking into account, in particular, product safety and compliance, obligations of economic operators, conformity assessment bodies, as well as accreditation bodies and designating authorities.

3. If a Party requires additional information beyond that provided under paragraphs 1 and 2 to understand the differences, it may submit the matter to the Committee in writing within a 30-day period from the notification described in paragraph 1.

4. The Committee, where necessary, shall:

   a. update the legislative, regulatory and administrative provisions listed in Annex I following the notification referred to in paragraph 1;

   b. keep a list of any differences identified during the procedure referred to in paragraph 1.

   c. decide on the appropriate course of action to ensure the good functioning of the Agreement.

5. The Parties shall review this Article in view of the inclusion of new sectors or in case the legislation in the relevant Section I in Annex I changes substantially; in the latter case the review shall take place within a year after the entry into force of the change.

ARTICLE 12

Missing Notification of Regulatory Change

1. If a Party has reasons to believe that the other Party has failed to notify a change in its legislation, it may request the missing notification from the other Party. The other Party shall promptly provide the missing notification in accordance with Article 11 or indicate the reasons for the absence of notification.

2. The Committee shall be informed of any missing notifications.

3. Where the requesting Party considers a notification necessary and notification is not subsequently submitted in accordance with paragraph 1, evidence from the competent

authority of the other Party shall be submitted to the Committee within 30 days from the request under paragraph 1 to determine that the notification was not necessary. The Committee shall decide within 30 days following the notification according to this paragraph 3.

4. Whenever a Party has failed to notify three times in a product sector – unless the Committee has confirmed that the notification was not necessary – the application of the impacted Chapter of Annex I shall be considered suspended, unless otherwise agreed by the Committee.

ARTICLE 13

Designating Authorities

1. The Parties shall ensure that designating authorities do not have a conflict of interest with conformity assessment bodies they designate. The Parties shall ensure that their designating authorities have the necessary power, competence and sufficient number of competent personnel to designate conformity assessment bodies or withdraw designation, suspend or remove suspension of designated conformity assessment bodies under their respective jurisdiction.

2. For the designation of conformity assessment bodies, the designating authorities shall ensure compliance with the requirements for designation set out in Annex II, subject to the provisions of the relevant Section IV in Annex I. These designating authorities shall observe the same principles when withdrawing designation, suspending or removing suspension.

ARTICLE 14

Notifying Authorities

1. The Parties shall appoint a single authority responsible for notifying designated conformity assessment bodies.

2. The notifying authorities shall exchange upon request in writing information concerning the procedures used to ensure that recognised conformity assessment bodies under their jurisdiction comply with the general principles of designation outlined in Annex II subject to the provisions of the relevant Section IV in Annex I.

3. The notifying authorities shall compare methods used to verify conformity of the bodies with the general principles of designation outlined in Annex II, subject to the provisions of the relevant Section IV in Annex I.

4. Following the recognition of a conformity assessment body by the other Party, the designating Party shall ensure that the information described in Annex II is kept up to date

and shall re-notify such information to the other Party in due time and before the expiry of the accreditation certificate of the recognised conformity assessment body.

5. Each Party shall publish and keep updated in a single website a list of conformity assessment bodies it recognises under this Agreement specifying the scope of the recognition.

ARTICLE 15

Cooperation of Market Surveillance Authorities with Economic Operators

1. If they differ from the designating authority, the competent market surveillance authority shall be listed in Annex I in the relevant Chapter. Amendments shall be notified to the other Party within 60 days.

2. The competent national market surveillance authority of a Party may, on reasoned request, ask the relevant economic operators in the other Party to provide all information and documentation necessary to demonstrate the conformity of a product with the legislation in Annex I, Section I of the corresponding Chapter.

3. That authority may contact the economic operator established within the territory of the other Party either directly or with the assistance of the competent national market surveillance authority of the other Party. It may request economic operators to provide the documentation in a language easily understood by that authority. It may request the economic operators to cooperate on any action taken to eliminate the risks posed by the product or any non-compliance.

ARTICLE 16

Mutual Assistance of Market Surveillance Authorities

1. The Parties shall ensure efficient cooperation and exchange of information between their market surveillance authorities. The market surveillance authorities of the Parties shall cooperate. They shall give each other assistance on an adequate scale for the purposes of market surveillance by supplying information or documentation on products, including concerning economic operators based in the United Kingdom or in Switzerland.

2. Where the market surveillance authorities of a Party have found that a product covered by this Agreement does not comply with requirements laid down in its legislation in Annex I, Section I of the corresponding Chapter, they may take all appropriate measures and if they consider that the product's non-compliance may also extend to or originate from the other Party, they shall inform the market surveillance authority of the other Party without undue delay taking into account the risk presented by the product. Information shall include available details, in particular:

- the data necessary for the identification of the non-compliant product;

- the product's origin;

- the nature of the non-compliance alleged and the risk involved;

- the nature and duration of the national measures taken;

- the arguments put forward by the relevant economic operator;

- the results of the evaluation and of the actions which they have required the economic operator to take; and

- any appropriate measures taken to prohibit or restrict the products being made available on their national market, to withdraw the product from that market or to recall it.

3. The other Party shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

4. Should either Party disagree with the national measure in paragraph 2, it shall inform the Committee of its objections within three months of the receipt of the information.

Where objections are raised by a Party against a measure taken by the other Party, the Committee shall without delay review the national measure. The Committee shall also consult the relevant market surveillance authorities to facilitate transparency and the finding of mutually acceptable solutions.

If following these discussions the objecting Party still disagrees with the national measure, this disagreement shall be added to the list of differences referred to in Article 11 paragraph 4. This shall not prevent the market surveillance authorities from taking the national measure.

5. Where the market surveillance authority of the United Kingdom or Switzerland finds that, although a product that an economic operator has made available on the United Kingdom and on the Swiss market is in compliance with the legislation referred to in Annex I, Section I of the corresponding Chapter, it nevertheless presents a risk for the health or safety of persons or animals, property, environment or national security, it may take all appropriate measures and shall immediately inform the Committee and the relevant market surveillance authority of the other Party. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

Where objections are raised by a Party against a measure taken by the other Party, that Party may forward the issue to the Committee pursuant to paragraph 4.

6. Nothing in this Article shall require the Parties to disclose information regarding sensitive personal data, in particular data in relation to ongoing administrative or criminal proceedings and sanctions.

ARTICLE 17

Joint Committee

1. A Joint Committee («Committee») is hereby established. It shall be composed of representatives of the Parties. It shall be responsible for the management and monitoring of the good functioning of this Agreement. To that end, it shall issue recommendations and take decisions in the circumstances provided for in this Agreement. It shall adopt its decision by mutual agreement.

2. The Committee shall establish its own rules of procedure, which shall include provisions on the convening of meetings, the appointment of the chairman and the chairman's term of office.

3. The Committee shall meet as and when necessary and at least once a year unless the Parties agree otherwise. Either Party may request the convening of a meeting. The Committee may meet in person or by other means.

4. The Committee may consider any matter related to this Agreement. In particular, it shall be responsible for:

a. deciding on verification and the future status of conformity assessment bodies in accordance with Article 7;

b. taking the necessary action in accordance with Article 11;

c. verifying and deciding on missing notifications in accordance with Article 12;

d. consulting with market surveillance authorities on mutual assistance in accordance with Article 16;

e. considering disputes in accordance with Article 20.

