Minutes of the first meeting of the Working Group on Medicinal Products established under the Trade and Cooperation Agreement (TCA) between the European Union and the United Kingdom of Great Britain and Northern Ireland on 24 April 2024

Item 1 & 2 - Introduction by the co-chairs, presentation of the participants and adoption of the agenda

The EU and UK Co-chairs presented the participants of the meeting and made their opening statements. The agenda, as published by both parties on 23 April 2024, was adopted by the co-chairs. In line with Article 9(4) of the Trade and Cooperation Agreement (TCA), the Parties agreed that the Working Group on Medicinal Products will operate under the model rules of procedure agreed at the level of the secretariat to the Partnership Council. These rules are included in Annex 3 of the minutes of this Working Group meeting.

Item 3 - Exchange on trends in the evolution of the EU and the UK regulatory frameworks for medicinal products

The EU presented to the UK the current proposals for the reform of the EU pharmaceutical legislation. The proposed six key political objectives of the reform were described in detail: to create a single market for medicines, to ensure timely and equal access to safe and affordable medicines, to improve the security of supply and availability of medicines for every patient in the EU, to continue to offer an innovation friendly, streamlined and agile regulatory framework, to combat antimicrobial resistance and to make medicines more environmentally sustainable. The EU shared with the UK its view that the reform of the EU pharmaceutical legislation will promote innovation by moving away from a "one-size-fits-all" system and by introducing a modern and simplified regulatory framework aimed at accelerating procedures, simplifying rules and using regulatory 'sandboxes' to test new innovative therapies. In addition, the EU reform includes the provision of early regulatory support by the European Medicines Agency, the facilitated use of real-world evidence and health data, and modulation of regulatory data protection and market exclusivity.

In line with Annex 12 of the TCA, the EU wanted to create awareness for the revision of Annex I of the EU Guidelines for Good Manufacturing Practice (GMP) for Medicinal Products, which concerns the manufacture of sterile medicinal products, and which was updated and published in parallel to the respective Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the World Health Organization (WHO) documents. As set out in Article 47 of Directive 2001/83/EC, the revised Annex I was published by the European Commission and is in force in the EU/European Economic Area (EEA) since 25 August 2023. The EU noted its relevance for recognising UK GMP documents and inspections and asked to be reassured that the UK will intend to comply with these revised international standards, of which the UK took note.

Post-meeting note: The UK confirmed that they remain aligned with EU GMP standards, including the revision to EU GMP Annex I.

The UK provided an update on new developments to the UK regulatory framework for medicines. The UK shared that the Medicines and Medical Devices Act was passed in 2021, which provides the UK with the ability to bring forward regulations to support their objective to drive innovation and economic growth, while putting patient safety at the forefront.

In addition, the UK provided information that the Medicines and Healthcare products Regulatory Agency (MHRA) is working to transform regulatory processes to drive medical innovation so patients

can benefit from the very latest in safe and effective medical products. The UK shared that their Early Access to Medicines Scheme, which was brought onto a statutory basis in April 2022, gives patients with life threatening or seriously debilitating conditions safe and timely access to medicines that do not yet have marketing authorisation, when there is an unmet medical need. The UK also updated on proposals to reform the clinical trials framework, which will make it easier and faster for applicants to gain approvals and help make pioneering medicines available for patients sooner.

The UK pointed out that the regulatory framework for medical devices is currently being reformed, but no details were shared as it was agreed that products that are out of the remit of the Working Group on Medicinal Products should be considered relevant for the Trade Specialised Committee on Technical Barriers to Trade as need be. The UK also provided an overview of their new regulatory framework for point of care medicines and modular manufacturing, to support broadened spectrum of decentralised manufacture, which will increase the range of medicine supply and manufacturing options.

The UK noted their continued collaboration in international forums on GMP and their alignment with overarching global standards and best practice on GMP.

In addition, the UK provided an update on their batch testing policy which includes maintaining a list of countries where no import batch testing is required.

