

# Revision of EMA Policy 0044

Policy 0044: European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts

# Overview of presentation

- Background to Policy revision
- Key changes and rules for handling competing interests
- Implementation of new policy & next steps
- Q&A

# Background to Policy revision

# Objective of Policies revision

## Recent appellate court judgments impacting the EMA policies on competing interests

[Appellate Judgment of the Court in Joined Cases C-6/21 P and C-16/21 P](#)

Germany and Estonia v Pharma Mar and Commission (22 June 2023)

[Appellate Judgment of the Court in Case C-291/22 P](#)

D & A Pharma v Commission and EMA (14 March 2024)

## Ensure alignment with the Court's findings and aim to rule out any possible doubts as to the objective impartiality of EMA's assessments while balancing access to expertise

The revision of the policy, in line with the findings of the recent court rulings, is driven by the following elements:

- Any current interest in a product should lead to restrictions not only on the product concerned but also on products in the same declared condition;
- Restrictions of an individual's participation should apply not only to final deliberation and voting but also to discussions;
- The handling of competing interests needs to be consistent across EMA activities (i.e. between committees and SAG / AHEGs) and across roles;
- Need to enable declaration, evaluation and proportionate management of competing interests from research organisations.

# Key changes and rules for handling competing interests

# Main changes

- Increased and **aligned restrictions across roles and groups** for experts with a **current interest on a product**, including exclusion from procedures related to the product concerned and **also products in the same declared condition**
- In case of restrictions, no participation to discussion, final deliberation and voting
- Aligned restrictions across roles and groups, including a **unified 3-year cooling-off period**, where applied.
- Strengthened handling of competing interests in the **medical device** industry: current employment, consultancy/strategic advisory role or financial interests in medical device companies are **no longer** allowed
- New rules to handle certain **interests in research organisations**, in a proportionate manner depending on the interest  
*Interests related to **repurposing** removed and will need to be declared, if applicable, as interests in research organisation*
- Clarification on the **use of expert witnesses**

## Revised policy adopted by Management Board in December 2024



Effective from 1 May 2025

# Revised policy

## 3 Annexes on the handling of current and past interests:

- in pharmaceutical companies, MD companies and research organisations
- each covering committees/ETF/MSSG/WP chairs, members, Rapporteur and experts, SAG chair/members and inspection + MDSSG

## Simplified colour coding

## Simplified and new restriction codes, eg

- for Rapporteur role 'XRapp'
- for restrictions on products and products in declared condition XP+
- for medical device: XD
- for research organisation: XRo

Annex 1 – Handling of current and past interests in pharmaceutical companies							
Declared interest in a pharmaceutical company	Time since declared interest ended	Committee <sup>(1)</sup> / ETF / MSSG (vice)-(co-) chair	Working Party / MSSG Working Party (vice-) chair	Committee <sup>(1)</sup> / ETF / MSSG Working Party Rapporteur	Committee <sup>(1)</sup> / ETF / MSSG Working Party Member/ expert	SAG/ad-hoc expert group Chair / member	Inspector
Employee (general)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RC	XRappC	XC	XC	XI
Employee (product-related)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RC RP+	XRappC XRapp+	XC	XC	XI
Consultancy/strategic advisory role (general)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RC	XC	XC	XC	XI
Consultancy/strategic advisory role (product-related)	Current	X	X	X	X	XP+	X
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Financial interests	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
(Principal) investigator	Current	X	RP+	XRappP+	XP+	XP+	XI
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Grant/other funding to organisation/institution	Current	RC	RC	XRappC	F	F	F
	Past (0-3 yrs)	F	F	F	F	F	F
Close family member	Current	RC	RC	XRappC	XC	XC	XI
	Past (0-3 yrs)	F	F	F	F	F	F

(1) In addition, for the CAT chair, members and alternates, current employment, current consultancy/strategic advisory role or current financial interests in a company in the biotechnology sector are not allowed. The Chair of the CAT may also not hold such past interests during a 3-year cooling-off period.  
X= No involvement in the activity allowed.  
RC= To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the declared company.  
RP+ = To be replaced as (vice)chair for the discussions, final deliberations and voting as appropriate in relation to the declared medicinal product and any medicinal product in the declared condition.  
XRappC = Cannot act as rapporteur in relation to any medicinal product from the declared company.  
XRappP+ = Cannot act as rapporteur in relation to the declared medicinal product and any medicinal products in the declared condition.  
XC = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product from the declared company.  
XP+ = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product in the declared condition.  
XP = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product or medical device in the declared condition.  
XI = Cannot participate in inspections relating to any medicinal product  
F = Full involvement.