5. The Committee may modify the Annexes to this Agreement.

ARTICLE 18

Confidentiality

1. Information exchanged among the Parties may not be used for purposes other than those envisaged by this Agreement.

2. Each Party shall treat the information obtained pursuant to Articles 15 and 16 as confidential. This paragraph shall not prevent disclosure of information as required by a Party's laws and regulations. In such a situation, a Party shall inform the other Party, giving reasonable notice before it discloses such information.

3. Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Agreement which is of the kind covered by the obligation of professional secrecy.

ARTICLE 19

Implementation of the Agreement

1. The Parties shall cooperate with a view to ensuring the satisfactory application of the legislative, regulatory and administrative provisions listed in Annex I.

2. The designating authorities shall ascertain that recognised conformity assessment bodies under their jurisdiction are observing the general principles of designation listed in Annex II, subject to the provisions listed in the relevant Section IV in Annex I.

3. The recognised conformity assessment bodies may be requested to cooperate to ensure the good functioning of this Agreement.

ARTICLE 20

Dispute Settlement

Each Party may refer any dispute relating to the interpretation or application of this Agreement to the Committee. The Committee shall endeavour to settle the dispute and must be supplied with any information which may facilitate a thorough examination of the situation with a view to finding an acceptable solution. For that purpose, the Committee shall consider every possible means of maintaining the good functioning of this Agreement.

ARTICLE 21

Agreements with Third Countries

1. The Parties hereby agree that mutual recognition agreements concluded by either Party with a country that is not party to this Agreement shall in no circumstances entail an obligation upon the other Party in terms of the acceptance of reports, certificates, authorisations or other results of conformity assessments issued by conformity assessment bodies in that third country, unless there is an explicit agreement between the Parties.

2. Upon request of a Party, the Parties shall without undue delay negotiate an arrangement extending to each other treatment related to this Agreement that each Party has granted to a third Party.

ARTICLE 22

Annexes

The Annexes to this Agreement constitute integral parts thereof.

ARTICLE 23

Territorial Application

1. This Agreement shall apply to the territory of the United Kingdom, and to the territory of Switzerland, in accordance with international law.

2. For as long as the Protocol on Ireland/Northern Ireland to the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, signed in London and Brussels on 24 January 2020 (the «Protocol») is in force, nothing in this Agreement shall preclude the United Kingdom from adopting or maintaining measures, or refraining from doing so, further to the Protocol, and amendments thereto and subsequent agreements replacing parts thereof, provided that such measures, or the absence of such measures, are not used as a means of arbitrary or unjustified discrimination against the other Party or as a disguised restriction on trade.

ARTICLE 24

Review

The Parties shall commence a review of this Agreement no later than one year after its entry into force with a view to considering the addition of further product sectors.

ARTICLE 25

Amendment and Modification

1. The Parties may agree, in writing, to amend this Agreement. An amendment made under this Article shall enter into force on the first day of the second month following the later of the Parties' notifications that they have completed their respective internal procedures, or on such other date as the Parties may agree.

2. The Committee may modify the Annexes to this Agreement according to Article 17.

ARTICLE 26

Suspension

Where a Party establishes that the other Party fails to comply with the conditions of this Agreement, it may, after consulting the Committee, suspend the application of the impacted chapters of Annex I in full or in part. Suspension shall be indicated on the lists referred to in Article 14 paragraph 5.

ARTICLE 27

Safeguard Clause

1. A Party that has challenged the competence of a recognised conformity assessment body in accordance with Article 7, may refuse to accept the results of that body's conformity assessment activities where there is an urgent risk for the health or safety of persons or to animals or property until the challenge is resolved.

2. Notwithstanding Article 9 paragraph 1, a Party that no longer recognises reports, certificates, authorisations and other results of conformity assessment procedures issued by a conformity assessment body may refuse to accept the results of that body's conformity assessment activities, before the date its recognition was suspended or withdrawn, where that Party can demonstrate that there is an urgent risk for the health or safety of persons or to animals or property.

ARTICLE 28

Acquired Rights

1. The Parties shall continue to recognise reports, certificates, authorisations and other results of conformity assessments issued in accordance with, and prior to the expiry of, this Agreement, provided that the request for conformity evaluation was made before the notice of non-renewal or denunciation was given.

2. In the sectors covered by this Agreement, the Parties shall continue to recognise reports, certificates and other results of conformity assessments issued in accordance with the measures in place from 31 December 2020 to 31 December 2022 until their expiry, in line with the provisions of this Agreement.

ARTICLE 29

Entry into Force and Duration

1. This Agreement shall be ratified or approved by the Parties in accordance with their own procedures. It shall enter into force on the date of receipt of the later of the Parties' notifications confirming completion of their internal procedures. Upon its entry into force, it will replace the Agreement between the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland on the mutual recognition of conformity assessments of 17 November 2022.

2. This Agreement shall be concluded for a period of five years. Either party may request in writing at least 6 months before the expiration of that initial period the extension of this Agreement.

3. Notwithstanding paragraph 2, the United Kingdom or Switzerland may denounce this Agreement in full or in part by a six months' written notice to the other Party.

4. The provisions of this Agreement shall prevail over provisions in the Trade Agreement between the United Kingdom of Great Britain and Northern Ireland and the Swiss Confederation of 11 February 2019, to the extent that the same subject matter is governed by this Agreement.

IN WITNESS WHEREOF the undersigned, duly authorised thereto by their respective Governments, have signed this Agreement.

Done at Bern on the Eleventh of December 2025, in two originals, each in the English and French languages, both texts being equally authentic. In the event of inconsistency, the English language text shall prevail.

For the United Kingdom of Great Britain and Northern Ireland:

JAMES SQUIRE

For the Swiss Confederation:

IVO GERMANN

ANNEX I

Product sectors
This Annex is divided up into the following Chapters by sector:

Chapter 1 **Electrical equipment and electromagnetic compatibility**
Chapter 2 **Measuring instruments**
Chapter 3 **Radio equipment**
Chapter 4 **Transportable pressure equipment**
Chapter 5 **Noise emitting equipment for use outdoors**
Chapter 6 **Motor vehicles**
Chapter 7 **Good laboratory practice (GLP)**
Chapter 8 **Medicinal products GMP inspection and batch certification**

Chapter 1 Electrical equipment and electromagnetic compatibility

Section I Legislative, regulatory and administrative provisions

Switzerland Federal Law of 24 June 1902 concerning the electrical weak and heavy current installations (RO 19 252 and RS 4 798), as last amended on 22 March 2019 (RO **2020** 6159).

Ordinance of 30 March 1994 on electrical weak current installations (RO **1994** 1185), as last amended on 20 April 2016 (RO **2016** 119).

Ordinance of 30 March 1994 on electrical heavy current installations (RO **1994** 1199), as last amended on 3 April 2019 (RO **2019** 1363).

Ordinance of 25 November 2015 on electrical low voltage equipment (OMBT, RO **2016** 105), as last amended on 24 November 2021 (RO **2021** 822).

