The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the Consultation on the Study on a monitoring framework of the implementation of the pharmaceutical legislation

On 12 November 2026, the CPME Board adopted the 'CPME response to the Consultation on the Study on a monitoring framework of the implementation of the pharmaceutical legislation' (CPME 2026/209 FINAL).

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Revised pharmaceutical legislation monitoring framework survey

Fields marked with * are mandatory.

Introduction

Context

In December 2025, the European Parliament and the Council of the European Union reached a provisional political agreement on the reform of the EU pharmaceutical legislation. Formal adoption of the agreed legal texts, a new Directive and a new Regulation, is expected by the end of 2026. The new Directive and Regulation will replace the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively).

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) - through the European Health and Digital Executive Agency (HaDEA) - has commissioned a study to support the Commission in monitoring the implementation of the above mentioned legislation on medical products for human use. The study is conducted by the contractor Technopolis Group, an independent policy research consultancy, and supported by IQVIA Solutions B.V. The study team will develop a framework with key performance indicators (KPIs) to support the Commission in its activities related to the future long-term monitoring of the performance of the new EU pharmaceutical legislation, following its adoption. This survey has as its objective to collect stakeholder views on the proposed monitoring framework.

Instructions

You do not need extensive prior knowledge of the new pharmaceutical legislation to complete this survey. We will provide information to help you answer the questions. For further background, you can find the final compromise texts of the Regulation here and of the Directive here.

The survey contains 3 main sections:

1) **Respondent profile:** Information about the organisation you represent.
2) **Overall feedback:** A presentation of the proposed monitoring framework and questions about its overall structure.
3) **Specific feedback:** Questions about the specific thematic aspects relevant to your expertise.

The survey takes approximately 20 minutes to complete, depending on how many aspects you choose to provide specific feedback for.

Please use the survey's navigation buttons to move between sections. When you have finished, click "Submit" to send your response. You will have the opportunity to download your survey response in a pdf file when you submit. By clicking on "next", you consent to participating in this survey and for your data to be processed as detailed above.
Thank you in advance for your contribution.

Data protection

All data provided to the study team (Technopolis Group, IQVIA Solutions) will be used for the purpose of this study only. Acting in full compliance with EU law, and within its limits, the study team will keep any specific information (raw data) collected at the individual level and all personal data strictly confidential and under no circumstances will individualised information be disclosed. The study team will ensure that the data is handled with the utmost care and protection. Only aggregated survey outcomes will be published and included in the final reports. More detailed information on data protection is available in the Data Protection Notice included in attachment to the email invitation to this survey.
If you have any further questions regarding the organisation of the study, please do not hesitate to contact SANTE-PHARMA-POLICY@ec.europa.eu and/ or the Task Manager, Bregtje Kamphuis (bregtje.kamphuis@technopolis-group.com).

Respondent profile

* Which stakeholder category best describes the organisation you represent?
  - ○ EU institutions, agencies and expert networks
  - ○ EU Member State national competent authorities and HTA bodies
  - ○ Industry
  - ○ Industry association
  - ○ Academic expert
  - ◉ Patient and healthcare organisations
  - ○ International organisations

What is the name of the organisation you represent?

Standing Committee of European Doctors (CPME)

* What is the geographical scope of the organisation you represent?
  - ○ Subnational- operates within one part of the country
  - ○ National- operates within one country

- (●) European level- operates across multiple EU Member States and other European countries
- ( ) International- operates across multiple countries, including outside Europe

