

# Targeted stakeholder consultation on the pilot project ‘Market Launch Intentions of Centrally Authorised Products’

Fields marked with \* are mandatory.

## Introduction

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### **Objective of the consultation**

In the EU, a medicinal product can be placed on the market after it has received a marketing authorisation. A centralized marketing authorisation granted by the European Commission is valid throughout the EU, allowing the marketing of the medicinal product in all Member States. However, in practice, there are still important differences as regards when (if at all) a newly (centrally) authorised medicine is made available in each EU Member State.

The lack of availability of medicinal products in many Member States, particularly in those with smaller population sizes, is a general concern that has also been highlighted in the roadmap of the recently published Pharmaceutical Strategy for Europe. It poses a particular challenge to the underlying principle of the centralised authorisation procedure. This procedure was designed to serve wide availability to patients and healthcare professionals throughout the EU by allowing marketing authorisation holders to commercialise authorised medicinal products in each Member State based on a single marketing authorisation.

In order to increase availability of CAPs, an ad hoc working group was set-up under the Human Pharmaceutical Committee, bringing together the Commission, national competent authorities and the European Medicines Agency, to consider possible actions which could help improve a wider roll-out of CAPs. One of the agreed actions is a ‘pilot project’ to raise awareness on this issue and engage with prospective marketing authorisation holders through voluntary sharing of their marketing intentions for specific types of CAPs in the pre-authorisation phase, and to improve regulators’ knowledge on the mechanism behind delayed market launch. . Prospective marketing authorisation holders participating in this pilot will be invited to share this information on a confidential basis.

This pilot will be restricted to MAHs of orphan medicines and/or oncology medicines.

With this online consultation, we seek the stakeholders’ feedback on the proposed pilot project and its template for ‘Market Launch Intentions.’

The comments and suggestions received will be considered in the work leading to the implementation of this pilot project, which should start later this year.

Thank you in advance for your time and feedback.

## About you

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\* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- Gaelic
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

\* I am giving my contribution as

- Academic/research institution
- Business association

- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

**\* First name**

*Text of 1 to 150 characters will be accepted*

**\* Surname**

*Text of 1 to 150 characters will be accepted*

**\* Email (this won't be published)**

*Text of 1 to 150 characters will be accepted*

**\* Organisation name**

*Text of 1 to 255 characters will be accepted*

**\* Organisation size**

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

**Transparency register number**

*Text of 1 to 255 characters will be accepted*

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

\* Country of origin

Please add your country of origin, or that of your organisation.

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- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago

- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
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- Rwanda
- Saint Barthélemy
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen

- Czechia
- Lebanon
- Saint Helena  
Ascension and  
Tristan da  
Cunha
- Zambia
- Democratic  
Republic of the  
Congo
- Lesotho
- Saint Kitts and  
Nevis
- Zimbabwe
- Denmark
- Liberia
- Saint Lucia

**\* Publication privacy settings**

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

**Anonymous**

Only your type of respondent, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.

**Public**

Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

I agree with the personal data privacy provisions.

[Privacy statement.pdf](#)

## Your input to this consultation

Please read the description of the Pilot Project on 'Market Launch Intentions of Centrally Authorised Products' (the consultation document), which can be downloaded below.

Download the consultation document:

[Pilot project Market Launch Intentions.pdf](#)

**Please provide your feedback below.**

*4000 character(s) maximum*



**Alternatively, please upload your feedback in Word or PDF format.**

**Please upload your file**

The maximum file size is 1 MB

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

**Thank you for your feedback!**