Annex 3 – Handling of current and past interests in research organisations							
Declared interest in a research organisation	Time since declared interest ended	Committee / ETF / MSSG / MDSSG (vice)-(co-) chair	Working Party / MSSG Working Party (vice-) chair	Committee / ETF / MSSG Working Party / MDSSG Working Party Rapporteur	Committee / ETF / MSSG Working Party / MDSSG Working Party Member/ expert	SAG/ad-hoc expert group Chair / member	Inspector
Involvement in a unit that manufactures medicinal products or medical devices	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RRo RP+	XRappRo XRappP+	XRo	XRo	XI
Involvement in a unit that acts as a marketing authorisation applicant or holder for a medicinal product	Current	X	X	X	X	X	X
	Past (0-3 yrs)	X	RRo RP+	XRappRo + XRappP+	XRo	XRo	XI
Involvement in the conduct of research and development activities together with a company	Current	X	X	X	X	XP+	X
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Regulatory engagement on academic research	Current	X	RP+	XRappP+	XP+	XP+	XI
	Past (0-3 yrs)	X	RP+	XRappP+	XP	XP	XI
Affiliation to a research organisation	Current	RRo	RRo	XRappRo	XRo	XRo	XI
	Past (0-3 yrs)	F	F	F	F	F	F

X= No involvement in the activity allowed.  
RRo= To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in relation to any medicinal product/medical device from the declared research organisation.  
RP+ = To be replaced as (vice)chair for the discussions, final deliberations and voting as appropriate in relation to the declared medicinal product or medical device and any medicinal product or medical device in the declared condition.  
XRappP+ = Cannot act as rapporteur in relation to the declared medicinal product or medical device and any medicinal product or medical device in the declared condition.  
XRappRo = Cannot act as rapporteur in relation to any medicinal product/medical device from the declared research organisation.  
XRo = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to any medicinal product/medical device from the declared research organisation.  
XP+ = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product or medical device and any medicinal products or medical devices in the declared condition.  
XP = No involvement (i.e. no part in discussions, final deliberations and voting as appropriate) in relation to the declared medicinal product or medical device.  
XI = Cannot participate in inspections relating to any medicinal product from the declared research organisation.  
F = Full involvement.

Annex 2 – Handling of current and past interests in medical device companies							
Declared interest in a medical device company or notified body	Time since declared interest ended	Committee / ETF / MSSG (vice)-(co-) chair	Working Party / MSSG Working Party (vice)chair	Committee / ETF / MSSG Working Party Rapporteur	Committee / ETF / MSSG Working Party / MDSSG Working Party member/ expert	SAG/ad-hoc expert group Chair / member	Inspector
Employee (general matters)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
Employee (product-related)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
Consultancy/strategic advisory role (general matters)	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
Consultancy/strategic advisory role (product-related)	Current	X	X	X	X	XD	X
	Past (0-3 yrs)	F	F	F	F	F	F
Financial interests	Current	X	X	X	X	X	X
	Past (0-3 yrs)	F	F	F	F	F	F
(Principal) investigator	Current	X	RD	XRappD	XD	XD	XI
	Past (0-3 yrs)	F	F	F	F	F	F
Grant/other funding to organisation/institution	Current	RC	RC	XRappC	F	F	XI
	Past (0-3 yrs)	F	F	F	F	F	F
Close family member	Current	RC	RC	XRappC	XC	XC	XI
	Past (0-3 yrs)	F	F	F	F	F	F






X= No involvement in the activity allowed.  
RC= To be replaced as (vice)(co)chair for the discussions, final deliberations and voting as appropriate in consultation procedures involving any medical device from the declared company.  
RD = To be replaced as (vice)chair in consultation procedures involving the declared medical device.  
XRappC = Cannot act as Rapporteur in consultation procedures involving any medical device from the declared company.  
XRappD = Cannot act as rapporteur in consultation procedures involving the declared medical device and if relevant in relation to any medicinal product in the declared condition.  
XD = Cannot participate in inspections relating to any medicinal product from the declared company.  
F = Full involvement.