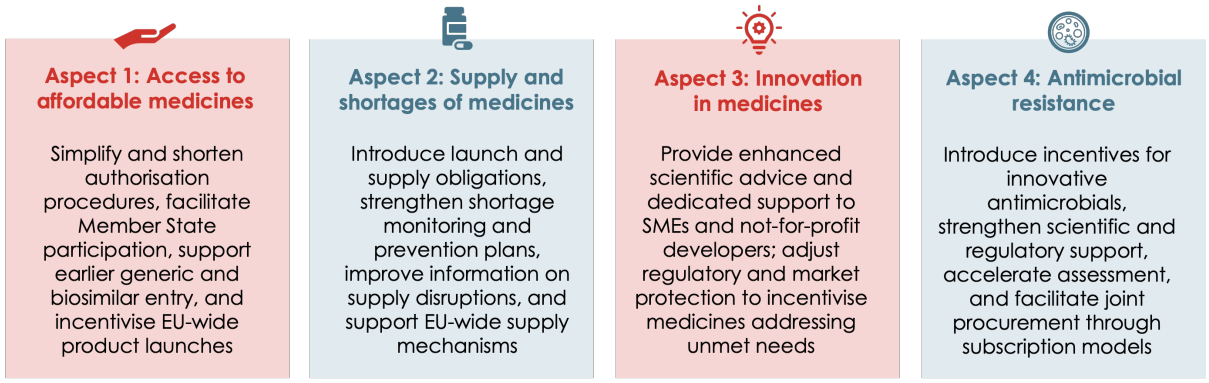
* Which country are you principally based in professionally?

Belgium

Overall feedback

The revised EU pharmaceutical legislation was developed to **update the regulatory framework in response to scientific and technological advances and persistent challenges**, including unequal access to medicines across Member States, medicine shortages, unmet medical needs and antimicrobial resistance. It seeks to strengthen the competitiveness of the EU pharmaceutical sector while maintaining high standards of quality, safety and efficacy. The proposed regulation would streamline authorisation procedures and the European Medicines Agency's governance, strengthen obligations and coordination for preventing and managing shortages, and introduce targeted incentives and regulatory support for the development of priority antimicrobials and medicines addressing unmet needs. It would also bring the rules for medicines for rare diseases and children into the same regulatory framework, strengthen environmental risk assessment, and provide more adaptable pathways for innovative medicines and public-health emergencies. Together, these changes aim to make the system more efficient and responsive while improving the availability of medicines for patients across the EU.

The monitoring framework we are developing will contain around **35 indicators, and is structured around 7 thematic aspects**. The 7 aspects are presented below, alongside the main legislative measures relevant to each. The indicators will be presented in later sections; for now we are interested in your views of the **structur e as a whole**.





Aspect 5: Environmental sustainability

Require environmental risk assessments for marketing authorisations, strengthen EMA environmental expertise, and enable additional post-authorisation environmental studies



Aspect 6: Simplification and digitalisation

Simplify and shorten marketing authorisation procedures and harmonise electronic applications and variations across Member States



Aspect 7: Competitiveness

Strengthen the EU pharmaceutical sector's capacity to attract investment, conduct clinical trials, manufacture medicines, and bring innovative therapies to market

To what extent do you agree that the framework structure **as a whole** is...

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
* Coherent with the objectives of the revised legislation	○	◉	○	○	○
* Clear and simple to understand	○	○	○	◉	○
* Comprehensive- covers all the key aspects of the legislation	○	◉	○	○	○
* Useful for EU-level monitoring	○	○	◉	○	○
* Useful for Member State-level monitoring	○	○	◉	○	○

Are there any **gaps** in the framework?

If so, please identify them and explain why you think they are important to include.

We highlight the importance of giving weight to the legislations' impact on access to medicines with a view to patient care. The clinical dimension is not covered in the proposed framework, as the proposed indicators measure regulatory and industry outputs (authorisations, timelines, number of shortages), but not whether the new legislation has improved health outcomes, e.g., access to medicines with added value to patients/clinical benefit, continuity of care and appropriate use. Also, healthcare professionals should always be involved in validating the indicators and they are the ones best placed to assess clinical relevance.

Other than gaps, are there any other ways you think the framework could be improved?

We propose that the framework will contain around 5 indicators per aspect, giving a total of 35 indicators. This aims to balance comprehensive coverage of the legislation with manageable data collection requirements and useful information for those using the framework.

* What do you think about the proposed **number of indicators** overall?

- ◉ Too few indicators
- ○ Correct number of indicators
- ○ Too many indicators

We aim for a broadly balanced distribution of indicators across the aspects. However, aspects considered more important for monitoring the legislation may warrant more indicators. In the matrix below, please indicate your views on the **relative importance of each aspect**.

