24 June 2026
European Medicines Agency

Webinar on Breakthrough program dd 24/04/2026 - Q&A

Clinical evidence

1. **Under the MDCG 2025-9 guidance and in the breakthrough device pilot, is the inclusion of in-silico clinical trials accepted and/or encouraged?**

   The guidance is not prescriptive of any specific method, but in general it endorses the inclusion of in-silico models where it can accelerate pre-clinical and/or clinical development for Breakthrough Devices, provided their credibility is demonstrated through robust verification and validation, and their contribution to the evidence generation is clearly defined and complementary to clinical data. For the purpose of meeting the breakthrough clinical impact criterion, the manufacturer may include relevant pre-clinical and clinical data to support a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use, keeping in mind that the level and type of information needed may vary depending on the intended use of the device, its technology and features, and the available standard of care alternatives. For more details, please refer to MDCG 2025-9 section 4.2.2.

2. **Will there be enhanced post-market surveillance mechanisms specifically tailored to these innovative devices?**

   MDCG 2025-9 does not establish a distinct post-market surveillance regime for breakthrough devices. However, it places particular emphasis on the importance and robustness of post-market evidence generation.

   In practice, this results in a more proactive and structured application of existing MDR requirements, ensuring that any uncertainties associated with innovative technologies are appropriately addressed throughout the device lifecycle.

NBs and breakthrough program

3. **Which benefits in the certification process at Notified Body side can be expected for a medical device with breakthrough designation? Will breakthrough designation accelerate the CE certification process with the NB, e.g. by shortening the dossier processing timelines?**

   The scope of the guidance and the breakthrough programme is to facilitate a timely certification process through three key mechanisms:

- *Prioritisation and early resource allocation by notified bodies*
- *Higher-quality submissions due to regulatory support during development, leading to fewer questions and fewer "clock stops" during conformity assessment, particularly in the context of the upcoming MDR Annex VII amendment.*
- *Balancing of clinical evidence requirements between pre-market and post-market, including the possibility of obtaining conditional certificates where appropriate.*

Taken together, these elements enable manufacturers to progress through conformity assessment more efficiently and achieve faster market access, even though the process is not formally labelled as accelerated.

Early and proactive engagement is also critical: manufacturers need to enter discussions with notified bodies at a sufficiently early stage, as late engagement makes prioritisation difficult.

The breakthrough guidance and framework call on all actors (notified bodies, manufacturers, and other stakeholders) to prioritise these files and plan resources accordingly. Manufacturers, in particular, are encouraged to submit complete, high-quality dossiers and to respond promptly and with priority to questions raised during assessment.

4. **Please clarify if breakthrough designation brings any timeline advantages for the conformity assessment considering MDR Annex VII.**
   The breakthrough designation is designed to facilitate prioritisation and early resource allocation from Notified Bodies. The priority review of breakthrough files is set out in guidance MDCG 2025-9 and, while not directly enforced in MDR Annex VII, is included in the proposed MDR revision[1].
5. **Is there a specific registration procedure for NBs required in order to contact the expert panels to receive advice?**

   All requests for advice from expert panels in support of a breakthrough device, both from manufacturers and from NBs, are received via submission of a letter of interest from the EMA website as demonstrated in the webinar. An EMA account is needed to be able to access the submission form. The form is intended for manufacturers/authorised representatives as well as for Notified Bodies, and no specific registration procedure is required beyond this online application.

6. **Are the conditional certificates (to post-market clinical evidence) of the NB only possible for breakthrough devices? Or may this be done for other devices as well?**

   Annex VII 4.8 of the MDR establishes the basis for the Notified Bodies to decide whether specific conditions or provisions need to be defined for the certification. This possibility applies to all devices subject to notified body conformity assessment.

7. **Should dialog with NB be initiated before application for designation? Or can both happen in parallel?**

   Manufacturers are not required to initiate dialogue with a Notified Body prior to application, as the guidance and programme are intended also for manufacturers at early stages of development who might not yet have a NB. The application for breakthrough designation can thus be submitted before or after initiating dialogue with the notified body. If a notified body is assigned already, the notified body should be informed and in agreement with the application, especially for the advice part.

