## DIRECTORATE OF LEGAL ADVICE AND PUBLIC INTERNATIONAL LAW

TREATY OFFICE



July 2022

COUNCIL OF EUROPE CONVENTION ON THE COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH of 28 October 2011

(CETS No. 211, entered into force on 1 January 2016)

I. Participation in the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health is not exclusively limited to member States of the Council of Europe, to the European Union and to the non-member States which have participated in its elaboration or are enjoying observer status with the Council of Europe, namely Canada, the Holy See, Israel, Japan, Mexico and the United States of America.

The Convention is also open for signature and ratification by other States, provided that they have been formally invited to sign and ratify it by the Committee of Ministers of the Council of Europe. The relevant provisions of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health - Article 28, paragraphs 1 and 2 - read as follows:

- "1. This Convention shall be open for signature by the member States of the Council of Europe, the European Union and the non-member States which have participated in its elaboration or enjoy observer status with the Council of Europe. It shall also be open for signature by any other non-member State of the Council of Europe upon invitation by the Committee of Ministers. The decision to invite a non-member State to sign the Convention shall be taken by the majority provided for in Article 20.d of the Statute of the Council of Europe, and by unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers. This decision shall be taken after having obtained the unanimous agreement of the other States/European Union having expressed their consent to be bound by this Convention.
- 2. The Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe."

Procedure for the signature and ratification by States which are not member States of the Council of Europe, have not participated in the elaboration of the Convention or are not enjoying observer status with the Council of Europe

II. The procedure for the signature and ratification by a State which is not a member of the Council of Europe, which has not participated in the elaboration of the Convention or is not enjoying observer status with the Council of Europe may be summarised as follows:

- 1. In principle, the Committee of Ministers may take the initiative of inviting a non-member State to sign and ratify a Council of Europe convention, in accordance with the relevant provisions of the said convention. It is nevertheless customary for the non-member State to request such invitation in a letter addressed to the Secretary General of the Council of Europe. The letter should be signed by the Minister for Foreign Affairs or a diplomatic representative acting upon instructions of his or her government (see as an example the Model application for accession to a treaty).
- 2. In accordance with the Council of Europe's practice and before formally inscribing the point on the agenda of the Committee of Ministers, the Secretariat consults at the same time all member States of the Council of Europe, whether they are Parties or not to the Convention, and Parties to this Convention that are not member States, on the request of invitation.
- 3. Requests for invitation to sign and ratify a Council of Europe convention are examined by the Committee of Ministers' Rapporteur Group on Legal Co-operation (GR-J) and, then, by the Committee of Ministers. In the case of the *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, the decision on whether or not to issue an invitation has to be unanimously agreed by those Council of Europe members which have ratified the Convention, as well as the other States/European Union having expressed their consent to be bound by this Convention. Then, an invitation to sign and ratify to the Convention is notified to the State concerned by the Secretariat General.
- 4. It must be noted that the Committee of Ministers decided, in April 2013, to limit the validity of invitations of non-member States to accede to conventions to a period of five years.
- 5. It is customary for the signature of a Council of Europe Convention to take place at the seat of the Council of Europe in Strasbourg, in the presence of a representative of the signatory State and of the Secretary General of the Council of Europe or his Deputy. The representative of the signatory State brings with him or her the original of the full powers of signature granted to him or her by the Head of State, the Head of Government or the Minister for Foreign Affairs of his or her country. A *procès-verbal* of signature is signed by both parties.
- 6. It is also customary for the instrument of ratification to be deposited at the seat of the Council of Europe, in Strasbourg, in the presence of a representative of the ratifying State and of the Secretary General of the Council of Europe or his Deputy. The representative of the ratifying State brings with him or her the original of the instrument of ratification and a *procèsverbal* of deposit is signed by both parties. Should it prove difficult for the ratifying State to send a representative to Strasbourg, the instrument of ratification may be sent by diplomatic courier. Deposit of the instrument of ratification is notified to all concerned, accordingly to Article 28 of the Convention.

- 7. In accordance with Article 28, paragraph 5, of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, in respect of any signatory State or the European Union which subsequently expresses its consent to be bound by it, it shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of the instrument of ratification, acceptance or approval with the Secretary General of the Council of Europe.
- 8. The instrument of ratification and any reservation or declaration appended to it shall be accompanied by a translation into one of the official languages of the Council of Europe (English or French). It is important to stress that, subject to the applicable provisions of each treaty (see Article 30 of this Convention) and in line with the 1969 Vienna Convention on the Law of Treaties, any reservations or declarations are to be made when depositing the instrument of accession. For reasons of legal certainty and in order to ensure the uniform implementation of conventions, reservations may not be made at any later date.

## Financial contribution to the Convention's monitoring mechanism

III. Article 23, paragraph 5, of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health provides that a Contracting Party which is not a member of the Council of Europe shall contribute to the financing of the Committee of the Parties set up by this Convention. The calculation of this financial contribution is governed by Resolution CM/Res(2022)6, adopted by the Committee of Ministers on 6 April 2022, concerning financial arrangements for the participation of the European Union and non-member States in Council of Europe conventions.

IV. The text of the Convention, its explanatory report, the chart of signatures and ratifications and all declarations and reservations made with regard to it can be consulted on the website of the Council of Europe's Treaty Office on <a href="https://conventions.coe.int">https://conventions.coe.int</a>.

For any further information, please contact the Treaty Office:

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