The EU noted that decentralised manufacturing has been included in the EU proposal for the pharmaceutical reform and questioned whether the UK rules coming into force before the EU rules could create some divergence between the two legislations and could lead or not lead to challenges in relation to the recognition of GMP documents. Both the UK and the EU noted however that these products will be produced at a point of care and are not meant to move across countries. The UK reassured that ensuring international alignment for the regulation of point of care products is being addressed through a group on decentralised manufacture/point of care as part of the International Coalition of Medicines Regulatory Authorities (ICMRA) innovation network.

Item 4 - Conclusion

The parties thanked each other for the shared information and agreed to take note of the updates shared during the first meeting of the Working Group. It was agreed that the frequency of the Working Group is to be decided under the mandate of the Trade Specialised Committee on Technical Barriers to Trade.

Annex 1 – Participants of the first meeting of the Working Group on Medicinal Products established under the EU UK TCA

UK Delegation

- UK Co-chair of the Working Group on Medicinal Products
- UK Government Officials from DHSC, FCDO, DBT, DHSC Legal Department, MHRA
- Scottish Government Officials
- Northern Ireland Executive Officials
- Welsh Government Officials

EU Delegation

- EU Co-chair of the Working Group on Medicinal Products
- EU Officials from SG, DGs SANTE, TRADE
- EU Member States

Annex 2 - Agenda

The first meeting of the Working Group on Medicinal Products established under the Trade and Cooperation Agreement between the European Union and the United Kingdom of Great Britain and Northern Ireland

Meeting on 24 April 2024

1.30pm- 4pm

European EU-Directorate General for Health and Food Safety-101 rue Froissart,-Brussels

AGENDA

1. Introduction by the Co-chairs and presentation of the participants
2. Adoption of the agenda
3. Exchange on trends in the evolution of the EU and the UK regulatory frameworks for medicinal products
    a. EU proposals for the reform of the EU pharmaceutical legislation
    b. Information on UK legislation
4. Conclusions

Annex 3 – Rules of Procedure

SECTION I

Model Rules of Procedure for Working Groups established by, or subsequently established under, the Trade and Cooperation Agreement

Trade and Cooperation Agreement

Working Groups

Rules of Procedure

Rule 1

Chair

The Union and the United Kingdom shall notify each other of the name, position and contact details of their respective designated Working Group co-chairs. A co-chair is deemed to have the authorisation for representing, respectively, the Union or the United Kingdom until the date a new co-chair has been notified to the other Party.

A co-chair may be replaced for a particular meeting or a part thereof by a designee. The co-chair, or his or her designee, shall notify the other co-chair and the Secretariat of the Working Group of the designation as early as possible. Any reference in these Rules of Procedure to the co-chairs shall be understood to include a designee.

Rule 2

Secretariat

The Secretariat of the Working Group shall be composed of an official of the Union and an official of the Government of the United Kingdom. The Secretariat shall perform the tasks conferred on it by these Rules of Procedure, under the supervision of the relevant Committee.

The Union and the United Kingdom shall notify each other of the name, position and contact details of the official who is the member of the Secretariat of the Working Group, respectively. This official is deemed to continue acting as member of the Secretariat for the Union or for the United Kingdom until the date either the Union or the United Kingdom has notified a new member.

Rule 3

Meetings

Each meeting of the Working Group shall be convened by the Secretariat at a date and time agreed by the co-chairs. Where either the Union or the United Kingdom has made a request for a meeting, the other Party shall give due consideration to such a request and reply within 30 days.

The Working Group shall hold its meetings alternately in Brussels and London, unless the co-chairs decide otherwise.

By way of derogation from the second paragraph, the co-chairs may agree that a meeting of the Working Group be held by video conference, teleconference or in hybrid form.

Rule 4

Participation in meetings

A reasonable period of time in advance of each meeting, the Union and the United Kingdom shall inform each other through the Secretariat of the intended composition of their respective delegations and shall specify the name and function of each member of the delegation.