[1] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

8. **How can manufacturers best prepare for early interactions with notified bodies in the context of breakthrough medical devices?**

   Manufacturers can best engage as early as possible when considering the breakthrough pathway. Early contact facilitates an effective exchange of information and supports preparation for the regulatory conformity assessment process. It is important to note that, for notified bodies to follow the formal processes associated with the breakthrough pathway, the manufacturer must obtain breakthrough status from the relevant expert panels. In addition, seeking scientific advice from the expert panels can support alignment and help ensure a more efficient conformity assessment.

9. **What are the cost implications of NB participation to the breakthrough program? What fees are associated with early dialogue with a notified body?**

   The cost implications of notified body participation in the breakthrough programme, including structured dialogue, will vary between notified bodies. Notified bodies are required to make their fees publicly available, covering both structured dialogue activities and conformity assessment services. Manufacturers are therefore encouraged to engage directly with their selected notified body to understand the specific costs associated with interactions and the broader conformity assessment process. Formal quotations can be provided by notified bodies to support financial planning.

10. **How much will the NB consider the expert panel decision / recommendation?**

    The manufacturer is expected to give due consideration to the advice from the expert panel (both on the breakthrough status and on the clinical development approach) and document it in the clinical evaluation report. Under the MDCG guidance, the notified body's assessment of a designated breakthrough device should take into account the considerations of the guidance and should endeavour to prioritise breakthrough files during planning and resource allocation.

<u>Timing for breakthrough application in relation to device development stage</u>

11. **At what stage of development is it recommended to apply to the breakthrough programme for designation and for advice? Is it appropriate for manufacturers to apply before initial clinical data are available, or even years before conformity assessment?**

    Manufacturers can apply at any stage of development before or after start of conformity assessment, provided that there is sufficient data supporting the breakthrough criteria and the advice request. It is recommended for manufacturers to use this possibility early on to seek expert panel advice on their planned clinical development and clinical investigation strategy. The guidance and programme have been developed so that devices can be designated and receive advice at early stages of development, months to years before market access.

12. **Can the breakthrough device program be applied to a device which is going through the process of certification?**

    Yes, breakthrough applications for devices that are already in conformity assessment can be made by NBs and by manufacturers, on condition that they are in mutual agreement. It is important to note that participation in the programme by manufacturers is encouraged at earlier stages of development, in order to make the most use of the benefits, e.g. early advice from expert panels on clinical development and priority review by notified bodies.

13. **Should a device that is completing preclinical stage enter breakthrough pilot first or apply directly to MDR Art 61(2) consultation?**

    The programme in support of breakthrough devices consists of two phases: breakthrough designation and advice. Manufacturers of devices having received breakthrough designation can

request advice within the breakthrough programme. Outside of the breakthrough pilot, advice to manufacturers under Article 61(2) remains available for Class III and Class IIb AARMP devices not designated breakthrough status or not seeking breakthrough designation, in which case the manufacturers do not need to enter the pilot, but can make use of the scientific advice for high-risk medical devices procedure.

Regarding the stage of development, manufacturers of medical devices or IVDs can apply for breakthrough designation at different stages, as long as there is sufficient data supporting the breakthrough criteria, i.e., an application with detailed supportive evidence on how the device in question meets the criteria set out in section 4 will be required (section 10.1 of MDCG 2025-9), as well as sufficient evidence supporting the provision of advice. For more information on the application requirements, the applicants can refer to the application templates available here.

14. For a device still in development, with technical documentation in preparation, and final tests/pivotal study not yet performed, is it possible to contact the expert panels to determine if the device can enter the breakthrough program?

Yes, it is possible to contact the expert panels' secretariat at this stage. Please note that submission of a letter of interest is always required as an initial step. This might be followed by an exploratory meeting, during which it will be assessed whether the request falls within the scope of the pilot.

Procedural aspects

15. When does this program start, and how to make a submission? Are there any detailed instructions available?

The pilot programme was opened on 28 April 2026. In phase Ia of the pilot, applications for breakthrough designation may be submitted until 22 May 2026 (included) via the EMA ServiceNow portal. Please note that an EMA account is necessary to access the webform. Detailed instructions, including a demonstration of the application platform, are available in the recording of the dedicated information session, and on the following webpage: https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices/expert-panel-support-breakthrough-medical-devices-pilot-programme.

