Council of the European Union

Brussels, 30 June 2026
(OR. en)

11328/26

API 146
INF 203

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Public access to documents - Confirmatory application N° 38/c/01/26 - Information to delegations

Delegations will find attached:

- the request for access to documents sent to the General Secretariat of the Council on 9 May 2026 and registered on 11 May 2026 (Annex 1);
- the reply from the General Secretariat of the Council dated 25 June 2026 (Annex 2);
- the confirmatory application dated 29 June 2026 and registered on 30 June 2026 (Annex 3).

ANNEX 1

From: document-request@cis.consilium.europa.eu
Sent: Saturday, May 9, 2026 6:44 PM
To: TRANSPARENCY Access to documents (COMM) <Access@consilium.europa.eu>
Subject: Consilium - Electronic Request for Access to documents [ENGLISH]

This e-mail has been sent to access@consilium.europa.eu using the electronic form available in the Register application.
This electronic form has been submitted in ENGLISH.

Title
DELETED

First name
DELETED

Family name
DELETED

E-mail
DELETED

Occupation
Academia
I submit this request on my own behalf.

Name of the organisation

Full postal address
DELETED

Telephone

Requested document(s)
Dear General Secretariat of the Council of the European Union,

My name is **DELETED** and I am **DELETED**. I request access, under Regulation (EC) No 1049/2001, to documents drawn up or received by the Council relating to the Critical Medicines Act proposal (COM(2025)102) for the period from 11 March 2025 (publication/adoption of the Commission proposal) to present, covering documents concerning the handling and negotiation of the proposal, to the extent held by the Council. Document language can be English or other EU language.

The requested documents include, where they exist and are held by the Council, for example: Council Legal Service opinions/notes (if any), Council preparatory bodies' documentation (e.g., agendas, outcomes of proceedings/summary notes, Presidency notes, delegations' comments/proposed amendments, ST/WK documents), documents relating to the Council's position/general approach and related mandate/negotiation guidance, negotiation preparation

and briefings, and any documents relating to trilogue and other interinstitutional negotiation documents (including any four-column documents/tables).

This request excludes documents already publicly available in the Council's document register. Please also provide a document list (possibly titles, dates, reference numbers, authors).

I kindly ask that any reliance on Article 4(3) be supported by a concrete and document-specific assessment. As confirmed by the EU case law on legislative documents, the fact that a legislative procedure is ongoing cannot, by itself, justify a general refusal. If any document cannot be disclosed in full, please grant partial access to the maximum extent possible, and provide a document list for all documents identified. Please also justify any redactions concretely and individually.

If you consider the scope still too broad, I kindly request that you provide me a document list first and further invite me to clarify the request in accordance with the Regulation, rather than rejecting it.

Kind regards,
DELETED

1st option
EN
2nd option

This is an automatic reply from the General Secretariat of the Council of the European Union concerning your request for access to Council documents.
This notification was sent from an unattended mailbox. Please do not reply.

ANNEX 2

Council of the European Union
General Secretariat
Directorate-General Communication and Information – COMM
Directorate Information and Outreach
Information Services Unit / Transparency
Head of Unit

Brussels, 25 June 2026

DELETED
E-mail: **DELETED**

Ref. 26/1780

Request made on: 09.05.2026
Registered on: 11.05.2026
Deadline extension: 04.06.2026

Dear **DELETED**,

Thank you for your request for access to documents of the Council of the European Union.[1]

We have identified the following documents as related to your request:

WK 4405/2025 REV 1	Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
WK 4405/2025 INIT	Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
8570/26	Proposal for a regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Critical Medicines Act) - Four-column table

[1] The General Secretariat of the Council has examined your request on the basis of the applicable rules: Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43) and the specific provisions concerning public access to Council documents set out in Annex II to the Council's Rules of Procedure (Council Decision No 2009/937/EU, OJ L 325, 11.12.2009, p. 35).