Where appropriate the co-chairs may, by mutual consent, invite experts (i.e. non-government officials), to attend meetings of the Working Group in order to provide information on a specific subject and only for the parts of the meeting where such specific subjects are discussed.

Rule 5

Documents

Written documents on which the deliberations of the Working Group are based shall be numbered and circulated to the Union and the United Kingdom by the Secretariat.

Rule 6

Correspondence

The Union and the United Kingdom shall send their correspondence addressed to the Working Group via the Secretariat. Such correspondence may be sent in any form of written communication, including by electronic mail.

The Secretariat shall ensure that correspondence addressed to the Working Group is delivered to the co-chairs and is circulated, where appropriate, in accordance with Rule 5.

All correspondence from or addressed directly to the co-chairs shall be forwarded to the Secretariat and shall be circulated, where appropriate, in accordance with Rule 5.

Rule 7

Agenda for the meeting

For each meeting, a draft provisional agenda shall be drawn up by the Secretariat. It shall be transmitted, together with the relevant documents, to the co-chairs no later than five days before the date of the meeting.

The provisional agenda shall include items requested by the Union or the United Kingdom. Any such request, together with any relevant document, shall be submitted to the Secretariat no later than seven days before the beginning of the meeting.

No later than three days before the date of the meeting, the co-chairs shall decide on the provisional agenda for a meeting.

The agenda shall be adopted by the Working Group at the beginning of each meeting. On request by the Union or the United Kingdom, an item other than those included in the provisional agenda may be included in the agenda by consensus.

The co-chairs may, by mutual consent, reduce or increase the time periods specified in the first, second and third paragraphs in order to take account of the requirements of a particular case.

Rule 8

Minutes

Draft minutes of each meeting shall be drawn up by the official acting as member of the Secretariat of the Party hosting the meeting, within seven days from the end of the meeting, unless otherwise decided by the co-chairs. The draft minutes shall be transmitted for comments to the member of the Secretariat of the other Party. The latter may submit comments within five days from the date of receipt of the draft minutes.

The minutes shall, as a rule, summarise each item on the agenda, specifying where applicable:

— the documents submitted to the Working Group;

—any statement that one of the co-chairs requested to be entered in the minutes; and

— operational conclusions adopted on specific items.

The minutes shall include as an annex a list of participants setting out for each of the delegations the names and functions of all individuals who attended the meeting.

The Secretariat shall adjust the draft minutes on the basis of comments received and the draft minutes, as revised, shall be approved by the co-chairs within 28 days of the date of the meeting, or by any other date agreed by the co-chairs.

Once approved, copies of the minutes shall be signed by the members of the Secretariat and transmitted to the Union and the United Kingdom, as well as to the supervising Committee. The co-chairs may agree that signing and exchanging electronic copies satisfies this requirement.

Rule 9

Confidentiality

Unless otherwise decided by the co-chairs, the meetings of the Working Group shall be confidential.

If the Union or the United Kingdom submits information that is confidential or protected from disclosure under its laws and regulations to the Working Group, the other party shall treat that information received as confidential.

The co-chairs may decide to make provisional agendas public before the meeting of the Working Group takes place. The co-chairs may also decide to make the minutes of the meeting public following their approval in accordance with Rule 8.

Publication of documents referred to in the third paragraph shall be made in compliance with both Parties' applicable data protection rules.

Rule 10

Languages

The working language of the Working Group shall be English. Unless otherwise decided by the co-chairs, the Working Group shall base its deliberations on documents prepared in English.

Rule 11

Expenses

The Union and the United Kingdom shall each meet any expenses they incur as a result of participating in the meetings of the Working Group.

Expenditure in connection with the organisation of meetings and reproduction of documents shall be borne by the party hosting the meeting.

Expenditure in connection with interpretation to and from the working language of the Working Group shall be borne by the party requesting such interpretation.

Rule 12

Reporting

The Working Group shall inform the supervising Committee of its meeting schedule and agenda sufficiently in advance of meetings, and shall report to this Committee on the results and conclusions of each meeting.