16. What kind of documentation do the experts panel need to designate a device as breakthrough?

The decision will be based on the briefing document and relevant annexes, provided by the applicant after EMA secretariat validates the request previously submitted through the EMA ServiceNow portal. As shown in the publicly available EMA template, the briefing documents allows the applicant to provide the following information:

i. Description of the device, its mechanism of action, intended purpose and proposed indication;
ii. Justification of the degree of novelty;
iii. Rationale for the expected significant positive clinical on patient or public health.

17. When and how are the expert panels appointed and who is the point of contact for requesting expert panel allocation for a breakthrough review? Will it be similar to the Performance Evaluation Consultation Procedure (PECP)?

Expert panels are established at Union level under article 106 of the Medical Device Regulation and article 48 of the In Vitro Diagnostics Regulation. They are organised into 13 panels and are appointed by the European Commission, based on scientific, clinical and technical expertise. The list of experts currently appointed is publicly available on the following webpage:

https://health.ec.europa.eu/medical-devices-expert-panels/experts/expert-panels_en.
Within the breakthrough pilot, the allocation and coordination of expert panels for individual procedures are managed by the EMA secretariat, which acts as single point of contact for requests related to breakthrough designation and advice.
While the breakthrough process builds on the existing expert panel framework, it is a voluntary pilot programme that provides free advice to manufacturers of breakthrough medical devices and to notified bodies. As such, it is distinct from the Performance Evaluation Consultation Procedure (PECP) and the Clinical Evaluation Consultation Procedure (CECP), which are mandatory, formal consultation steps within the conformity assessment processes for certain high-risk IVDs and medical devices. However, the EMA secretariat is indeed also coordinating the allocation of these procedures to expert panels.

18. How can a manufacturer contact expert panels at EMA?

Manufacturers do not contact expert panels directly. All interactions are coordinated via the EMA secretariat, using the dedicated breakthrough pilot submission procedures. This ensures transparent allocation, independence of experts, and procedural consistency.

19. Is there a defined timeline from submission to Secretariat to Expert Panel decision?

The designation assessment process – from submission of the briefing document to the final assessment outcome – is expected to take approximately 60 days. The timeline for the subsequent advice stage is also expected to be around 60 days from submission of the final briefing document to expert panel advice, in line with the MDCG 2025-9 guidance. For further details on the pilot phases and associated timelines, please refer to the dedicated page on the EMA website.

20. Can you please explain who decides on the breakthrough status of a device?

The initiative for submission of a breakthrough designation request is with the manufacturer. The formal decision on granting the breakthrough designation rests with the expert panels, after evaluating the submitted documentation.

21. Is it possible to apply for the breakthrough program for a device if you are neither a manufacturer, authority or NB? Especially for devices very early in development, the legal manufacturer might not yet have been defined.

The guidance MDCG 2025-9 allows breakthrough designation at very early development stages, potentially years before CE marking. Any applicant who falls under the MDR definition of "manufacturer"[2] can apply for breakthrough designation of a device, thus also a company that "designs" (or develops) medical devices.

22. What is the difference between the "submission for designation" and the "designation briefing document"?

The submission for designation refers to the completion and submission of the letter of interest via the EMA ServiceNow portal to request breakthrough designation.
Applications that are selected may be invited to an exploratory meeting, which provides an opportunity for a high-level discussion on the device and the designation procedure. Following this step, applicants are required to submit a designation briefing document, prepared in accordance with the EMA template. This document will be evaluated by the assigned Expert Panels, who are

[2] MDR Art 2(30): 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

responsible for assessing the application and deciding whether to grant the breakthrough designation.

23. Would a device that is designated breakthrough, go back to the expert panel for review at the end of the conformity assessment process prior to CE marking?

There is no automatic requirement for a second expert panel review on the breakthrough status prior to CE marking. Further interactions with the expert panels occur only if the manufacturer requests additional advice or if required under the scope of the Clinical Evaluation Consultation Procedure (CECP) and Performance Evaluation Consultation Procedure (PECP) for certain high-risk medical devices.