# Summary of handling of interests in pharmaceutical companies







# Current interests in pharmaceutical companies








## Direct interests

Employment		incompatible with any EMA activities
Financial		incompatible with any EMA activities
Consultancy or strategic advisory role (general matters)		incompatible with any EMA activities
Consultancy or strategic advisory role (specific products)	 	incompatible with role in committee/working party (WP) allowed <i>for SAG</i> but with restrictions on product concerned and products in the same declared condition

## Indirect interests

(Principal) investigator		incompatible with role of committee (vice-)chair
		allowed but with restrictions on product concerned and products in the same declared condition
Grant/funding to organisation/institution		Committee/WP chairs to be replaced Members cannot be appointed Rapporteur on products from company
Close family member direct interest		allowed but with restrictions on products from the company concerned

# Past (3 years) interests in pharmaceutical companies

Direct interests			Indirect interests		
Employment		No involvement on products from company concerned*	(Principal) investigator		No involvement on product concerned*
Financial		Full involvement			
Consultancy or strategic advisory role (general matters)		No involvement on products from company concerned	Grant/funding to organisation/institution		Full involvement
Consultancy or strategic advisory role (specific products)		No involvement on product concerned*	Close family member direct interest		Full involvement

\* With additional restrictions for key roles, see next slide

*Note: MDSSG are not subject to restrictions (i.e. full involvement) in case of any past interest in pharmaceutical companies*

# Past interests: additional restrictions for key roles

## Committee (vice-)chairs



Member cannot be elected (vice-)chair during a 3-year cooling-off period if they have:

- past direct interests
- past interests as (principal) investigator

## Working parties (vice-)chairs



During a 3-year cooling-off period, in case of past interest on specific product(s), will be replaced not only on the concerned product(s) but also for *all products in the same declared condition*

## Committee/WP members








During a 3-year cooling-off period, in case of past interest on specific product(s), cannot be appointed **Rapporteur** not only on the concerned product(s) but also for *all products in the same declared condition*





# Summary of handling of interests in medical device companies

# Current interests in medical device (MD) companies

## Direct interests

Employment		incompatible with any EMA activities
Financial		incompatible with any EMA activities
Consultancy or strategic advisory role (general matters)		incompatible with any EMA activities
Consultancy or strategic advisory role (specific products)	 	incompatible with role in committee/WP allowed <i>for SAG</i> but with restrictions on MD concerned and, if relevant, products in the same declared condition

## Indirect interests

(Principal) investigator		incompatible with role of committee (vice-)chair
		allowed but with restrictions on MD concerned and, if relevant, products in the same declared condition
Grant/funding to organisation/institution		Committee/WP chairs to be replaced Members cannot be appointed Rapporteur on MD from company
Close family member direct interest		allowed but with restrictions on MD from the company concerned

# Past (3 years) interests in medical device (MD) companies

## Direct interests

Employment	✓	Full involvement
Financial	✓	Full involvement
Consultancy or strategic advisory role (general matters)	✓	Full involvement
Consultancy or strategic advisory role (specific products)	✓	Full involvement

## Indirect interests

(Principal) investigator	✓	Full involvement
Grant/funding to organisation/institution	✓	Full involvement
Close family member direct interest	✓	Full involvement

*Note: MDSSG chairs, members and experts are subject to restrictions on the MD or company concerned during 3-yr cooling-off period in case of past employment, consultancy/strategic advisory role or role as (principal) investigator*

# Summary of handling of interests in research organisations

# Current interests in research organisations

## Direct interests

Involvement in a unit that manufactures medicinal products or medical devices



incompatible with any EMA activities

Involvement in a unit that acts as MAA or MAH for a medicinal product



incompatible with any EMA activities

Involvement in the conduct of R&D subject to an agreement with a company



incompatible with role in committee/WP



allowed *for SAG* but with restrictions on product concerned and products in the same declared condition

