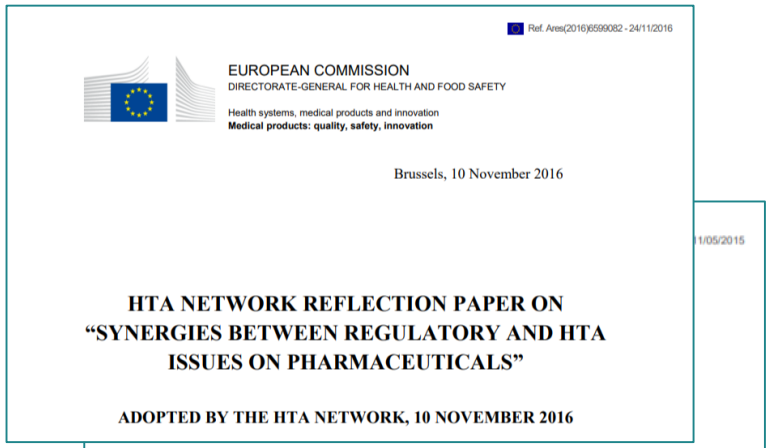
Aims and next steps for the implementation of the EU HTA Regulation

Valentina BARBUTO, Policy Officer SANTE C2

Gemeinsamer Bundesausschuss, 10 November 2023

Strengthening EU HTA cooperation


Ref. Ares(2016)6599082 - 24/11/2016

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels, 10 November 2016

HTA NETWORK REFLECTION PAPER ON "SYNERGIES BETWEEN REGULATORY AND HTA ISSUES ON PHARMACEUTICALS"

ADOPTED BY THE HTA NETWORK, 10 NOVEMBER 2016

HTA NETWORK REFLECTION PAPER ON "REUSE OF JOINT WORK IN NATIONAL HTA ACTIVITIES"

ADOPTED BY THE HTA NETWORK, APRIL 2015

JA1 (2010 – 2012)
JA2 (2012 – 2015)
JA3 (2016 – 2021)

HTA Regulation

European Commission

Regulation (EU) 2021/2282 on HTA

- Adoption 15.12.2021; in force 11.01.2022; in application **12.01.2025**
- Establishing: **a support framework and procedures** for cooperation of Member States on health technologies at Union level; **a mechanism for the submission of evidence** for joint clinical assessments only once at Union level; **common rules and methodologies** for joint clinical assessments.
- Vision: improve **patient access** to innovative technologies, strengthen the **quality** of HTA across the EU, avoid duplication and ensure **efficiency** (incl. on clinical evidence generation), secure the **long-term sustainability** of EU HTA cooperation.

HTA Regulation – Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Ensure **high quality, evidence-based** decision-making;
- Ensure **transparency & inclusiveness** (stakeholders' engagement)
- **Driven by Member State HTA bodies**
- Ensure **use of joint work in national HTA processes**

Member States remain responsible for:

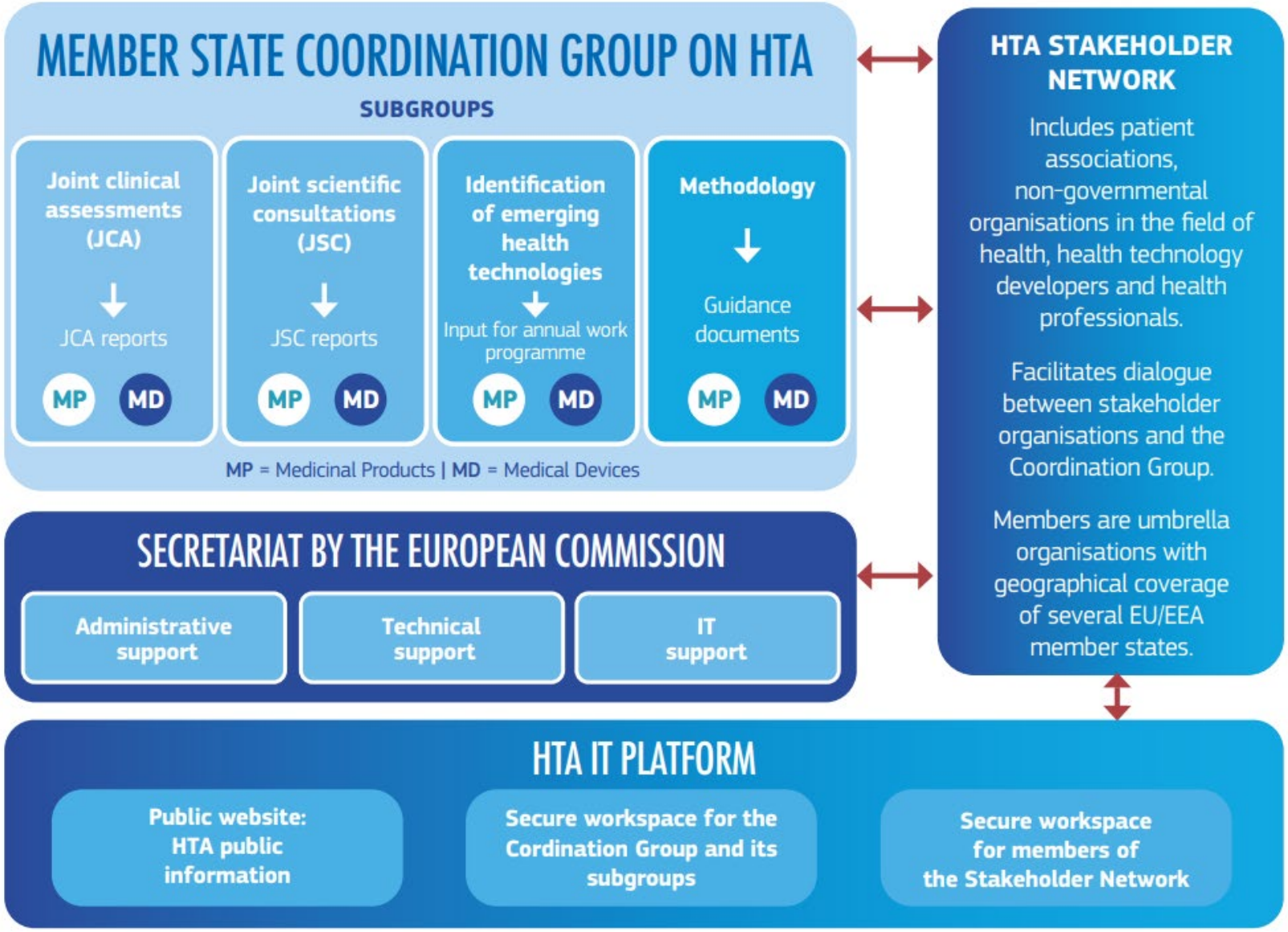
- Drawing **conclusions on added value** for their health system
- Taking **decisions on pricing & reimbursement**

- **Progressive implementation**

Joint HTA activities

- **Joint Clinical Assessments (JCA)** on:
  - **medicines** first 3 years: cancer medicines and advanced therapy medicinal products
    from January 2028: + orphan medicinal products
    from 2030: full scope
  - **a selection of high-risk medical devices and in-vitro medical devices**
- **Joint Scientific Consultations (JSC)**
  - with HTACG only or in parallel with the European Medicines Agency
- **Emerging Health Technologies**
- **Methodology and procedures for joint HTA work**
- **Voluntary cooperation**

Governance



European Commission

The HTA Stakeholder Network

Article 29

Stakeholder network

1. The Commission shall establish a stakeholder network. The stakeholder network shall support the work of the Coordination Group and its subgroups upon request.

2. The stakeholder network shall be established through an open call for applications addressed to all eligible stakeholder organisations, in particular patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals. The eligibility criteria shall be set out in the open call for applications and shall include:

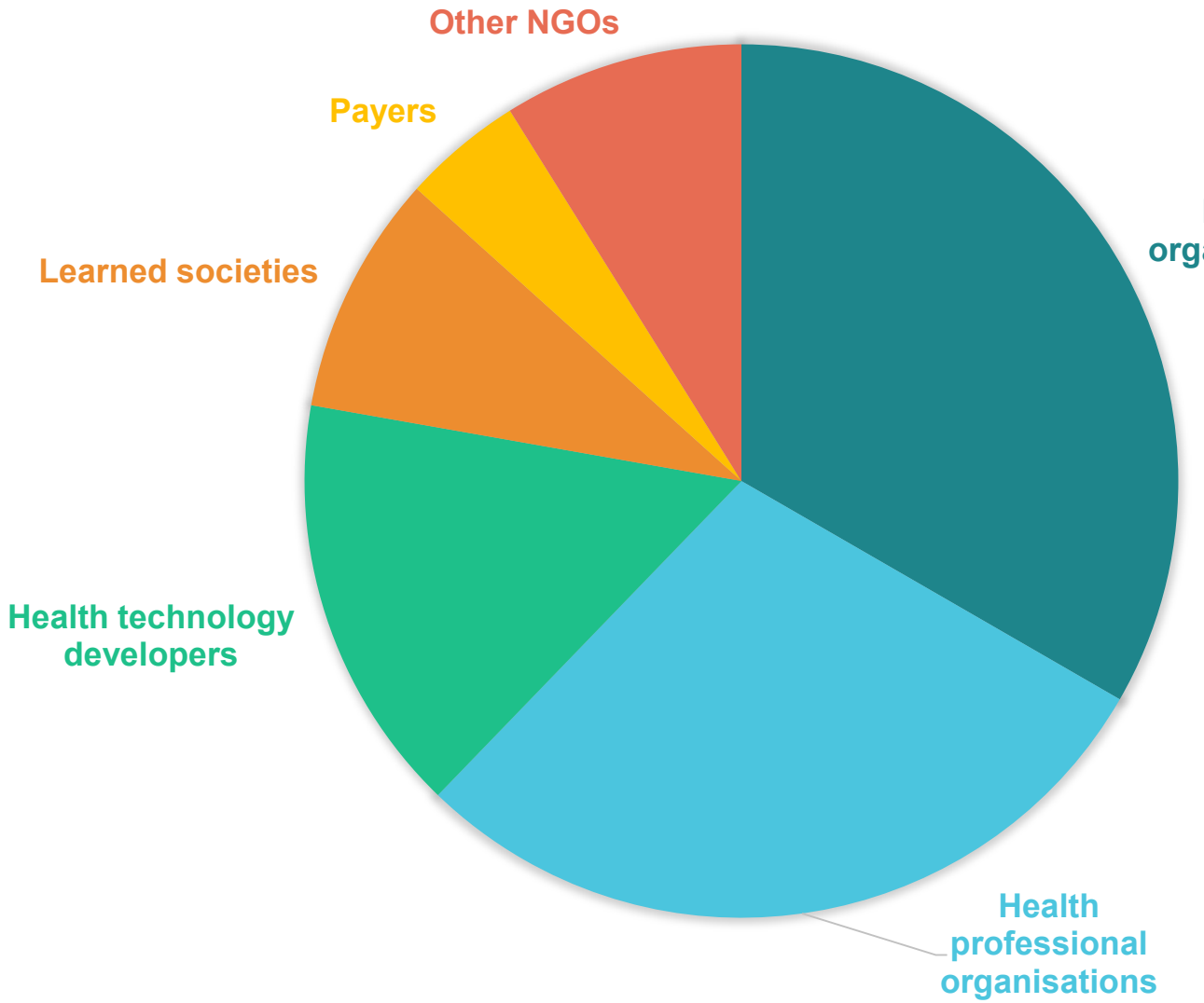
(a) proof of current or planned engagement in HTA development;

(b) professional expertise relevant to the stakeholder network;

(c) geographical coverage of several Member States;

(d) communication and dissemination capabilities.