24. What is the respective role of EMA expert panels and Notified Bodies in the breakthrough framework, particularly regarding the evaluation of clinical evidence and alignment with conformity assessment under MDR?

EMA's expert panels support breakthrough devices by providing early scientific and clinical input, including opinions on breakthrough designation and advice on the credibility and appropriateness of clinical or performance evidence generation strategies for highly innovative technologies.
Notified Bodies remain fully responsible and legally accountable for evaluating clinical evidence against MDR requirements and for issuing CE certification.
breakthrough status facilitates better-coordinated, lifecycle-based evidence generation, but does not lower clinical evidence standards or bypass conformity assessment.

25. Is a CER or results of a pivotal study required to help determine if a device can be designated as breakthrough?

MDCG 2025-9 does not require the submission of a full Clinical Evaluation Report (CER) or the results of a pivotal (confirmatory) clinical study for the purpose of breakthrough device designation. Where such documents are already available, they may be included as supporting information and appended to the briefing document, but their submission is not mandatory.
For breakthrough designation, expert panels assess whether there is a high degree of novelty together with a reasonable scientific expectation of significant clinical benefit, and not whether the full clinical evidence requirements for conformity assessment under the MDR or IVDR have already been met. This information should be presented in the designation briefing document.

Impact on other procedures/programs

26. Can the same device be designated Orphan and Breakthrough if it complies with the requisites of both programmes? If the device is participating in the Orphan programme, can it be eligible to participate also in the Breakthrough pilot?

Yes. If the criteria for both frameworks are met, a device may benefit from both designations, which serve distinct objectives and offer different benefits to the manufacturer. More specifically, the orphan status is indication- and population-specific, it does not imply technological novelty, and it allows flexibility in evidence generation due to population constraints. Whereas, the breakthrough status is not based on population size, it requires technological or clinical novelty and it allows prioritisation, and cross-body recognition of the breakthrough status, e.g. for HTA assessments, for grants and other financial supports.
The choice of one programme or both depends on the manufacturer's regulatory strategy. Please note the breakthrough programme is at an early pilot stage, which may affect the likelihood of selection in the near term in accordance with the applicable prioritisation criteria, whereas the orphan framework is already operating in regular mode, with all eligible submissions processed and no prioritisation applied. Early engagement with the EMA Secretariat is recommended to allow

case-specific considerations to be anticipated and to ensure that appropriate resources can be planned and allocated by all parties involved.

27. Can an orphan device having received orphan status benefit from leveraging evidence assessment for the advice on breakthrough status?

Yes. Where a device has already been granted orphan status, relevant evidence generated and assessed in support of that designation may be leveraged when seeking expert panel advice on breakthrough device status. In particular, information on disease context, unmet medical need, limitations of the available alternatives, and constraints affecting evidence generation due to small patient populations may be relevant and informative for the breakthrough designation assessment. However, breakthrough designation remains a distinct determination, and the expert panel will separately assess whether the device meets the breakthrough-specific criteria, including the degree of technological or clinical novelty and the reasonable expectation of significant positive clinical impact.

28. How will this pilot apply if at all to combination products?

Combination products are not excluded per se, however the breakthrough designation applies to the device/IVD component within the existing MDR/IVDR framework.

<u>Roll-out of pilots</u>

29. How many companies will be allowed to participate in the pilot programme, and what will be its duration before transitioning to the full programme?

The pilot is conceived as a phased, learning-based exercise rather than a permanent framework. In the first phase (Phase Ia), a maximum of five (5) applications will be selected for participation, based on predefined prioritisation criteria, including representation of cardiovascular therapeutic area, inclusion of paediatric populations, different types of devices and different stages of development according to the Technology Readiness Levels (TRLs).

This numerical cap is intentionally applied to ensure manageable resource allocation, effective testing of the framework, and meaningful learning before future scale-up.

Later phases (Phase Ib and beyond) will expand the scope of the pilot and the number of participants, with no fixed number of applications selected.

The establishment of a full, formal breakthrough device programme is expected only after completion of the pilot and following the adoption of the proposed MDR/IVDR revision[1] and the secondary legislation. A fixed start date for the full program has not been defined yet, as this will depend on the pilot learnings and the legislative progress. It is currently expected for 2028.