	Not at all important	Not important	Neutral	Important	Very important
* Access to affordable medicines	○	○	○	○	◉
* Supply and shortages of medicines	○	○	○	○	◉
* Innovation in medicines	○	○	○	◉	○
* Antimicrobial resistance	○	○	○	○	◉
* Environmental sustainability	○	○	○	◉	○
* Simplification and digitalisation	○	○	◉	○	○
* Competitiveness	○	○	◉	○	○

Please provide further detail on your response, if you like.

Specific feedback

* We would now like you to respond to a set of more in-depth questions about one aspect in particular. You can decide which aspect you would like to focus on. You can also select more than one aspect if you wish. Please note that it will take around 5 minutes to respond to the questions for each aspect.

- [x] Access to affordable medicines
- [x] Supply and shortages of medicines
- [x] Innovation in medicines
- [x] Antimicrobial resistance
- [ ] Environmental sustainability
- [x] Simplification and digitalisation
- [ ] Competitiveness

Access to affordable medicines

High medicine prices, delayed generic and biosimilar competition, fragmented regulatory procedures and companies' launch or withdrawal decisions contribute to unequal access to medicines across the EU. Proposed measures include simplifying and shortening authorisation procedures, facilitating Member States' participation, expanding the Bolar exemption to support timely generic and biosimilar entry, requiring EU-wide

launch of paediatric products within two years, rewarding EU-wide launches with additional regulatory protection, and strengthening stakeholder dialogue. Together, these measures aim to accelerate market entry and improve equitable access to better, more affordable treatments, regardless of where patients live in the EU.

Proposed indicators for this aspect are as follows:

- Number of medicines authorised in a given year
- Number of medicines available to patients in European countries
- Level of use of Bolar exemptions (the Bolar exemption allows generic/biosimilar companies to start testing and preparing a product before the original medicine's patent expires)
- Number of EU-wide medicines launches within the last two years
- Average time before a medicine loses protection and competitors can enter the market
- Number of times existing medicines are approved for new uses or patient groups in a year
- Number of new medicines which receive a positive scientific recommendation for approval
- Time between marketing authorisation and the date of availability to patients
- Number of new medicines in clinical trial phases I, II, III
- Number of molecules reimbursed with restrictions per country
- Number of scientific advice requests received by the EMA

We would like your views on both the relevance and feasibility of the indicators proposed for this aspect:

- **Relevance**: How important and useful the indicators are for monitoring progress in access to affordable medicines
- **Feasibility**: How practical it is to obtain reliable data for these indicators on an ongoing basis, considering data availability, costs and effort.

The first three questions focus on relevance. Please consider the indicators' importance and usefulness regardless of whether data are readily available. The last set of questions address feasibility.

* Please rank the indicators from **most to least important for monitoring progress in access to affordable medicines**. Place the most important indicator first.

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- Number of medicines available to patients in European countries
- Time between marketing authorisation and the date of availability to patients
- Number of EU-wide medicines launches within two years
- Average time before a medicine loses protection and competitors can enter the market

- Number of times existing medicines are approved for new uses or patient groups in a year
- Number of new medicines which receive a positive scientific recommendation for approval
- Number of medicines authorised in a given year
- Level of use of Bolar exemptions
- New medicines in clinical trial phases I, II, III
- Number of molecules reimbursed with restrictions per country
- Number of scientific advice requests received by the EMA

Are **any important indicators missing** from the proposed set for monitoring progress in access to affordable medicines?
If yes, please suggest additional indicators and explain what they would help measure.

Continued unmet medical need, variation in price and reimbursement rules, sanctions against companies not complying with obligation to supply rules, number of negative government decisions under obligation to supply rules.

Other than gaps, are there any other ways you think the set of indicators for this aspect could be improved to ensure better coverage of the aspect *access to affordable medicines*?

For each of the indicators, we would like to hear if you have any concerns about the **feasibility** of collecting data for the indicator, and to hear of any **relevant data sources** you are aware of. Please enter this information in the table below.