Type of stakeholders in the network



45 organisations

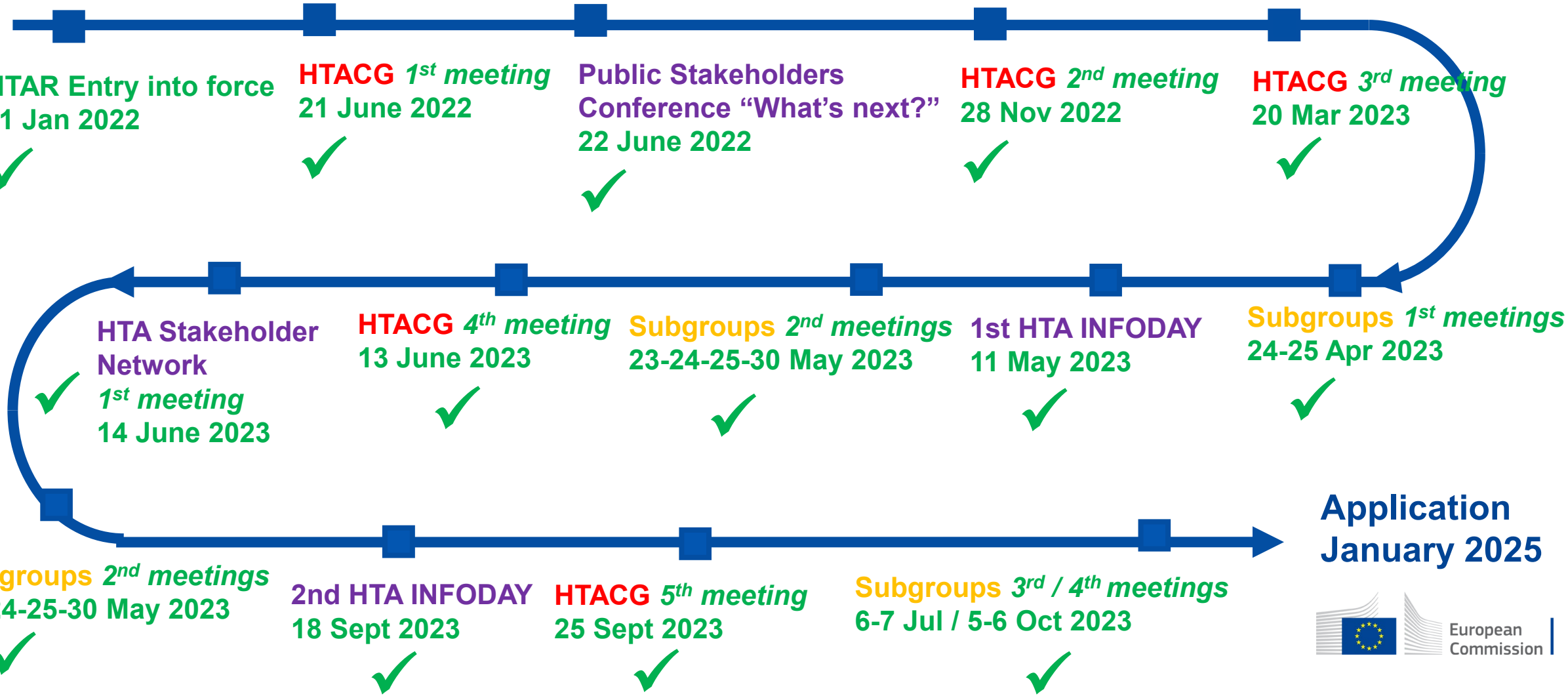
Terms of Reference

- Support the **work** of the HTACG upon request;
- Provide **advice and expertise** as required on issues of general relevance for the joint work and for the implementation of the Regulation;
- Facilitate **dialogue** between stakeholder organisations and the HTACG;
- Provide **input** as appropriate, on relevant outputs of the HTACG;
- Contribute to identifying **experts** for the joint work upon request;
- Be consulted and comment on the **annual work programme** and **annual report** of the HTACG;
- Share expertise on **state of the art** of HTA;
- **Meet** with the Coordination Group at least once a year.

Awareness raising – HTA information events

European Commission

EU HTA Regulation – Achievements so far



European Commission

Rolling plan regularly updated

IMPLEMENTATION ROLLING PLAN

2023-2024

REGULATION (EU) 2021/2282 ON HEALTH TECHNOLOGY ASSESSMENT

This rolling plan contains a list of key activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the "HTAR"). The plan is subject to regular review to provide national authorities and stakeholders with the most updated information.

The HTAR entered into force on January 11, 2022. It will be applicable as of January 12, 2025.

Latest update: October 2023

SUBJECT	LEGAL BASIS	DESCRIPTION	EXPECTED TIMELINE	STATUS
Member State Coordination Group on Health Technology Assessment (HTACG) HTAR Article 3				
Sixth meeting of the HTACG	HTAR Article 3		**16 November 2023**	In preparation
Fifth meeting of the subgroup on methodological and procedural guidance			9 November 2023	In preparation
Fifth meeting of the subgroup on Joint Clinical Assessments			10 November 2023	In preparation

hta_htar_rolling-plan_en.pdf (europa.eu)

European Commission

Factsheet in 23 EU languages

[Factsheet on the implementation of the HTA Regulation (europa.eu)]

European Commission

Next Steps: by end 2024

- Adoption of six implementing acts
- Full implementation of the HTA IT Platform
- Integration of the Stakeholder Network into the new system
- Continued support to the HTACG in its preparatory work
- Continued provision of capacity building, training and awareness raising opportunities

Vielen Dank!

If you have any additional question or remark you can contact us at:

SANTE-HTA@ec.europa.eu

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