30. Why is the pilot focusing on cardiovascular and paediatric devices in its initial phase?

In the initial phase of the pilot programme, priority has indeed been given to cardiovascular and paediatric devices. This approach reflects considerations related to public health needs and the operational design of the pilot.

Cardiovascular conditions represent a significant burden of disease within the European Union, with considerable impact on morbidity and mortality. Prioritising devices in this field enables the pilot to focus on technologies that may have a notable clinical and public health impact. In addition, it also supports the prioritisation of the Safe Hearts Plan put in place by the European Commission. Paediatric medical devices are also included in recognition of the specific challenges associated with developing and assessing technologies for children. There is a recognised specific need for dedicated solutions for novel devices for children, a vulnerable population that is often underrepresented in medical device development.

In this way, the pilot programme is designed with a limited number of applications in its initial phase, allowing for controlled testing and evaluation of the new framework. Prioritising specific therapeutic areas supports a gradual, balanced and representative selection of cases, and an efficient and manageable assessment of the new process.

31. The pilot programme is set to launch in the second quarter of 2026. What specific timelines are envisaged from application to patient access?

The pilot programme introduces a structured process from initial application to completion of early regulatory support. It is designed to provide earlier and more coordinated regulatory support, rather than to establish a fixed time-to-market.

Breakthrough designation does not replace existing requirements for demonstrating safety, performance, and clinical benefit as part of the conformity assessment and certification of devices.

While this pilot may facilitate a more efficient development pathway, the overall timeline to patient access remains dependent on conformity assessment and national implementation processes and is therefore not predefined. Time to patient access depends on subsequent regulatory, clinical, and health system processes beyond the scope of the pilot.

32. Can manufacturers of Class I digital medical devices submit a breakthrough designation request before the official pilot launch, and what is the expected intake process?

During the initial phase of the pilot programme, eligibility for participation is restricted to Class III implantable devices and class IIb active devices that are intended to administer or remove medicinal products from the body.
Submissions for Class I digital medical devices can only be accepted from Phase II of the pilot, foreseen to start in Q1 2027, when the scope of the programme will be expanded to include medical devices from all risk classes.

However, manufacturers should carefully consider what the breakthrough program could bring them, especially for devices class I that are self-certified.

33. As there will be 5 applications selected for phase Ia, is it possible to apply for phase Ib or in future phases if the application is not selected for phase Ia? And how many applications are expected to be selected in phase Ib?

The class III and Class II AARMP devices that were not selected for phase Ia will be candidates for phase Ib if their manufacturer is still interested in participating in the pilot. No maximum number of applications has been decided for the designation step in Phase Ib. Phase Ib will build upon the experience from phase Ia, and is intended to scale up and learn from capacity building. If demand (number of submissions) exceeds capacity, mitigation actions might be necessary.

34. Will IVD applications for the breakthrough program only be accepted from Q3 2027?

IVD applications will indeed be accepted from Q3 2027 (phase III), not during the initial phases of the pilot.

35. If a medical device is NOT classified as Class III or Class IIb AARMP, will it only become eligible for the Breakthrough Pilot programme starting from Phase II?

Correct, such applications will be accepted from Phase II onwards, thus from Q1 2027 onwards.

36. Is it possible to apply to the Breakthrough Pilot Programme before the full technical dossier is complete, and submit for conformity assessment only after finalizing the dossier while already participating in the pilot?

Sure: as the pilot intends to accept devices at different stages of development, also devices still in early development are targeted. However, the manufacturer should be able to demonstrate a reasonable expectation that the device could provide for more effective treatment or diagnosis of the disease or condition identified in the proposed indications for use and intended purpose.

37. What risks have been identified at this pilot stage, and how does the EMA plan to mitigate them?

The pilot phase of the breakthrough programme is to test the new procedure with real test cases and as such there may be a number of potential operational and implementation challenges. These relate mainly to the novelty of the framework, the involvement of multiple stakeholders, and the need to ensure consistency and effective use of resources. The programme includes specific measures to address these challenges such as limiting the number of applications in the first phase of the pilot with a gradual expansion, the progressive involvement of notified bodies with a more structured coordination to ensure impartiality, support a consistent approach with the experts to harmonise robust outputs.