	Please enter any concerns you have about the feasibility of collecting data for this indicator	Please enter any suggested data sources for this indicator, with links to the relevant data where possible.
Number of medicines authorised in a given year		Also measure numbers of alternative treatments
Number of medicines available to patients in European countries		
Level of use of Bolar exemptions		
Number of EU-wide medicines launches within the last two years		
Average time before a medicine loses protection and competitors can enter the market		
Number of times existing medicines are approved for new uses or patient groups in a year		
Number of new medicines which receive a positive scientific recommendation for approval		
Time between marketing authorisation and the date of availability to patients		
Number of new medicines in clinical trial phases I, II, III		
Number of molecules reimbursed with restrictions per country		
Number of scientific advice requests received by the EMA		

Please provide further detail on your responses to the questions in this section, if you like.

Supply and shortages of medicines

Supply chain vulnerabilities, delayed market entry and medicine withdrawals contribute to shortages that threaten patient care and health system resilience across the EU. Proposed measures include allowing Member States to impose launch and supply obligations, incentivising EU-wide launches, requiring explanations for supply disruptions and shortage prevention plans, strengthening national and EU-level monitoring and public information, requesting supply roll-out plans, and introducing a voluntary solidarity mechanism as a last resort. Together, these measures aim to prevent and mitigate shortages, strengthen security of supply, particularly in smaller markets, and ensure continuous access to medicines regardless of where patients live in the EU.

Proposed indicators for this aspect are as follows:

- How often medicine shortages are reported in advance (e.g. 6 months before shortage)
- Number of shortages
- Number of production facilities with enhanced capacities in increasing security and continuity of supply
- Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union
- Reasons for ongoing or resolved shortages monitored at EU level
- Average duration of resolved shortages monitored at EU level

We would like your views on both the relevance and feasibility of the indicators proposed for this aspect:

- **Relevance**: How important and useful the indicators are for monitoring progress in supply and shortages of medicines
- **Feasibility**: How practical it is to obtain reliable data for these indicators on an ongoing basis, considering data availability, costs and effort.

The first three questions focus on relevance. Please consider the indicators' importance and usefulness regardless of whether data are readily available. The last set of questions address feasibility.

* Please rank the indicators from **most to least important for monitoring progress in supply and shortages of medicines**. Place the most important indicator first.

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- How often medicine shortages are reported in advance (e.g. 6 months before shortage)
- Average duration of resolved shortages monitored at EU level
- Number of shortages
- Reasons for ongoing or resolved shortages monitored at EU level
- Number of production facilities with enhanced capacities in increasing security and continuity of supply
- Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union

Are any **important indicators missing** from the proposed set for monitoring progress in supply and shortages of medicines?
If yes, please suggest additional indicators and explain what they would help measure.

Other than gaps, are there any other ways you think the set of indicators for this aspect could be improved to ensure better coverage of the aspect *supply and shortages of medicines*?

For each of the indicators, we would like to hear if you have any concerns about the **feasibility** of collecting data for the indicator, and to hear of any **relevant data sources** you are aware of. Please enter this information in the table below.

	Please enter any concerns you have about the feasibility of collecting data for this indicator	Please enter any suggested data sources for this indicator, with links to the relevant data where possible.
How often medicine shortages are reported in advance		
Number of shortages		
Number of production facilities with enhanced capacities in increasing security and continuity of supply		
Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union		
Reasons for ongoing or resolved shortages monitored at EU level		
Average duration of resolved shortages monitored at EU level		

Please provide further detail on your responses to the questions in this section, if you like.

Innovation in medicines

Pharmaceutical innovation has addressed medical needs unevenly, leaving gaps in treatments for unmet medical needs, rare diseases and children, while SMEs and not-for-profit developers require additional support. Proposed measures include early and enhanced scientific advice, dedicated support schemes for these organisations, and adjusted regulatory and market protection periods to incentivise novel medicines and additional therapeutic indications. Together, these measures aim to stimulate innovation in underserved areas and expand the availability of treatments that better meet patients' needs.

- Number of submissions for marketing authorisation in a given year
- Number of medicines with an orphan designation
- Number of medicines that receive extra patent protection for addressing important unmet health needs

We would like your views on both the relevance and feasibility of the indicators proposed for this aspect:

- **Relevance**: How important and useful the indicators are for monitoring progress in innovation in medicines
- **Feasibility**: How practical it is to obtain reliable data for these indicators on an ongoing basis, considering data availability, costs and effort.

