Minute

II Subcommittee on Technical Barriers to Trade (TBT)

Trade Agreement between the Andean Countries and the United Kingdom

Tuesday, 04 July 2023
08h30 – 13h00 EC time /14h30 – 18h00 UK time

1. Greetings and Opening Remarks

1.1. Opening Remarks by the Head of Delegation of Ecuador

The Head of Delegation of Ecuador welcomed the second meeting of the Subcommittee on Technical Barriers to Trade (TBT) of the Trade Agreement between Colombia, Ecuador, Peru and the United Kingdom, foreseeing a constructive meeting and collaborative work between the Parties. The meeting was carried out via video conference.

1.2. Introductory Remarks by the Heads of Delegation of the Andean Countries and the United Kingdom

The Heads of Delegation of each of the countries expressed their desire to continue working for the correct implementation of the Trade Agreement and presented their respective participating institutions. It was mentioned that it was the first meeting of the Subcommittee in which Colombia participated as a full Member, thanks to the ratification of the Trade Agreement in that country.

2. Approval of the Agenda for the Meeting of the II Subcommittee on TBT

The agenda items, which had been previously shared, were reviewed and approved.

3. Updates on the Topics from Last Meeting

The topics that remained as "Next Steps" in the Minutes of the previous Subcommittee meeting were reviewed and an update on their current status was given:

- In September 2022, the United Kingdom sent the answers to the technical questions related to the equivalence procedure for organic products.
- In June 2022, Ecuador sent to the United Kingdom the presentation on its regulations for organic products.
- In July 2022, the United Kingdom sent to Colombia, Ecuador and Peru the presentation on the UKCA marking.
- The United Kingdom said it would resend a weblink to UK guidance on trading with the UK. It was included as an agenda item for this Subcommittee.
- The United Kingdom said it would provide an update on the implementation of its due diligence legislation, under the agenda item for this Subcommittee.

4. Rules of Procedure for the TBT Subcommittee

The Parties agreed to continue using the Rules of Procedure of the Trade Agreement between the European Union and the Andean Countries, until the Rules of Procedure of this Agreement are approved. The Rules of Procedure were approved during the Trade Committee meeting to be held on 19 July 2023.

5. Topics of Interest of the Countries

5.1. Ecuador and Peru

5.1.1. Procedure for the Mutual Recognition of Organic Products

Ecuador and Peru expressed interest in being able to initiate the equivalence procedure for organic products with the United Kingdom. Ecuador thanked the United Kingdom for the information that was sent and made a presentation on the Ecuadorian organic legislation, clarifying that its interest is in negotiating the equivalence procedure for organic products: for agricultural production and for human consumption products with agricultural processing.

Peru asked the United Kingdom to send again the information on organic products since the information was not received at the time. Colombia also expressed its interest in receiving that information. United Kingdom stated it would resend the information by 07 July 2023.

Ecuador and Peru stated the importance of learning about the formal procedure that must be followed to initiate the negotiations for an Equivalence Procedure for Organic Products. The United Kingdom pledged to have internal discussions and report back as appropriate, and indicated that it was open to talks with the Andean countries in the future. The United Kingdom requested to receive a copy of the presentation made by Ecuador on its certification system for organic products.

5.2. Ecuador

5.2.1. Regulation on Deforestation

Ecuador recalled that during the previous Subcommittee it consulted the United Kingdom on how it will implement its due diligence regulation for forest risk commodities, presented in the 2021 Environment Act, and requested an update on the subject.

The United Kingdom reported that it is developing measures to improve the sustainability of the value chains for the products consumed within its territory and committed to continue informing its trading partners about the progress made in regard to the regulation and any other related information. The UK has designated a contact point in the region for this purpose.

5.2.2. Exporter Help Service Database

The United Kingdom will send the Andean countries by 07 July 2023 a weblink to access UK guidance to help exporters trading their products in the UK market, which includes information on tariffs and other market access topics.

5.3. The United Kingdom

5.3.1. Procedures for Approval of Medicines and Health Technology Assessments

The United Kingdom emphasized the importance of the health care sector within UK – Andean trade exchanges. It was also mentioned that UK companies had frequently reported problems with medicines approvals in the region although it recognizes that progress has been made. The UK also

mentioned its interest to keep working with the Andean countries in these areas to continue building capacity and sharing experiences and progress.

5.3.1.1. Implementation of Reliance Approaches by Ecuador

The UK thanked Ecuador for its openness to work together to adopt regulatory best practices on the approval procedures for biologics and advanced therapy medicine products. The UK also thanked Ecuador for the new regulation that was issued on Good Manufacturing Practices and asked Ecuador for an update on the new medicines regulation that it was progressing and on the timeline that it is considering for its socialization and adoption.