Ordinance of 25 November 2015 on electromagnetic compatibility (OCEM, RO **2016** 119), as last amended on 18 November 6137).

Ordinance of 25 November 2015 on Telecommunications Equipment (OIT) (RO **2016** 179), as last amended on 1 October 2021 (RO **2021** 589).

United Kingdom The Electrical Equipment (Safety) Regulations 2016 (SI 2016/1101) (as amended).

The Electromagnetic Compatibility Regulations 2016 (SI 2016/1091) (as amended).

Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	**Designating authority (Electromagnetic compatibility)** Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail: info@bakom.admin.ch

Authority responsible for market surveillance information sharing UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	**Authority responsible for market surveillance information sharing (Electromagnetic compatibility)** Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail: faa@bakom.admin.ch
Authority responsible for market surveillance information sharing (Electrical safety) UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	**Authority responsible for market surveillance information sharing (Electrical safety)** Federal Inspectorate for Heavy Current Installations Market Surveillance Luppmenstrasse 1 CH-8320 Fehraltorf Switzerland Phone: +41 58 595 18 18 e-mail: info@esti.admin.ch

Section IV Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

Section V Supplementary provisions

Chapter 2 Measuring instruments

Section I Legislative, regulatory and administrative provisions
Switzerland Federal Law of 17 June 2011 on metrology (RO **2012** 6235).

Ordinance of 23 November 1994 on units measurement (RO **1994** 3109), as last amended on 20 May 2019 (RO **2019** 1133).

Ordinance of 15 February 2006 concerning measuring instruments (RO **2006** 1453), as last amended on 25 November 2015 (RO **2015** 5835).

Ordinance of the Federal Ministry of Justice and Police of 16 April 2004 on non-automatic weighing instruments (RO **2004** 2093), as last amended on 5 December 2015 (RO **2016** 5225).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments of length (RO **2006** 1433), as last amended on 24 August 2020 (RO **2020** 3759).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measure of volume (RO **2006** 1525), as last amended on 25 November 2015 (RO **2016** 245).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring systems for liquids other than water (RO **2006** 1533) as last amended on 20 October 2020 (RO **2020** 4625).

Ordinance of the federal Ministry of Justice and Police of 19 March 2006 on automatic weighing instruments (RO **2006** 1545), as last amended on 5 December 2016 (RO **2016** 5225).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on instruments for thermal energy (RO **2006** 1569), as last amended on 7 December 2012 (RO **2012** 7183).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for gas quantities (RO **2006** 1591), as last amended on 7 December 2012 (RO **2012** 7183).

Ordinance of the Federal Ministry of Justice and Police of 19 March 2006 on measuring instruments for exhaust gases of combustion engines (RO **2006** 1599), as last amended on 4 March 2021 (RO **2021** 147).

Ordinance of the Federal Ministry of Justice and Police of 26 August 2015 on measuring instruments for the electrical energy and power (RO **2015** 3085), as last amended on 31 October 2017 (RO **2017** 7183).

Ordinance of the Federal Ministry of Justice and Police of 15 August 1986 on weights (RO **1986** 2022), as last amended on 7 December 2012 (RO **2012** 7183).

Ordinance of the Federal Ministry of Justice and Police of 5 November 2013 on taximeters (RO **2013** 4333), as last amended on 19 November 2014 (RO **2014** 4547).

Ordinance of 5 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RO **2012** 7245), as last amended on 30 October 2019 (RO **2019** 3493).

Ordinance of the Federal Ministry of Justice and Police of 10 September 2012 on the declaration of quantities for unpackaged and prepackaged products (RO **2012** 5301), as last amended on 11 November 2019 (RO **2019** 4273).

United Kingdom The Measuring Instrument Regulations 2016 (SI 2016/1153) (as amended).

The Non-automatic Weighing Instruments Regulations 2016 (SI 2016/1152) (as amended).

Section II Conformity assessment bodies
Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	**Designating authority** Federal Department of Justice and Police FDJP General Secretariat, Legal Service Federal Palace, West Wing 3003 Berne Switzerland Phone +41 58 462 21 11 e-mail: info@gs-ejpd.admin.ch
Authority responsible for market surveillance information sharing UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	**Authority responsible for market surveillance information sharing** Federal Institute of Metrology Surveillance and Metrological Supervision Lindenweg 50 3003 Berne-Wabern Switzerland Phone +41 58 387 01 11 e-mail: info@metas.ch

Section IV Special rules relating to the designation of conformity assessment bodies
For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

Section V Supplementary provisions

1. The conformity mark shall indicate the number of the conformity assessment body according to its legislation as well as the country code in which the conformity assessment body is domiciled.

2. The conformity mark required by the legislation of Switzerland according to Article 1 paragraph 2 is the Swiss marking as specified in Annex 2 of the Ordinance of the Federal Ministry of Justice and Police of 26 August 2015 on measuring instruments for the electrical energy and power.

Chapter 3 Radio equipment

Section I Legislative, regulatory and administrative provisions

Switzerland Federal Law of 30 April 1997 on Telecommunications (LTC) (RO **1997** 2187), as last amended on 22 March 2019 (RO **2020** 6159).

Ordinance of 25 November 2015 on Telecommunication Equipment (OIT) (RO **2016** 179), as last amended on 18 November 2020 (RO **2020** 6213).

Ordinance of 9 March 2007 on Telecommunication Services (RO **2007** 945), as last amended on 18 November 2020 (RO **2020** 6183).

Ordinance of 26 May 2016 of the Federal Office of Communications (OFCOM) on Telecommunications Equipment (RO **2016** 1673), as last amended on 21 November 2017 (RO **2017** 7137).

United Kingdom The Radio Equipment Regulations 2017 (SI 2017/1206) (as amended).

Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	**Designating authority** Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail:
Authority responsible for market surveillance information sharing UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201	**Authority responsible for market surveillance information sharing** Federal Office of Communications Market Access and Conformity (MK) Zukunftstrasse 44 P.O. Box 256 2501 Biel Switzerland Phone: +41 58 460 55 11 e-mail: faa@bakom.admin.ch

ukproductsafetycp@beis.gov.uk	

Section IV Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

Section V Supplementary provisions

Chapter 4 Transportable pressure equipment

Section I Legislative, regulatory and administrative provisions

Switzerland Federal Law of 12 June 2009 on product safety (RO **2010** 2573).

Ordinance of 19 May 2010 on product safety (RO **2010** 2583), as last amended on 1 October 2021 (RO **2021** 589).

Ordinance of 31 October 2012 relating to the placing on the market of dangerous goods receptacles and the market surveillance (RO **2012** 6607), as last amended on 25 May 2016 (RO **2016** 1859).

Ordinance of 29 November 2002 on the transport of dangerous goods by road (RO **2002** 4212), as last amended on 20 September 2022 (RO **2022** 531).

Ordinance of 31 October 2012 on the transport of dangerous goods by rail and cableway, as last amended on 4 December 2020(RO **2020** 6155).

United Kingdom The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009/1348) (as amended).

Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority The Vehicle Certification Agency (VCA) The VCA Dangerous Goods Office Cleeve Road Leatherhead Surrey KT22 7NF tanks@vca.gov.uk	**Designating authority** Federal Department of the Environment, Transport, Energy and Communications 3003 Berne Switzerland Phone: +41 (0)58 462 57 11 e-mail: info@gs-uvek.admin.ch
Authority responsible for market surveillance information sharing Health and Safety Executive Redgrave Court Merton Road Bootle Merseyside L20 7HS	**Authority responsible for market surveillance information sharing** Federal Office of Transport Safety Division Environment Section 3003 Berne Switzerland Phone: +41 (0)58 462 57 11 e-mail:umwelt@bav.admin.ch

Section IV Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

Section V Supplementary provisions

1. The conformity mark shall indicate the number of the conformity assessment body according to its legislation as well as the country code in which the conformity assessment body is domiciled.

2. In addition to Article 2, owners and operators are also economic operators.

Chapter 5 Noise emitting equipment for use outdoors

Section I Legislative, regulatory and administrative provisions

Switzerland Ordinance of 22 May 2007 on the noise emission in the environment by equipment for use outdoors (RO **2007** 2827), as last amended on 25 November 2019 (RO **2019** 4253).

United Kingdom The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001 (SI 2001/1701) (as amended).

Section II Conformity assessment bodies

Each Party shall maintain an up-to-date list online of recognised conformity assessment bodies for its jurisdiction as well as of recognised conformity assessment bodies designated by the other Party.

Section III Designating authorities and authorities responsible for market surveillance information sharing

UK	SWITZERLAND
Designating authority Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom approvedbodies@beis.gov.uk	**Designating authority** Federal Office for the Environment FOEN Aircraft, Industrial and Shooting Noise Section 3003 Bern Switzerland Phone.: +41 58 462 93 11 e-mail: noise@bafu.admin.ch
Authority responsible for market surveillance information sharing UK Product Safety Contact Point Office for Product Safety and Standards Department for Business, Energy and Industrial Strategy (BEIS) 1 Victoria Street London SW1H OET United Kingdom +44 121 345 1201 ukproductsafetycp@beis.gov.uk	**Authority responsible for market surveillance information sharing** Federal Office for the Environment FOEN Aircraft, Industrial and Shooting Noise Section 3003 Bern Switzerland Phone: +41 58 462 93 11 e-mail: noise@bafu.admin.ch

Section IV Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, designating authorities shall comply with the general principles contained in Annex II to this Agreement and any assessment criteria set out in the legislative, regulatory and administrative provisions, as set out in Section I, applicable to the designating authorities.

Section V Supplementary provisions

In addition to the Swiss marking on the guaranteed sound power level or the UK marking, the number of the conformity assessment body according to its legislation as well as the country code in which the conformity assessment body is domiciled shall be indicated.

Chapter 6 Motor vehicles

Section I Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

Switzerland Ordinance of 19 June 1995 relating to the technical requirements for power-driven transportation vehicles and their trailers (RO 1995 4145), as amended until 16 November 2016 (RO 2016 5195).

Ordinance of 19 June 1995 relating to the type approval of road vehicles (RO 1995 3997), as amended until 16 November 2016 (RO 2016 5213) and taking into account amendments accepted according to the procedure described in Section V, paragraph 1.

European Union Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1), as last amended by Regulation (EU) 2015/758 of the European Parliament and of the Council of 29 April 2015 (OJ L 123, 19.5.2015, p. 77), and taking into account the acts listed in Annex IV of Directive 2007/46/EC, as amended until 29 April 2015 (hereinafter together referred to as "Framework Directive 2007/46/EC").

Section II Conformity assessment bodies

The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

Section III Designating authorities

The Committee established under Article 10 of this Agreement shall draw up and keep up to date a list of the designating authorities notified by the Parties.

Section IV Special rules relating to the designation of conformity assessment bodies

For the designation of conformity assessment bodies, the designating authorities shall refer to their respective legislative, regulatory and administrative provisions as listed in section I.

Section V Supplementary provisions

1. Information exchange

The competent type-approval authorities in Switzerland and the Member States shall in particular exchange the information referred to in Article 8(5) to (8) of the Framework Directive 2007/46/EC.

In the event of refusal by Switzerland or a Member State to grant type-approval in accordance with Article 8(3) of the Framework Directive 2007/46/EC, it shall immediately send the other Member States, Switzerland and the Commission a detailed file explaining the reasons for its decision and setting out the evidence for its findings.

2. Recognition of vehicle type-approval

Switzerland shall also recognise vehicle type-approval granted before the entry into force of this Agreement in accordance with Council Directive 70/156/EEC of 6 February 1970 (OJ L 42, 23.2.1970, p. 1), as last amended by Commission Directive 2007/37/EC of 21 June 2007 (OJ L 161, 22.6.2007, p. 60), by the authorities responsible for type-approval where that approval is still valid in the European Union.

The European Union shall recognise Swiss type-approval where Switzerland's requirements are deemed to be equivalent to those of the Framework Directive 2007/46/EC.

The recognition of a type-approval issued by a Party shall be suspended should that Party fail to adapt its legislation to all the European Union type-approval legislation in force. The recognition of type-approval for national small series motor vehicles issued by a Party may be suspended on the basis of overriding public interests, such as security or environmental concerns.

3. Safeguard clauses

Vehicles, systems, components or separate technical units in compliance with the applicable legislation

1. If a Member State or Switzerland finds that new vehicles, systems, components or separate technical units, albeit in compliance with the applicable requirements or properly marked, present a serious risk to road safety, or seriously harm the environment or public health, that State may, for a maximum period of six months, refuse to register such vehicles or to permit the sale or entry into service in its territory of such vehicles, components or separate technical units.

In such cases, the Member State concerned or Switzerland shall immediately notify the manufacturer, the other Member States, Switzerland and the Commission accordingly, stating the reasons on which its decision is based.

2. The Parties shall hold consultations as soon as possible and, in particular, with the respective approval authorities that granted the type-approval. The Committee shall be kept informed and, where necessary, shall hold appropriate consultations with the view to reaching a settlement.

Vehicles, systems, components or separate technical units not in conformity with the approved type

1. If a Member State or Switzerland which has granted a type-approval finds that new vehicles, systems, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the type it has approved, it shall take the necessary measures, including, where necessary, the withdrawal of type-approval, to ensure that production vehicles, systems, components or separate technical units, as the case may be, are brought into conformity with the approved type. The approval authority of that Member State or Switzerland shall advise the approval authorities of the other Member States and/or Switzerland of the measures taken.

2. For the purposes of paragraph 1, deviations from the particulars in the type-approval certificate or the information package shall be deemed to constitute failure to conform to the approved type.

A vehicle shall not be deemed to deviate from the approved type where tolerances are permitted by the relevant regulatory acts and those tolerances are respected.

3. If a Member State or Switzerland demonstrates that new vehicles, components or separate technical units accompanied by a certificate of conformity or bearing an approval mark do not conform to the approved type, it may ask the Member State or Switzerland which granted the type-approval to verify that vehicles, systems, components or separate technical units in production continue to conform to the approved type. On receipt of such a request, the Member State concerned or Switzerland shall take the requisite action as soon as possible and in any case within six months of the date of the request.