The first three questions focus on relevance. Please consider the indicators' importance and usefulness regardless of whether data are readily available. The last set of questions address feasibility.

* Please rank the indicators from **most to least important for monitoring progress in innovation in medicines**. Place the most important indicator first.

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- The number of medicines that receive extra patent protection for addressing important unmet health needs
- Number of submissions for marketing authorisation in a given year
- Number of medicines with an orphan designation

Are any **important indicators missing** from the proposed set for monitoring progress in innovation in medicines?

If yes, please suggest additional indicators and explain what they would help measure.

Continued unmet health needs, number of rejected applications for extra patent protection for addressing unmet health needs

Other than gaps, are there any other ways you think the set of indicators for this aspect could be improved to ensure better coverage of the aspect *innovation in medicines*?

For each of the indicators, we would like to hear if you have any concerns about the **feasibility** of collecting data for the indicator, and to hear of any **relevant data sources** you are aware of. Please enter this information in the table below.

	Please enter any concerns you have about the feasibility of collecting data for this indicator	Please enter any suggested data sources for this indicator, with links to the relevant data where possible.
Number of submissions for marketing authorisation in a given year		
Number of medicines with an orphan designation		
The number of medicines that receive extra patent protection for addressing important unmet health needs		

Please provide further detail on your responses to the questions in this section, if you like.

Antimicrobial resistance

Antimicrobial resistance (AMR) is a growing health threat, while scientific challenges, high development costs and low commercial returns constrain antibiotic innovation. Proposed measures include transferable data exclusivity vouchers, extended protection for qualifying products, enhanced scientific support through PRIME, accelerated assessment and a voluntary subscription model for joint antimicrobial procurement. Together, these measures aim to stimulate development and market entry of innovative antimicrobials, improving treatment options and affordability alongside prudent use to preserve their effectiveness.

The following indicators are proposed for this aspect:

- Number of AMR incentive vouchers awarded and/or used in a given year
- Levels of antibiotic use and/or antibiotic resistance in the EU
- Number of antibiotics approved in the EU
- Level of R&D investment in antibiotics

We would like your views on both the relevance and feasibility of the indicators proposed for this aspect:

- **Relevance**: How important and useful the indicators are for monitoring progress in antimicrobial resistance
- **Feasibility**: How practical it is to obtain reliable data for these indicators on an ongoing basis, considering data availability, costs and effort.

The first three questions focus on relevance. Please consider the indicators' importance and usefulness regardless of whether data are readily available. The last set of questions address feasibility.

* Please rank the indicators from **most to least important for monitoring progress in antimicrobial resistance**. Place the most important indicator first.

Use drag&drop or the up/down buttons to change the order or accept the initial order.

- ⠿ Levels of antibiotic use and/or antibiotic resistance in the EU
- ⠿ Number of AMR incentive vouchers awarded and/or used in a given year
- ⠿ Number of antibiotics approved in the EU
- ⠿ Level of R&D investment in antibiotics

Are any **important indicators missing** from the proposed set for monitoring progress in antimicrobial resistance?

If yes, please suggest additional indicators and explain what they would help measure.

Other than gaps, are there any other ways you think the set of indicators for this aspect could be improved to ensure better coverage of the aspect *antimicrobial resistance*?

For each of the indicators, we would like to hear if you have any concerns about the **feasibility** of collecting data for the indicator, and to hear of any **relevant data sources** you are aware of. Please enter this information in the table below.

	Please enter any concerns you have about the feasibility of collecting data for this indicator	Please enter any suggested data sources for this indicator, with links to the relevant data where possible.
Number of AMR incentive vouchers awarded and/or used in a given year		Revenue through vouchers per company, impact on health system expenditure
Levels of antibiotic use and/or antibiotic resistance in the EU		
Number of antibiotics approved in the EU		
Level of R&D investment in antibiotics		

Please provide further detail on your responses to the questions in this section, if you like.