8569/26	Proposal laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Critical Medicines Act) - Preparation for the trilogue
WK 5995/2026 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Presidency
WK 5359/2026 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
8238/26	Proposal for a regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 (Critical Medicines Act) - Four-column table
WK 1123/2026 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
WK 14620/2025 REV 1	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
WK 14620/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
14721/25	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicinal products of common interest, and amending Regulation (EU) 2024/795 - Presidency's third compromise proposal
WK 14489/2025 REV 1	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
WK 14014/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
WK 13653/2025 INIT	Critical Medicines Act - Comments from delegations
WK 12334/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission

WK 10885/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission
WK 10880/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission
WK 10876/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the European Medicines Agency
12444/25	COMMISSION STAFF WORKING DOCUMENT Summarising evidence supporting the legislative proposal laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicines of common interest and amending Regulation (EU) 2024/795
12134/25 COR 1	Attendance of a third party at the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025 - Approval
12134/25	Attendance of a third party at the Working Party on Pharmaceuticals and Medical Devices on 3 September 2025 - Approval
WK 9776/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Flash from the Presidency
WK 9798/2025 INIT	Meeting of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission
WK 4601/2025 INIT	Working Party on Pharmaceuticals and Medical Devices - Presentation by the Commission on the Critical Medicines Act
WK 8778/2025 INIT	Meeting of the Working Party on Public Health and of the Working Party on Pharmaceuticals and Medical Devices - Presentation by the Presidency

The documents 8569/26, 8238/26 and WK 8778/2025 INIT are now available on the Council's public register. In document WK 8778/2025 INIT, only personal data have been redacted.[2]

[2] See Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295 21.11.2018, p. 39).

Please find the remaining documents attached to this letter.

In documents WK 4405/2025 INIT, WK 4405/2025 REV 1 and WK 14489/2025 REV 1, elements that were outside the scope of your request have been redacted.

Yours sincerely,

Fernando FLORINDO

Enclosures: 22 – Link to the documents: https://we.tl/t-nPVX2BYSpeeDQtmb

From: DELETED
Sent: Monday, June 29, 2026 6:06 PM
To: TRANSPARENCY Access to documents (COMM) <Access@consilium.europa.eu>
Subject: Confirmatory application (Art 7(2)) – Ref. 26/1780

Dear Mr Florindo and the Council,

Thank you for your reply of 25 June 2026 and for providing access to the documents identified in connection with my request **Ref. 26/1780**. I appreciate the work involved in identifying and transmitting the documents listed, and I am grateful for the partial access granted.

I am, however, writing to submit a **confirmatory application** under Article 7(2) of Regulation (EC) No 1049/2001, kindly asking the General Secretariat to reconsider its position concerning the redactions made to documents WK 4405/2025 INIT, WK 4405/2025 REV 1 and WK 14489/2025 REV 1, on the following grounds.

1. *Absence of a document-specific justification for the redactions*

Your letter states that, in the three documents listed above, "*elements that were outside the scope of your request have been redacted.*" No further explanation is provided, either as to which subject matters the redacted passages relate to, or as to the legal basis on which the redactions were made.

In my initial request, I asked that "*any redactions [be justified] concretely and individually*". I note that Article 4 of Regulation (EC) No 1049/2001 sets out an exhaustive list of exceptions to the right of access, none of which corresponds, as such, to "scope of the request."

2. *No invitation to clarify the scope of the request*

In my initial request, I also indicated the following: "*If you consider the scope still too broad, I kindly request that you provide me a document list first and further invite me to clarify the request in accordance with the Regulation, rather than rejecting it*." This was intended as an invitation to engage in the fair-solution procedure foreseen in Article 6(2) of the Regulation.

Since the three documents in question appear to be "Flash from the Presidency" notes covering the proceedings of the Working Party on Pharmaceuticals and Medical Devices as a whole – and therefore potentially containing information on other legislative files discussed at the same meetings – I would have welcomed the opportunity to confirm whether I wished to receive those parts as well. No such clarification was sought before the redactions were made.

Request

In view of the above, I would respectfully ask the General Secretariat to:

(a) reconsider the redactions applied to WK 4405/2025 INIT, WK 4405/2025 REV 1 and WK 14489/2025 REV 1, and grant full access to those documents to the extent that no exception under Article 4 of Regulation (EC) No 1049/2001 applies;or, alternatively,

(b) provide a document-specific and reasoned justification for each redacted passage, identifying the applicable exception under Article 4 and, where relevant, the outcome of the partial access and overriding public interest assessments required by Article 4(6) and Article 4(3).

I would also be grateful if you could **confirm the registration of this confirmatory application and the date of its registration**.

Thank you in advance for your consideration. I remain at your disposal should any further information be needed.

Yours sincerely,

DELETED
DELETED