4. The approval authority shall request the Member State or Switzerland which granted the system, component, separate technical unit or incomplete vehicle type-approval to take the necessary action to ensure that vehicles in production are brought back into conformity with the approved type in the following cases:

(a) in relation to a vehicle type-approval, where the non-conformity of a vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit;

(b) in relation to a multi-stage type-approval, where the non-conformity of a completed vehicle is attributable exclusively to the non-conformity of a system, component or separate technical unit being part of the incomplete vehicle, or of the incomplete vehicle itself.

On receipt of such a request, the Member State concerned or Switzerland shall take the requisite action, if necessary in conjunction with the Member State making the request or Switzerland, as soon as possible and in any case within six months of the date of the request. Where a failure to conform is established, the approval authority of the Member State or Switzerland which granted the system, component or separate technical unit type-approval or the approval of the incomplete vehicle shall take the measures set out in paragraph 1.

5. The approval authorities shall inform each other within 20 working days of any withdrawal of type-approval and of the reasons there for.

6. If the Member State or Switzerland that granted type-approval disputes the failure to conform notified to it, the Member States concerned and Switzerland shall endeavour to settle the dispute. The Committee shall be kept informed and, where necessary, shall hold appropriate consultations with a view to reaching a settlement.

Chapter 7 Good laboratory practice (GLP)

Scope and coverage

The provisions of this Chapter shall apply to the testing of chemicals according to GLP, being either substances or preparations, covered by the legislative, regulatory and administrative provisions listed in Section I**.** For the purposes of this Chapter the provisions of Article 4 of this Agreement concerning origin do not apply.

Unless specific definitions are given, the definition of terms in the "OECD Principles of Good Laboratory Practice" as revised in 1997 [ENV/MC/CHEM(98)17] based on OECD Council Decision of 12 May 1981 [C(81)30(Final)] amended on 26. November 1997 [C(97) 186 FINAL], as well as Council Decision-Recommendation of 2 October 1989 [C(89)87(Final)] amended on 9 March 1995 [C(95)8(Final)] and GLP Consensus documents, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, and all amendments made thereto, shall apply.

The Parties recognise the equivalence of each other's compliance monitoring programmes on Good Laboratory Practice that are in accordance with the OECD decisions and recommendations mentioned above and the legislative, regulatory and administrative procedures and principles listed in section IV.

The Parties mutually accept studies and data generated therefrom, produced by the test facilities of the other Party provided they participate in the Good Laboratory Practice compliance monitoring programme of that Party in accordance with the principles and provisions stated above.

The Parties mutually accept the conclusions of study audits and test facility inspections performed by the GLP monitoring authorities.

Section I Legislative, regulatory and administrative provisions

With regard to the testing of chemicals according to GLP, the relevant parts of the legislative, regulatory and administrative provisions listed below shall apply.

Provisions covered by Article 1 paragraph 2

Switzerland	Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 20 June 2014 (RO 2016 689).
	Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 20 June 2014 (RO 2016 689).
	Ordinance of 5 June 2015 on protection against dangerous substances and preparations (RO 2015 1903), as last amended on 22 March 2017 (RO 2017 2593).
	Ordinance of 18 May 2005 on biocidal products (RO 2005 2821) as last amended on 28 March 2017 (RO 2017 2441).

Ordinance of 12 May 2010 on the authorisation of plant protection products (RO 2010 2331), as last amended on 22 March 2017 (RO 2017 2593).

Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 21 June 2013 (RO 2013 4137).

Ordinance of 17 October 2001 on medicinal products (RO 2001 3420), as last amended on 23 March 2016 (RO 2016 1171).

European Union *Food and feed:*

Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1-65).

Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 64, 11.3.2011, p. 15-24).

3. Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1–48).
New and existing chemicals:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1-851), as last amended by Commission Regulation (EU) No 348/2013 of 17 April 2013 (OJ L 108, 18.4.2013, p. 1-5).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No

1907/2006 (OJ L 353, 31.12.2008, p. 1-1355), as last amended by Commission Regulation (EU) No 944/2013 of 2 October 2013 (OJ L 261, 3.10.2013, p. 5-22).
Medicinal products:

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ L 299, 27.10.2012, p. 1-4). NB: Directive 2001/83/EC has been amended and the GLP requirement is now contained in the Introduction and General Principles chapter of Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46).

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1–76).

Veterinary medicinal products:

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1), as last amended by Commission Directive 2009/9/EC of 10 February 2009 (OJ L 44, 14.2.2009, p. 10-61).

Plant protection products:

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1-50).

Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1-84).

Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85-152).

Biocidal products:

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1-123).

Cosmetic products:
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59-209).

Detergents:
Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1-35).

Medical Devices:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1–175).

Section II Conformity assessment bodies

For the purpose of this Sectoral Chapter, "Conformity Assessment Bodies" means the test facilities recognised under each Party's GLP monitoring programme.
The Committee established under Article 10 of this Agreement shall draw up and keep up to date, according to the procedure described in Article 11 of the Agreement, a list of the conformity assessment bodies.

Section III Designating authorities

For the purpose of this Sectoral Annex, the term “Designating Authorities” means the GLP Monitoring Authorities of the Parties. The Contact Details of the GLP Monitoring Authorities of the Member States of the European Union and of Switzerland can be found in the websites indicated below.

For the United Kingdom:
http://www.gov.uk/guidance/good-laboratory-practice-glp-for-safety-tests-on-chemicals

For Switzerland:
http://www.glp.admin.ch/

Section IV Special rules relating to the designation of conformity assessment bodies

For the purpose of this Sectoral Chapter, "designation of conformity assessment bodies" means the procedure by which the GLP Monitoring Authorities recognise that test facilities comply with the GLP principles. To this end they shall apply the principles and procedures

of their provisions listed below, that are recognised to be equivalent and in conformity with the aforementioned OECD Council Acts C(81)30 Final and C(89)87 (Final):

Switzerland	Federal law of 7 October 1983 on the protection of the environment (RO 1984 1122), as last amended on 22 March 2013 (FF 2012 8671). Federal law of 15 December 2000 on protection against dangerous substances and preparations (RO 2004 4763), as last amended on 17 June 2005 (RO 2006 2197). Federal law of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 21 June 2013 (RO 2013 4137). Ordinance of 18 May 2005 on Good Laboratory Practice (RO 2005 2795) as last amended on 11 November 2012 (RO 2012 6103).
United Kingdom	Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44). Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28).

Section V Supplementary provisions

1. Information exchange

In accordance with Article 10 of this Agreement, the Parties in particular provide each other at least annually with a list of the test facilities which, in the light of the results of the inspections and study audits, conform to Good Laboratory Practice, as well as of the dates of inspection or audit and their compliance status, if this information is not provided through the OECD Working Group on Good Laboratory Practice.

In accordance with Article 17 of the Agreement, the Parties shall inform each other in a timely manner when a test facility coming under the terms of section II of this sectoral Chapter which states that it applies Good Laboratory Practice fails to conform to such practice to an extent which may jeopardise the integrity or authenticity of any such studies it conducts, if this information is not provided through the OECD Working Group on Good Laboratory Practice.

The Parties shall supply each other with any additional information on a test facility inspection or study audit in response to a reasonable request from the other Party

2. Test Facility Inspections

Each Party may request further test facility inspection or study audits if there is a documented doubt as to whether a test was conducted in accordance with Good Laboratory Practice.