## Indirect interests

Regulatory engagement on academic research



incompatible with role of committee (vice-)chair



allowed but with restrictions on product concerned and products in the same declared condition

Affiliation to a research organisation



Restrictions on applications/products from the research organisation concerned



# Past (3 years) interests in research organisations

## Direct interests

Involvement in a unit that manufactures medicinal products or medical devices



No involvement on products from research organisation concerned\*

Involvement in a unit that acts as MAA or MAH for a medicinal product



No involvement on products from research organisation concerned\*

Involvement in the conduct of R&D subject to an agreement with a company



No involvement on product concerned\*

## Indirect interests

Regulatory engagement on academic research



No involvement on product concerned\*

Affiliation to a research organisation



Full involvement

\* With additional restrictions for key roles on products from same declared condition, similarly to pharmaceutical company

# Implementation of new policy and next steps

# Revised declaration of interest form aligned with policy

*reworded* →

## INTRODUCTION

SECTION 1: PERSONAL  
DETAILS

*updated* →

SECTION 2.1:  
PHARMACEUTICAL  
INDUSTRY

*updated* →

SECTION 2.2: MEDICAL  
DEVICE INDUSTRY

*new* →

SECTION 2.3: RESEARCH  
ORGANISATIONS

*updated* →

SECTION 2.4: ANY OTHER  
INFORMATION

*updated* →

SECTION 3:  
CONFIDENTIALITY  
UNDERTAKING



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Public declaration of interests and confidentiality undertaking

European expert (Regulation (EC) No 726/2004)

### INSTRUCTIONS

This form consists of the following parts: Personal details, Public declaration of interests and Confidentiality undertaking.

The Public declaration of interests and Confidentiality undertaking parts must be duly completed. The form is designed to be completed electronically and the data entered are stored electronically.

If you have interests to declare, please select 'Yes' for the relevant type of interest and provide further information. Your declaration will not be accepted if any of the mandatory fields, indicated with \*, are left empty.

Current interests should be declared as well as past interests which occurred in the last 3 years, as specified in the relevant section.

**Current** is interpreted as existing at time of completion of this declaration of interests, during a member's mandate or at the time of involvement of an individual in a specific European Medicines Agency (EMA) activity. An engagement/contract with a company of a recurring nature is considered a current interest.

For more information on which interests to declare, please see the [European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts](#) and [the procedural guidance to scientific committees' members and experts on inclusion of declared interests in the European Medicines Agency's declaration of interests in the Experts Management Tool](#).

# Update of procedural guidances

## Procedural guidance on completing the European Medicines Agency's declaration of interests (DoI) in the Experts Management Tool

- **helps experts to complete the DoI** in accordance with the policy
- explains who needs to submit a DoI and gives examples of EMA activities not falling under policy 0044 (e.g. trainings and workshops)
- gives general consideration on completing and updating the DoI
- **gives guidance on each type of interest: definition from policy, what is expected to be declared, what is not expected to be declared, how to declare**

## Procedural guidance on handling member's declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector

- to include also intention to be involved in a **unit within a research organisation** that manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices or that act as a marketing authorisation applicant or holder for a medicinal product
- to include also reference to **Management Board members**

**To be available on :** [Handling competing interests | European Medicines Agency \(EMA\)](#)

# Next steps

**27 March 2025:** new DoI form **go-live** in the Experts Management Tool (EMT)

**31 March 2025:** communication to all experts requesting to submit a DoI in the new format in the EMT by 1 May 2025 (in particular for those regularly involved in EMA activities)

- The **DoI in the new format is blank**, i.e. not pre-filled with previous interests, due to reorganisation of sections
- All current and past – within the last 3 years – interests which are still applicable need to be declared as well as any interests in research organisations
- CV remains available and can be updated if and as necessary

***If no DoI is received by 1 May 2025, the member/expert cannot be involved in an EMA activity/meeting falling under Policy 0044 after 1 May 2025 until a new DoI is submitted.***

