EUROPEAN COMMISSION

Expert decision and opinion in the context of the Clinical Evaluation Consultation Procedure (CECP)

Expert panels on medical devices and in vitro diagnostic devices (Expamed)

Contents

Scope of this expert opinion

This scientific opinion reflects the views of independent experts (MDR Article 106) on the clinical evaluation assessment report (CEAR) of the notified body. The advice is provided in the context of the clinical evaluation consultation procedure (CECP), which is an additional element of conformity assessment by notified bodies for specific high-risk devices (MDR Article 54 and Annex IX, Section 5.1).

The notified body is obliged to give due consideration to views expressed in the scientific opinion of the expert panel and in particular in case experts find the level of clinical evidence not sufficient or have serious concerns about the benefit-risk determination, the consistency of the clinical evidence with the intended purpose including the medical indication(s) or with the post-market clinical follow-up (PMCF) plan.

Having considered the expert views, the notified body must, if necessary, advise the manufacturer on possible actions, such as specific restrictions of the intended purpose, limitations on the duration of the certificate validity, specific post-market follow-up (PMCF) studies, adaption of instructions for use or the summary of safety and clinical performance (SSCP) or may impose other restrictions in its conformity assessment report.

In accordance with MDR Annex IX, 5.1.g., the notify body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report.

1 ADMINISTRATIVE INFORMATION

Date of reception of the dossier	01/08/2022
Notified Body number	2797
Internal CECP dossier #	2022-000227
Medical device type	[redacted] is a fully resorbable mesh with a resorbable hydrogel coating. It is a sterile mesh device designed for the reinforcement and reconstruction of soft tissue deficiencies, co-knitted using poly-4-hydroxybutyrate (P4HB, < 60%) and polyglycolic acid (PGA, < 15%) fibers.
Intended purpose	The device is indicated for use in the reinforcement of abdominal soft tissue, where weakness exists, in ventral and hiatal hernia repair procedures.
Risk class / type	☒ class III implantable ☐ class IIb active device intended to administer or remove medicinal products(s)
Screening step: medical field / competence area	General and plastic surgery and dentistry

2 DECISION AND OPINION

PART 1 – DECISION OF SCREENING EXPERTS: NOTIFICATION OF NB AND COMMISSION REGARDING THE INTENTION TO PROVIDE AN OPINION

1.1 Decision of the screening experts

Table covers all three criteria, intended to support their consistent and conscientious application

Date of decision	23/08/2022
Screening panel decision	
Is there intention to provide a scientific opinion?	☒ **Yes** ☐ **No** ☐ **Insufficient information to reach a conclusion**
In case the information was found insufficient to reach a conclusion: summary of reasons	
Not applicable	
Summary as to why there is intention to provide an opinion	
The device is being used in daily surgical practice. The group of devices that this device belongs to, is commonly used and is no novelty. Also, the type of surgery is no novelty. However, there is insufficient data with sufficient follow-up time to assess whether the device is safe. It is clearly seen in surgical practice, supported by the literature, that complications after the use of this device occur over time. Current scientific data shows no sufficient follow-up to appropriately assess the device's safety.	
Summary as to why there is *no* intention to provide an opinion	
Not applicable	
Any other comments	
Not applicable	

1.2 Assessment of the three screening criteria

Criterion 1: Novelty of device under assessment and possible clinical / health impact
1.1 Novelty of device and/or of related clinical procedure
☒ No novelty: Neither device nor clinical procedure is novel ☐ Novelty: **Device** is novel ☐ Novelty: **Procedure** is novel
Short description of the novelty, including main dimension(s) of novelty

Not applicable
Overall degree of novelty
☐ Low level *or* ☐ Medium level *or* ☐ High level ☒ Not Applicable (neither the device nor the procedure is novel)
Uncertainties related to novelty
Not applicable
1.2 Possible negative clinical / health impact resulting from novelty
Not applicable
Estimated* severity of clinical and/or health impact
☒ No clinical or health impact ☐ Minor clinical or health impact ☐ Moderate clinical or health impact ☐ Major clinical or health impact
Uncertainties related to clinical/health impact
Not applicable