Simplification and digitalisation

Fragmented regulatory processes across Member States lead to duplicated assessments, longer approval timelines and slower market entry, weakening the EU's attractiveness for pharmaceutical research and innovation. Proposed measures include simplifying and shortening marketing authorisation procedures and harmonising electronic applications for authorisations and variations to reduce administrative burdens for industry and national authorities. Together, these measures aim to accelerate market access and strengthen EU competitiveness while balancing rewards for innovation with affordability for health systems.

The following indicators are proposed for this aspect:

- Average duration of centralised marketing authorisation procedures
- Median time taken by regulators to respond to regulatory requests and/or provide scientific/regulatory feedback
- Average number of days spent in clock stops during CHMP assessment
- Number of harmonised marketing applications
- Number of electronic applications
- Number of MS having adopted electronic leaflets only
- Number of NCAs automatically sharing information with the EMA platform

We would like your views on both the relevance and feasibility of the indicators proposed for this aspect:

- **Relevance**: How important and useful the indicators are for monitoring progress in simplification and digitalisation
- **Feasibility**: How practical it is to obtain reliable data for these indicators on an ongoing basis, considering data availability, costs and effort.

The first three questions focus on relevance. Please consider the indicators' importance and usefulness regardless of whether data are readily available. The last set of questions address feasibility.

* Please rank the indicators from **most to least important for monitoring progress in simplification and digitalisation**. Place the most important indicator first.

Use drag&drop or the up/down buttons to change the order or accept the initial order.

⠿ Average duration of centralised marketing authorisation procedures

⠿ Number of harmonised marketing applications

- Median time taken by regulators to respond to regulatory requests and/or provide scientific/regulatory feedback
- Average number of days spent in clock stops during CHMP assessment
- Number of electronic applications
- Number of MS having adopted electronic leaflets only
- Number of NCAs automatically sharing information with the EMA platform

Are any **important indicators missing** from the proposed set for monitoring progress in simplification and digitalisation?

If yes, please suggest additional indicators and explain what they would help measure.

It would be good to evaluate whether healthcare professionals and patients can actually reach up-to-date information where electronic product information leaflets replace paper versions. This could be assess through collection of EMA national surveys from healthcare professionals and patient organisations.
We also advise to collect data on the number of rejected electronic applications, and the number of withdrawals following electronic applications.

Other than gaps, are there any other ways you think the set of indicators for this aspect could be improved to ensure better coverage of the aspect *simplification and digitalisation*?

For each of the indicators, we would like to hear if you have any concerns about the **feasibility** of collecting data for the indicator, and to hear of any **relevant data sources** you are aware of. Please enter this information in the table below.

	Please enter any concerns you have about the feasibility of collecting data for this indicator	Please enter any suggested data sources for this indicator, with links to the relevant data where possible.
Average duration of centralised marketing authorisation procedures		
Median time taken by regulators to respond to regulatory requests and/or provide scientific/regulatory feedback		
Average number of days spent in clock stops during CHMP assessment		
Number of harmonised marketing applications		
Number of electronic applications		
Number of MS having adopted electronic leaflets only		Number of adverse events linked to electronic leaflets only
Number of NCAs automatically sharing information with the EMA platform		

Please provide further detail on your responses to the questions in this section, if you like.

Closing

If you have any final comments or feedback on the monitoring framework, please enter them here.

We will be conducting further consultation activities as part of this project in the coming months. If you would be interested to be considered as a participant for these activities, please indicate this by ticking the box below, and entering your contact email address.

☑ **Validation workshop:**
An online validation workshop will serve both to present and validate findings and to increase buy-in from stakeholders who will be involved in the collection of data. The online validation workshop will last approximately 3 hours, will involve approximately 30 stakeholders and will be moderated by a senior member of the study team.

Please enter your contact email address here, if you would like to be considered for participation in the coming consultation activities.

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As specified at the outset, if you have any questions regarding the organisation of the study, please do not hesitate to contact SANTE-PHARMA-POLICY@ec.europa.eu and/ or the Task Manager, Bregtje Kamphuis (bregtje.kamphuis@technopolis-group.com).

Thank you for your contributions, please click submit to close the survey.

Contact

Contact Form