If, in exceptional cases, doubts persist and the requesting Party can justify special concern, it may, in accordance with Article 8 of the Agreement, designate one or more experts of its GLP monitoring authorities to participate in a laboratory inspection or the audit of a study conducted by the authorities of the other Party.

3. Confidentiality

In conformity with Article 13 of the Agreement, the Parties shall keep confidential any information brought to their knowledge pursuant to this Sectoral Chapter or that came to their knowledge in the framework of participation in an inspection or study audit and which falls within the definition of a trade secret or confidential commercial or financial information.
They shall treat such information with at least the same confidentiality as that accorded to it by the providing Party and ensure that any authority to whom the information is transmitted treats it in the same way.

4. Cooperation

Based on Article 9 of the Agreement, each Party may, on request, participate as an observer in an inspection of a test facility conducted by the authorities of the other Party with the consent of the
test facility concerned in order to maintain a continuing understanding of the other Party's inspection procedures.

Chapter 8 Medicinal products GMP inspection and batch certification

Scope and coverage

The provisions of this Sectoral Chapter cover all medicinal products which are industrially manufactured and to which Good Manufacturing Practice (GMP) requirements apply.

For medicinal products covered by this Chapter, each party shall recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the competent authorities of the other Party. This includes that each Party recognises conclusions of inspections of manufacturers in third countries carried out by the relevant inspection services of the other Party, inter alia within the framework of the European Directorate for the Quality of Medicines & HealthCare (EDQM).

The Parties shall cooperate in order to achieve the best use of inspection resources by an appropriate burden sharing.

The manufacturer's certification of the conformity of each batch to its specifications shall be recognised by the other Party without re-control at import. To the products imported from a third country and further exported to the other Party this provision applies only (1) if each batch of the medicinal products has been subject to the re-control in the territory of one of the Parties, and (2) if the manufacturer in the third country has been subject to the inspection by the competent authority of either Party of which the outcome has been that for the products or products category the manufacturer complies with Good Manufacturing Practice. If the above conditions are not met, each Party can require a re-control in its territory.

In addition, official batch releases carried out by an authority of the exporting Party will be recognised by the other Party.

"Medicinal products" means all products regulated by pharmaceutical legislation in the European Union and Switzerland as listed in Section I of this Chapter. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radio-pharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs and, where appropriate, vitamins, minerals, herbal remedies and homeopathic medicinal products.

"GMP" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation and products specifications. For the purpose of this Chapter it includes the system whereby the manufacturer receives the specification of the product and the process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification.

With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request, for the purpose of this Agreement, an inspection

be made by the locally competent inspection service. This provision shall apply i.a. to the manufacture of active pharmaceutical ingredients, intermediate products and investigational medicinal products, as well as to pre-marketing inspections. Operational arrangements are detailed under section III, paragraph 3.

Certification of manufacturers
At the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products shall certify that the manufacturer:

– is appropriately authorised to manufacture the relevant medicinal product, or to carry out the relevant specified manufacturing operation

– is regularly inspected by the authorities

– complies with the national GMP requirements recognised as equivalent by the two parties, and which are listed in Section I of this Chapter. Should different GMP requirements be used as reference, this is to be mentioned in the certificate.

For inspections in third countries, at the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for the inspection shall certify that the manufacturer complies or does not comply with the GMP requirements recognised as equivalent by the two Parties, and which are listed in Section I of this Chapter.

The certificates shall also identify the site(s) of manufacture (and contract quality control laboratories, if any) and the date of the inspection.
Certificates shall be issued expeditiously, and the time taken should not exceed thirty calendar days. In exceptional cases, i.e. when a new inspection has to be carried out, this period may be extended to ninety days.

Batch certification
Each batch exported shall be accompanied by a batch certificate established by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active ingredients and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate shall attest that the batch meets its specifications and shall be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer shall take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate shall detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It shall contain a statement that the batch processing and packaging records were reviewed and found in conformity with GMP. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Union the "qualified person" referred to in Article 48 of Directive 2001/83/EC and Article 52 of Directive 2001/82/EC, and in Switzerland the “responsible person” referred to in Articles 5 and 10 of the Ordinance on establishment licences.

Official Batch Release

When an official batch release procedure applies, official batch releases carried out by an authority of the exporting Party (listed in section II) will be recognised by the other Party on the basis of Official Control Authority Batch Release network standards. Further to Article 10 of this Agreement, each Party shall inform the other Party when it expects that its product requirements shall deviate from Official Control Authority Batch Release network standards. In this case, recognition under this paragraph may be suspended and the matter will be referred to the Committee. Where there is an overriding public health concern, a Party may test a product falling under the scope of this paragraph provided that notice and justification have been given to the other party. The manufacturer shall provide the certificate of the official batch release.

For the European Union, the official batch release procedure is specified in document "Control Authority Batch Release of Vaccination and Blood Products, 2001" or subsequent versions and in different specific batch release procedures. For Switzerland, the official batch release procedure is specified in Article 17 of the Federal Law on medicinal products and medical devices and in Articles 18-21 of the Ordinance of the Swiss Agency for Therapeutic Products on the requirements for the marketing authorisation of medicinal products.

Section I Legislative, regulatory and administrative provisions

Provisions covered by Article 1 paragraph 2

Switzerland	Federal Act of 15 December 2000 on medicinal products and medical devices (RO 2001 2790), as last amended on 1 January 2014 (RO 2013 4137).
	Ordinance of 17 October 2001 on the establishment of licences (RO 2001 3399), as last amended on 1 May 2016 (RO 2016 1171).
	Ordinance of the Swiss Agency for Therapeutic Products of 9 November 2001 on the requirements for the marketing authorisation of medicinal products (RO 2001 3437), as last amended on 1 May 2016 (RO 2016 1171).
	Ordinance of 20 September 2013 on clinical trials in human research, (RO 2013 3407) as last amended on 1 May 2017 (RO 2017 2439).
European Union	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1) as last amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L316 of 14.11.2012, p. 38).

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 of 28.11.2001, p. 67) as last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299 of 27.10.2012, p. 1).

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1) as last amended by Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83 as regards variations to the terms of marketing authorisations for medicinal products (OJ L168, 30.6.2009, p. 33-34)

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70) and Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community (OJ L 92, 7.4.1990, p. 42–48).

Guidelines on Good Distribution Practice of medicinal products for human use (OJ C 343, 23.11.2013, p. 1)

EudraLex Volume 4 — Medicinal Products for Human and Veterinary Use: EU Guidelines to Good Manufacturing Practice (published on website of the European Commission)

Directive 2001/20/EC of 04 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34) and Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on

medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.05.2014, p. 1-76).

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1).

Section II Conformity assessment bodies

For the purpose of this Chapter "Conformity Assessment Bodies" means the official GMP inspection services of each Party.

The list of the official GMP Inspection Services of the Member States of the European Union and of Switzerland can be found below.