Scope of breakthrough program

38. What types of innovation are you aiming to attract - digital health, artificial intelligence, advanced diagnostics? Are there priority areas?

The breakthrough framework is designed to support a wide range of innovative medical technologies, rather than focusing on specific technology categories.

In the pilot phase, targeted prioritisation, particularly for cardiovascular and paediatric devices in the initial phase, is applied for operational reasons. However, the overall approach remains focused on clinical impact and unmet medical need, ensuring that the programme can accommodate a wide spectrum of innovation.

39. Would a novel sterilisation method, particularly one that reduces environmental impact, be considered a breakthrough manufacturing process?

No - under MDCG 2025-9, a novel sterilisation method, even if environmentally beneficial, would not in itself be considered a "breakthrough" device eligible for the breakthrough programme.

The breakthrough framework is device-centric and clinically driven, not a general innovation or manufacturing-process programme.

Transparency of breakthrough designation

40. Will there be a new logo for breakthrough devices in ISO 15223?

The breakthrough designation is a regulatory support and prioritisation mechanism, not a product labelling status, and it does not create new requirements for device marking or symbols. Breakthrough designation does not alter the applicable conformity assessment, CE-marking, or labelling requirements under the MDR or IVDR. Devices designated as breakthrough will continue to use the standard symbols and markings applicable to their regulatory status, including the CE marking, as set out in existing legislation and harmonised standards.

41. Will the decisions of the expert panel be made public, and will other manufacturers be bound by or required to follow the decisions or recommendations issued to another manufacturer?

Expert panel opinions or recommendations issued in the context of the breakthrough framework are not intended to be made fully public in a manner that discloses confidential or commercially sensitive information. While high-level information on the functioning of the breakthrough

framework, aggregated experience, or general principles may be communicated publicly, expert panel input provided within the breakthrough framework is case-specific and advisory, is not intended to be made publicly available in a device-specific manner, and does not create binding precedents for other manufacturers or devices.

Other

42. What types of financial incentives are being considered or planned for breakthrough devices?

No direct financial incentives are linked to breakthrough designation. However, by leveraging both EU-wide programs and national initiatives, medical device companies can access a broad spectrum of funding opportunities to support their innovation and growth objectives.

43. Will prior designation of the device as a Breakthrough Device in the United States be taken into account?

A breakthrough designation granted outside the EU (e.g. by the FDA) may be submitted as background information and may help contextualise the device's development history. While this information may be considered as supportive background information, breakthrough designation under MDCG 2025-9 is based on an independent EU assessment against EU criteria, and is not automatically conferred on the basis of non-EU regulatory decisions.

44. What are the breakthrough criteria for an innovative medical device and the regulatory requirements for startups in and outside the European Union?

The breakthrough device criteria are in MDCG 2025-9, chapter 4 "Breakthrough device criteria". The regulatory requirements are the same for all medical device and IVD manufacturers, irrespective of whether they are startup companies or established companies in the EU or outside the EU.

45. Has there been consideration amongst member states around healthcare reimbursement for EU for breakthrough-designated devices?

There is no automatic direct link between breakthrough designation and reimbursement. While the breakthrough programme focuses on support at Union level, national health systems retain responsibility for the organisation and delivery of healthcare services, pricing and reimbursement decisions, and the introduction and use of devices in clinical practice. Breakthrough devices are however particularly good candidates for parallel joint scientific consultation[3] with HTA bodies in the advice phase. Involving both HTA authorities and expert panels, supports early alignment on regulatory and HTA evidence expectations, which may facilitate later reimbursement decisions.

46. Does the EMA have any expectation/estimation on what percentage of devices might be able to receive breakthrough designation in a given year once the programme is fully launched?

No estimate or target percentage of devices expected to receive "breakthrough" designation per year is available. The framework is deliberately non-quota-based and driven by strict eligibility criteria rather than volume targets. The criteria "high degree of novelty", and "significant clinical benefit/unmet need" inherently limit eligibility to a small subset of genuinely transformative technologies.

[3] https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-scientific-consultations_en