



Strasbourg, 21 December 2023

Decision of the MEDICRIME Committee

During the 6th Plenary meeting of the Committee of the Parties to the MEDICRIME Convention (hereinafter, “the CoP” of the MEDICRIME Committee) held on 10-12 May 2023, the Secretariat of the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (hereinafter, “the CMED”) asked for an opinion to the CoP on the draft recommendation *on best practices for the remote and online provision of medicines* (hereinafter, the draft recommendation).

By mandate of the CoP, the Bureau examined the comments received from Parties to the draft recommendation, discussed them and decided to provide an opinion to the draft recommendation once the drafting process of such legal instrument is finalised. Such decision was provided by e-mail to the CMED Secretariat on 25 September 2023.

On 24 October 2023, the CoP received a request from the EDQM:

1. to evaluate whether the draft Recommendation aligns with the MEDICRIME Committee of the Parties' mandate and to notify the EDQM Secretariat once the assessment is completed.
2. If the MEDICRIME Committee of the Parties determines that their mandate permits them to provide feedback on the draft Recommendation, to exceptionally extend the deadline for receiving such feedback until 31 December 2023.
3. If no comments are received by 31 December 2023, to conclude that the scope of the Recommendation exceeds the mandate of the MEDICRIME Committee of the Parties or that Committee of the Parties has opted not to provide comments.

Against this background, the Bureau members agreed to deal with this request during the 7th Plenary meeting of the CoP (28-29 November 2023). During that meeting, the Parties were both informed of the above request and invited to provide comments in written to the draft recommendation (deadline 14 December 2023). Parties mandated its Bureau to examine the comments received from Parties, discuss them and take the necessary measures.

The CoP welcomes EDQM's efforts to put a policy frame in place to provide safe remote provision of care/medicines taking due regard to existing national and European Union legislation.

In relation to the first request, the MEDICRIME Committee recalls that Articles 25§2 and 25§3 of the MEDICRIME Convention, as well as Articles 1 and 31 of its Rules of Procedure, provide that the MEDICRIME Committee may, following its monitoring functions and as a result of any discussion during its work, issue comments and opinions on the interpretation of the Convention.

The CoP welcomes the draft recommendation in its version of May 2023¹. Its comments only refer to that version (enclosed). In general terms, the MEDICRIME Committee considers that the draft recommendation does not interfere with the CoP's mandate. No comment is made on the public health aspects of the draft Recommendation.

However, the MEDICRIME Committee takes note that the draft recommendation has been opened to external consultation. It should be recalled that any amendment to the current draft recommendation may alter the MEDICRIME Committee's opinion as this may potentially fall within the mandate of the MEDICRIME Committee. Only the MEDICRIME Committee has competence to decide what is or not within its remit.

The MEDICRIME Committee considers that to provide a proper opinion, the CMED/EDQM should inform the CoP of the following elements, which consolidate the principle of legal certainty:

- whether the drafting of the draft recommendation will both include any further matters or take into consideration views by other contributors whom CMED sought views;
- if the draft final text, i.e., after all other contributions are included, be made available to CoP with sufficient time to allow it to provide its opinion on the final draft.

Therefore, the MEDICRIME Committee welcomes the receipt of the final text of the draft recommendation before its submission to the Committee of Ministers to ensure the principle of legal certainty. The review by the MEDICRIME CoP at that time should not raise any significant delay provided the amendments to the current draft are highlighted for its convenience.

*
* *

¹ The draft recommendation provided has no date.