For conformity assessment bodies of the European Community:

Competent Authorities of the European Union are the following authorities of the Member States of the European Union or authorities succeeding them:

Country	**For medicinal products for human use**	**For medicinal products for veterinary use**
Austria	Austrian Agency for Health and Food Safety / Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	See responsible authority for human medicinal products
Belgium	Federal agency for medicines and health products / Federaal Agentschap voor geneesmiddelen en gezondheidsproducten/ Agence fédérale des médicaments et produits de santé	See responsible authority for human medicinal products
Bulgaria	Bulgarian Drug Agency / ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА	Bulgarian Food Safety Agency/ Българска агенция по безопасност на храните

Cyprus	Ministry of Health - Pharmaceutical Services / Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας	Ministry of Agriculture, Rural Development and Environment-Veterinary Services / Κτηνιατρικές Υπηρεσίες-Υπουργείο Γεωργίας, Αγροτικής Ανάπτυξης και Περιβάλλοντος
Czech Republic	State Institute for Drug Control/ Státní ústav pro kontrolu léčiv (SÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (ÚSKVBL)
Croatia	Agency for Medicinal Products and Medical Devices / Agencija za lijekove i medicinske proizvode (HALMED)	Ministry of Agriculture, Veterinary and Food Safety Directorate / Ministarstvo Poljoprivrede, Uprava za veterinarstvo i sigurnost hrane
Denmark	Danish Medicines Agency/ Laegemiddelstyrelsen	See responsible authority for human medicinal products
Germany	Federal Institute for Drugs and Medical Devices / Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institute (PEI), Federal Institute for Vaccines and Biomedicines / Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel Federal Ministry of Health / Bundesministerium für Gesundheit (BMG)/ Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG) [1]	Federal Office for Consumer Protection and Food Safety / Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Federal Ministry of Food and Agriculture, Bundesministerium für Ernährung und Landwirtschaft
Estonia	State Agency of Medicines / Ravimiamet	See responsible authority for human medicinal products

1 For the purpose of this Annex, and without prejudice to the internal division of competence in Germany on matters falling within the scope of this Annex, ZLG shall be understood as covering all the competent Laender authorities issuing GMP documents and conducting pharmaceutical inspections.

Greece	National Organisation for Medicines / Ethnikos Organismos Farmakon (EOF) - (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ))	See responsible authority for human medicinal products
Spain	Spanish Agency of Medicines and Medical Devices / Agencia Española de Medicamentos y Productos Sanitarios [2]	See responsible authority for human medicinal products
Finland	Finnish Medicines Agency / Lääkealan turvallisuus- ja kehittämiskeskus (FIMEA)	See responsible authority for human medicinal products
France	French National Agency for Medicines and Health Products Safety Agence nationale de sécurité du médicament et des produits de santé (ANSM)	French agency for food, environmental and occupational health safety-*National Agency for Veterinary Medicinal Products/* Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail-Agence Nationale du Médicament Vétérinaire (Anses-ANMV)
Hungary	Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet / National Institute of Pharmacy and Nutrition	National Food Chain Safety Office, Directorate of Veterinary Medicinal Products / Nemzeti Élelmiszerlánc-biztonsági Hivatal, Állatgyógyászati Termékek Igazgatósága (ÁTI)
Ireland	Health Products Regulatory Authority (HPRA)	See responsible authority for human medicinal products
Italy	*Italian Medicines Agency /* Agenzia Italiana del Farmaco	*Direction General for Animal Health and Veterinary Medicinal Products* Ministero della Salute, Direzione Generale della Sanità Animale e dei Farmaci Veterinari

2 For the purpose of this Annex, and without prejudice to the internal division of competence in Spain on matters falling within the scope of this Annex, Agencia Española de Medicamentos y Productos Sanitarios shall be understood as covering all the competent regional authorities issuing GMP documents and conducting pharmaceutical inspections.

Latvia	State Agency of Medicines / Zāļu valsts aģentūra	Assessment and Registration Department of the Food and Veterinary Service/Pārtikas un veterinārā dienesta Novērtēšanas un reģistrācijas departaments
Lithuania	State Medicines Control Agency / Valstybinė vaistų kontrolės tarnyba	State Food and Veterinary Service / Valstybinės maisto ir veterinarijos tarnyba
Luxembourg	Minìstere de la Santé, Division de la Pharmacie et des Médicaments	See responsible authority for human medicinal products
Malta	Medicines Regulatory Authority	Veterinary Medicines and Animal Nutrition section VMANS) (Veterinary Regulation Directorate (VRD) within The Veterinary and Phytosanitary Regulation Department (VPRD)
Netherlands	Healthcare Inspectorate / Inspectie voor de Gezondheidszorg (IGZ)	Medicines Evaluation Board / Bureau Diergeneesmiddelen, College ter Beoordeling van Geneesmiddelen (CBG)/
Poland	The Main Pharmaceutical Inspectorate / Główny Inspektorat Farmaceutyczny (GIF) /	See responsible authority for human medicinal products
Portugal	National Authority of Medicines and Health Products / INFARMED, I.P Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	General Directorate of Food and Veterinary / DGAV - Direção Geral de Alimentação e Veterinária (PT)
Romania	National Agency for Medicines and Medical Devices / Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale	National Sanitary Veterinary and Food Safety Authority / Autoritatea Naţională Sanitară Veterinară şi pentru Siguranţa Alimentelor
Sweden	Medical Products Agency / Läkemedelsverket	See responsible authority for human medicinal products

Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia / Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)	See responsible authority for human medicinal products
Slovak Republic (Slovakia)	State Institute for Drug Control / Štátny ústav pre kontrolu liečiv (ŠÚKL)	Institute for State Control of Veterinary Biologicals and Medicaments / Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (USKVBL)
United Kingdom	Medicines and Healthcare products Regulatory Agency	Veterinary Medicines Directorate

For Swiss conformity assessment bodies:

For all products for human and veterinary use:
http://www.swissmedic.ch/?lang=2

For the official batch release of immunobiological products for veterinary use:
http://www.blv.admin.ch/ivi/index.html?lang=en

Section III Additional provisions

1. Transmission of inspection reports

Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing site or, in case analytical operations are contracted out, of the control site. The request may concern a "full inspection report" or a "detailed report" (see item 2 below). Each party shall deal with these inspection reports with the degree of confidentiality requested by the providing Party.
Parties will ensure that inspection reports are forwarded in no more than thirty calendar days, this period being extended to sixty days should a new inspection be carried out.

2. Inspection reports

A "full inspection report" comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A "detailed report" responds to specific queries about a firm by the other Party.

3. GMP Reference

(a) Manufacturers shall be inspected according to the applicable GMP legislation listed in section I.

(b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting country, the competent inspection service of the Party willing to carry out an inspection of the relevant manufacturing operations shall inspect according to its own GMP or, in the absence of specific GMP requirements, according to the applicable GMP of the importing Party.

For specific products or classes of products (e.g. investigational medicinal products, starting materials not limited to active pharmaceutical ingredients), equivalence of GMP requirements shall be determined according to a procedure established by the Committee.

4. Nature of inspections

(a) Inspections shall routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).

(b) "Product- or process-oriented" inspections (which may be "pre-marketing" inspections as relevant) focus on the manufacture of one or a series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) shall be provided in confidence to the inspectorate.

5. Fees

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees shall not be charged to manufacturers located on the territory of the other Party.

6. Safeguard clause for inspections

Each Party reserves the right to have its own inspection conducted for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party and shall, in accordance with Article 8 of this Agreement, be carried out jointly by the competent authorities of the two Parties. Recourse to this safeguard clause should be an exception.