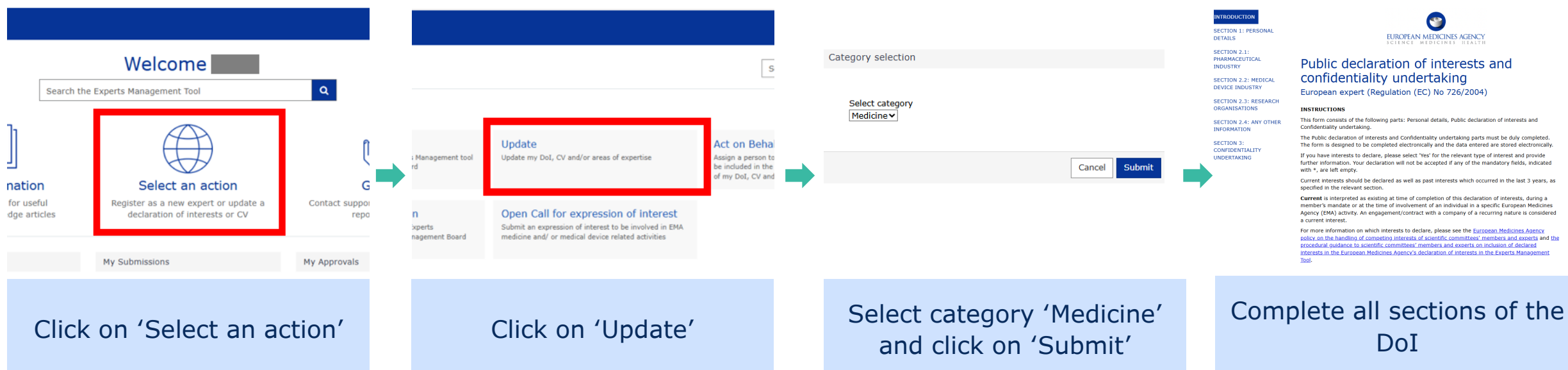
Questions on the completion of the DoI can be sent to [ExpertsDB@ema.europa.eu](mailto:ExpertsDB@ema.europa.eu)

For technical issues with accessing the EMT, please contact the [EMA Service Desk](#)

***Under development:***  
factsheet with overview of competing interests targeted at experts from patient and healthcare professionals organisations

# How to update your DoI (1)

Go to the Experts Management Tool: <https://experts.ema.europa.eu>



# How to update your DoI (2)

**\*EMPLOYMENT**

Yes

**\*EMPLOYMENT DETAILS (PHARMACEUTICAL COMPANY)**

**Add** **Remove All**

Name of	Job title

**Add Row**

\*Time period

Past

\*Start Date

DD-MM-YYYY

\*End Date

DD-MM-YYYY

\*Name of pharmaceutical company

\*Function

Medicinal product-related (one or more medicinal products)

\*Active substance name

\*Therapeutic indication

**Cancel** **Add**

In case of an interest, click on 'Add' and provide details in the pop-up window

**SECTION 2.4: ANY OTHER INFORMATION**

**SECTION 3: CONFIDENTIALITY UNDERTAKING**

☒ I undertake to submit an up-to-date declaration of interests and curriculum vitae at least on an annual basis and to update this declaration of interests and my curriculum vitae promptly should any changes occur, indicating additional interests that should be known to the Agency.

☒ I agree to abide by the above confidentiality undertaking.

This declaration does not discharge me from my obligation to declare any potential conflicting interest(s) at the start of any EMA activity in which I participate.

FULL NAME  DATE

<sup>1</sup> Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

**Previous** **Submit**

Complete the section on confidentiality undertaking

Click on 'Submit'

Note: Previous DoI can be found under 'My Documents'

EMA | Experts Management Tool

**My Documents** Submissions

File name	Created	Created by
DOI MED [redacted] 2025-01-22 10-09....	22-01-2025 10:09:13	[redacted]@id.ema.europa.eu
DOI MED [redacted] 2024-01-30 09-26....	30-01-2024 09:26:01	[redacted]@id.ema.europa.eu
CV [redacted] 2024-01-30 09-25.pdf	30-01-2024 09:25:59	[redacted]@id.ema.europa.eu
CV [redacted] 2023-03-22 23-21.pdf	22-03-2023 23:21:19	rest_user
DOI MED [redacted] 2023-03-22 20-49.pdf	22-03-2023 20:49:19	rest_user

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EUROPEAN MEDICINES AGENCY  
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# Thank you

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