The representative from ARCSA (Ecuador's Regulatory Agency) thanked the United Kingdom for the training it has received on topics of Reliance. The Ecuadorian representative indicated that its regulation, both for chemical synthesis medicines and for biologics, is being reformed. Ecuador informed that it is including Reliance principles for the approval processes for biologics and mentioned that for the other medicines the reform is considering more simplified processes and will eliminate some restrictions. As an example of streamlined procedures, Ecuador mentioned that the current legislation does not include a deadline for review and approval and the new legislation would provide a period of three months, which will give certainty. Ecuador explained that the amendments to the general medicines regulation are at an advanced stage, and it expects to have them ready within two months. In regard to the regulation on biologics, it expects to issue this in the coming months since it is starting the analysis. It will notify the WTO in due course.

5.3.1.2. Implementation by Colombia of the Draft Resolution Establishing the Independence between Sanitary Registration Processes and Health Technology Assessments

The United Kingdom presented its interest in knowing about the status and estimated timeframe for the approval of legislation that will clarify the independence between sanitary approvals and the Health Technology Assessment procedures. In this regard, Colombia indicated that the Resolution that establishes the independence between sanitary registration processes and the evaluation of therapeutic products has been in force since 2018; however, the issuance of one Regulation is still pending. Colombia mentioned that it is working on it and explained that for its implementation, it is necessary to establish prices for new drugs in the Colombian market.

Colombia also explained that both the Resolution that establishes the independence of the two processes and the circular of the National Commission of Prices of Medicines and Medical Devices already underwent public consultation and the texts are currently being adapted for publication. Colombia expects this process to be completed by the end of July 2023.

The United Kingdom also indicated that its companies have reported that the approval process is quite lengthy and that when applications are rejected, it does not receive solid scientific information. The UK asked Colombia if it has plans to implement Good Regulatory Practices (GRP) on this topic.

In this regard, Colombia informed that the Government is aware of the bottlenecks and is planning to streamline procedures. It explained that this is being carried out as part of the process to update some regulations, for example, the sanitary registration and the implementation of guidelines that accompany Decree 334 of 2022, that seeks to streamline the procedures. Colombia also indicated that since joining the OECD it has worked to adapt its standards based on the GRPs.

5.3.1.3. Implementation by Peru of Good Regulatory Practices, particularly for Over the Counter (OTC) Products

The United Kingdom mentioned that companies recognize the improvements and efforts that have been made through the implementation of legislation for a fast-track process for prescription products that have been already approved by Stringent Agencies. However, timeframes for approvals seem to still be lengthy and uncertain. The UK also recognized and congratulated Peru for being vocal in its plans for implementing Reliance in its procedures.

On the other hand, the UK mentioned that there is a concern about uncertainty in the approval processes for renewals and modifications of over the counter (OTC) products, where the requirements and timelines are variable and not necessarily aligned to international practices and requirements on labelling and advertising approvals.

In this regard, Peru informed that there is no specific regulation related to GRP for OTC products. Peru indicated that it is aware of these problems for prescription medicines and that, even when it has established streamlined procedures in its legislation, lack of resources has caused delays. However, Peru mentioned that it is working to strengthen technical staffing to reduce the registration time for pharmaceutical products in general (both biologics and medicines of chemical synthesis). Peru stated that it has hired 35 new professionals to reduce the time it takes to register those products. Peru is implementing GRPs on administrative procedures related to other issues.

In regard to the concerns presented by the UK about OTC products, Peru mentioned that it has not considered changes to legislation and that there is a specific team, different to the one that covers prescription medicines, in charge of OTC products. Peru also mentioned that its legislation allows the marketing of OTC products in commercial and pharmaceutical places.

5.3.1.4. Work between Colombia, Ecuador and Peru on Strengthening Health Technology Assessment Procedures

The United Kingdom expressed its interest in continuing to collaborate with the Andean countries to implement GRPs. It is awaiting confirmation of the availability of funds to continue technical assistance and will inform the Andean countries accordingly.

On Health Technology Assessment, the United Kingdom recalled that it has extensive and recognized international experience in this area. The United Kingdom acknowledged that the Andean countries are trying to adopt international practices through initiatives at the Andean Community level and with national initiatives. The United Kingdom noted the importance of allowing access to high-quality health products and requested an update on the progress made by the Andean Countries.

The Andean countries indicated that within the framework of the Andean Health Agency, they are working with Chile to evaluate and prepare Andean Health Technologies Policy. Therefore, the technical assistance that the UK can offer would be timely.

The United Kingdom will inform the Andean countries once it has confirmed funding for this matter.