7. Exchange of information on manufacturing/import authorisations and GMP compliance

The competent authorities of the Parties shall exchange information on the authorisation status of manufacturers and importers and on the outcome of the inspections, in particular by entering authorisations, GMP certificates and information on GMP non-compliance into a publicly available database, or a national or international database accessible to the other Party.

In accordance with the general provisions of this Agreement, the Parties shall exchange any information necessary for the mutual recognition of inspections and operation of this chapter.

The relevant authorities in Switzerland and in the European Union shall also keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult the other before their adoption and shall endeavour to proceed towards their approximation.

8. Inspectors training

In accordance with Article 19 of the Agreement, training sessions for inspectors, organised by the authorities, shall be accessible to inspectors of the other Party. The Parties to the Agreement shall keep each other informed on these sessions.

9. Joint Inspections

In accordance with Article 10 of this Agreement, and by mutual agreement between the Parties, joint inspections may be organised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Committee established under Article 17 of this Agreement.

10. Alert system

Contact points shall be agreed between both Parties to permit authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed.

The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could have public health implications, are communicated to each other with the appropriate degree of urgency.

11. Contact points

For the purpose of this Agreement, the contact points for any technical question, such as exchanges of inspection reports, inspectors training sessions, technical requirements, are:

For the United Kingdom:

The official GMP inspection services listed in Section II above.

For Switzerland

The official GMP inspection services listed in Section II above.

12. Divergence of views

Both Parties shall use their best endeavours to resolve any divergence of views concerning *inter alia* compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Committee as established under Article 10 of this Agreement.

The Joint Declaration on the Mutual Recognition of Good Clinical Practice and Inspections, made by the parties to the Mutual Recognition Agreement, shall apply between the Parties to this Agreement, with the same legal effect, mutatis mutandis, subject to the provisions of this Instrument.

ANNEX II

General rules regarding the designation of conformity assessment bodies

A. General terms and conditions

1. The designating authorities shall remain solely responsible for the competence of the bodies they have designated according to this Agreement. They shall only designate bodies under their jurisdiction.

2. Designating authorities shall designate conformity assessment bodies able to demonstrate that they understand and have the requisite experience and competence to apply the requirements and certification procedures laid down in the legislative, regulatory and administrative provisions of the other Party referred to in Annex I in the relevant Section I, that are applicable to the specific product, product category or sector for which they are designated.

3. Demonstration of technical competence shall cover:

- the conformity assessment body's technical knowledge of the relevant products, processes or services which it is willing to treat;
- the understanding of the technical standards and legislative, regulatory and administrative provisions for which designation is sought;
- the physical capability to perform a given conformity assessment activity;
- the adequate management of the activity concerned; and
- any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed at all times.

4. The technical competence criteria shall be based as far as possible on internationally accepted documents, such as the ISO 17000 series of standards or equivalents as well as on supplemented interpretative documents as appropriate. These documents need to be interpreted to take account of the requirements laid down in the applicable legislative, regulatory and administrative provisions in Annex I in the relevant Section I.

5. The Parties shall encourage harmonisation of designation procedures and coordination of conformity assessment procedures through cooperation between designating authorities, national accreditation bodies and conformity assessment bodies. Cooperation may include coordination meetings, participation in mutual recognition arrangements, and ad hoc working party meetings.

B. System for verification of conformity assessment bodies' competence

6. In order to verify the technical competence of conformity assessment bodies, the authorities concerned may use various procedures ensuring an appropriate level of trust between the Parties. If necessary, a Party shall indicate to the designating authority possible ways of demonstrating competence.

a) Accreditation

7. Accreditation shall constitute a presumption of the technical competence of conformity assessment bodies in relation to the application of the requirements of the other Party provided that the competent accreditation body:

- complies with the relevant international provisions in force (ISO 17000 standards or ISO/IEC guides); and
- is signatory to multilateral arrangements under which it is subject to peer evaluation, in particular International Laboratory Accreditation Cooperation («ILAC») or International Accreditation Forum «IAF») as well as European co-operation for Accreditation («EA»).

8. Where the criteria applicable to conformity assessment bodies require them to assess the conformity of products, processes or services directly to standards or technical specifications, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it enables assessment of those bodies' ability to apply standards or technical specifications. Designation shall be limited to those accredited activities of the conformity assessment body.

9 Where the criteria applicable to conformity assessment bodies require them to assess the conformity of products, processes or services not directly to standards or technical specifications, but to general (essential) requirements, the designating authorities may use accreditation as a presumption of the conformity assessment body's technical competence provided that it incorporates elements which will enable assessment of the capacity of the conformity assessment body (technical knowledge of the product, of its use, etc.) to assess the conformity of the product to those essential requirements. Designation shall be limited to those accredited activities of the conformity assessment body.

b) Other means

10 If there is no accreditation scheme, or the accreditation scheme cannot be used, the authorities concerned shall require the conformity assessment bodies to demonstrate their competence by other means, e.g.:

- participation in regional or international mutual recognition arrangements or certification systems;
- regular peer evaluation, based on clear criteria and conducted with the appropriate expertise;
- aptitude tests; or
- comparison of conformity assessment bodies.

c) Evaluation of the verification system

11 The Parties may define a verification system to evaluate the competence of conformity assessment bodies. Once established, each Party will be invited to check that the system ensures the conformity of the designation process to its own legal requirements. Checks shall focus on the appropriateness and effectiveness of the verification system rather than on the conformity assessment bodies themselves.

d) Notification of a designated conformity assessment body

12 When the Parties submit their proposals to the Committee for inclusion of conformity assessment bodies in the list under Article 14 paragraph 5, they shall provide the following details in respect of each body:

a) its name;
b) its postal address;
c) its e-mail address;
d) the scope of designation, i.e. sectoral Chapter, product categories or products, processes and services covered by the designation (not exceed that body's scope of accreditation);
e) the conformity assessment procedures covered by the designation;
f) the methods used to establish the body's competence;
g) the accreditation certificate and the related scope of accreditation where applicable.

ANNEX III

General rules regarding the national accreditation body

1 The accreditation body shall be technically competent to accredit conformity assessment bodies to assess conformity to the other Party's designated standards and technical regulations within the scope for which recognition is requested.

2 The Parties encourage their nationally appointed accreditation bodies to create and manage actively a regular cooperative dialogue on accreditation and other relevant conformity assessment issues. This will enable the dissemination of best practices in accredited conformity assessment, including the understanding and use of new technologies where appropriate. It will also support the notification of conformity assessment bodies under this Agreement and the mutual understanding of the regulatory requirements of the Parties.

3 As members of European co-operation for Accreditation, the national accreditation bodies of the Parties shall undergo periodic peer evaluation by European co-operation for Accreditation, or its successor institution.

4 One Party may challenge the competence of an accreditation body of the other Party on the grounds that any of the conditions required under paragraph 1 – 3 is no longer met. The Party shall immediately notify the other Party of its challenge and the Parties shall cooperate to promptly resolve the challenge.

5 If the challenge is not resolved within 120 days after the other Party received the notification referred to in paragraph 4, the party shall cease to recognise any conformity assessment bodies.

E03684030

978-1-5286-6815-6