5.3.2. Medicines / Health Labelling

5.3.2.1. Update from Peru on the Implementation of Front-of-Package Nutritional Warning Labelling

The United Kingdom indicated that the extension given by Peru to allow the use of removable labels ended in June 2023. Therefore, it asked Peru if it has evaluated the relevance of permanently allowing the use of adhesive labels. It also asked about the use of octagonal labels for infant formula.

Peru reported that Supreme Decree 017/2023 was issued on 30 June 2023, approving the use of adhesive labelling indefinitely, in response to the request made by several trading partners.

Regarding the labelling for infant formulas, Peru informed that the modification to current parameters was notified to the WTO and it has received several comments from trading partners. Those comments are under analysis by the Peruvian health authority, and it will communicate its responses to the trading partners.

5.3.2.2. Clarification from Colombia on its Labelling Requirements (Prior Approval for Advertisement Pieces) for Over the Counter Medicines

The United Kingdom expressed its concern regarding the postponement of the entry into force of Decree 334 of 2022, which eliminated the requirements for prior approval of advertising pieces for OTC medicines. The United Kingdom explained that its understanding is that the new Colombian legislation established that OTC products will not require prior approval of advertising pieces anymore; however, the entry into force of this Decree, which was meant for March 2023, has been delayed until 2024 (Circular 600-4772-16), causing uncertainty and concern for companies that stopped submitting their advertising pieces for INVIMA's approval with enough time in advance.

For this reason, United Kingdom companies asked if INVIMA is planning to comply with the timeframe for approval established by the current legislation, and mentioned that UK companies are concerned that this process usually takes more than one year even though the legislation establishes a 90-day approval period.

Colombia indicated that it was necessary to delay the entry into force since the new regulation seeks to change the control methodology from prior approval to subsequent control. This requires a whole adaptation of INVIMA's dynamics and operations and it was not ready to start the implementation of those changes. Colombia also informed that Resolution 4320 of 2004 provides for eight working days for obtaining approval of the advertising pieces, time that definitely cannot be met.

The United Kingdom also requested to learn about the mitigation plan that INVIMA will apply to comply with the eight-day period established in the regulations. Colombia indicated that the process and timeframe for the approval of advertising pieces for OTC medicines are currently carried out in accordance to article 79 of Decree 677 of 1995, and Resolution 4320 of 2004. However, it reported that the current delays in these processes are caused by technological problems. Therefore, Colombia explained that, to date, it is evaluating the advertising pieces submitted in March 2023, both the initial ones and the responses to additional requirements. It explained that, for this reason, the approval process is taking approximately four months when in normal conditions it would take a maximum of one month. However, it considers that, in no case, has this process taken a year.

Finally, Colombia informed that it activated contingency plans to progress quickly and be up to date soon; for example, it is currently implementing extraordinary committees and increasing the time dedicated to the evaluation processes in order to comply with the established timeframes.

5.3.3. UKCA Recognition for UK Exports of Medical Devices to Peru

The United Kingdom asked about the process to obtain rapid recognition of the UKCA marking for medical devices in Peru, as has been done with the European Union CE marking. It asked about the next steps in the process, and whether it applies only to medical devices or to other devices as well.

Peru indicated that its Regulation recognizes the CE marking and eventually UKCA marking based on compliance with medical device safety standards. However, this recognition is not a mandatory requirement, since its Regulation allows and requires it to receive other certificates related to compliance with international quality standards (ISO and the EU), provided that they are issued by the competent authority of the country where the medical devices come from. Peru informed that it will send the United Kingdom a copy of the relevant legislation for the UKCA marking recognition process.

6. Conclusions and Next Steps

- The United Kingdom will send again to Peru and Colombia answers to the technical questions about the equivalence procedures for organic products by 07 July 2023.
- The United Kingdom will send again to the Andean countries a weblink to UK guidance for exporters on trading with the UK by 07 July 2023.
- Ecuador will send the United Kingdom a copy of the presentation it made on its certification system for organic products.
- The United Kingdom will continue informing its trading partners about the progress made in regard to the forest risk commodities regulation.
- Peru will send the United Kingdom the relevant legislation for the UKCA marking recognition process.
- The United Kingdom will inform the Andean countries about the funding of its technical assistance program to help strengthen GRPs within the life sciences sector and in the Andean Countries.

7. Any Other Business

There was no need to discuss other topics during the Subcommittee meeting.

8. Closing Remarks

Ecuador undertook to send a draft of the Minutes to receive the comments and observations of the Parties. Once the Minutes are agreed upon, they will be exchanged for signatures.

The Parties expressed their appreciation for the fruitful meeting and pledged to continue to collaborate.

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ANNEX I
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