Criterion 2: Scientifically valid health concerns leading to significantly adverse changes in the benefit-risk profile of a specific group / category of devices and relating to **a) Component(s)** **b) Source material(s)** **c) Impact on health in case of failure of the device**	
2.1 Information received from Secretariat:	☐ Yes ☒ No
2.2 Other information available to experts:	☒ Yes ☐ No
2.3 Reference to peer-reviewed publications/information sources:	
1. Claessen JJM, Timmer AS, Atema JJ, Boermeester MA. Outcomes of mid-term and long-term degradable biosynthetic meshes in single-stage open complex abdominal wall reconstruction. Hernia. 2021 Dec;25(6):1647-1657. doi: 10.1007/s10029-021-02415-7. Epub 2021 Jun 7. PMID: 34097187; PMCID: PMC8182350. 2. Miserez M, Jairam AP, Boersema GSA, Bayon Y, Jeekel J, Lange JF. Resorbable Synthetic Meshes for Abdominal Wall Defects in Preclinical Setting: A Literature Review. J Surg Res. 2019 May;237:67-75. doi: 10.1016/j.jss.2018.11.054. Epub 2019 Jan 30. PMID: 30710881. 3. Van Rooijen MMJ, Tollens T, Jørgensen LN, de Vries Reilingh TS, Piessen G, Köckerling F, Miserez M, Windsor ACJ, Berrevoet F, Fortelny RH, Dousset B, Woeste G, van Westreenen HL, Gossetti F, Lange JF, Tetteroo GWM, Koch A, Jeekel J. Slowly resorbable biosynthetic mesh: 2-year results in VHWG grade 3 hernia repair. Hernia.	

2022 Feb;26(1):131-138. doi: 10.1007/s10029-021-02453-1. Epub 2021 Jul 19. PMID: 34282506; PMCID: PMC8881263.

4. Christopher AN, Morris MP, Jia H, Broach R, Fischer JP. Resorbable Synthetic Ventral Hernia Repair in Contaminated Fields: Outcomes with Poly-4-Hydroxybutyrate Mesh. Plast Reconstr Surg. 2021 Dec 1;148(6):1367-1375. doi: 10.1097/PRS.0000000000008579. PMID: 34757999.
5. [redacted]
6. Christopher AN, Morris MP, Patel V, Mellia JA, Fowler C, Messa CA 4th, Broach RB, Fischer JP. An evaluation of clinical and quality of life outcomes after ventral hernia repair with poly-4-hydroxybutyrate mesh. Hernia. 2021 Jun;25(3):717-726. doi: 10.1007/s10029-021-02394-9. Epub 2021 Apr 27. PMID: 33907919.
7. [redacted]

In case information was used from either the Secretariat or other sources

2.4 Groups/categories of devices:

The device under evaluation is part of the specific group of devices that the provided information is related to.

2.5 Relationship to component(s), source material(s) or health impact in case of device failure

☒ Health concern(s) relates to **component(s)**
☒ Health concern(s) relates to **source material(s)**
☒ Health concern(s) relates to **impact on health in case of device failure**

2.6 Description of health concern(s):

As mentioned before, the safety of the device cannot be fully assessed for the long-term use. Multiple adverse events have been described in the literature occurring over time after use of the device. There is sufficient scientific research on the group of devices but insufficient research on the specific device.

2.7 Reliability of information:

Reliable. Scientific research executed by world-known expert scientists in this field.

2.8 Relevance of information:

The information found is relevant. Existing clinical research with the medical device under analysis, demonstrates that the follow-up time after surgery with this device is very short. Therefore, we believe that to understand the true safety of the same a longer follow-up time is necessary.
2.9 Summary:
There are doubts about the follow-up time after use of this device. Our search in the scientific literature confirmed this and also revealed that some adverse events can occur over time.

Criterion 3: Significant increase of serious incidents of a specific group / category of devices relevant for the device under assessment ***(if information is available, it will always be provided by the expert panel secretariat)***	
3.1 Information received from secretariat?	☐ Yes ☒ No

1.3 Indication of appropriate thematic panel in case opinion is required

Indication of appropriate thematic panel and competence area		
	Expert panels	Medical and scientific/technical competence areas (these may correspond to sub-groups)
☐	**Orthopaedics, traumatology, rehabilitation, rheumatology**	☐ 1. Joint replacements (hip, knee, shoulder) ☐ 2. Spinal devices ☐ 3. Non-articulating devices, rehabilitation
☐	**Circulatory system**	☐ 1. Prosthetic heart valves and devices for heart valve repair ☐ 2. Cardiovascular stents (metallic and bio-resorbable) and vascular prostheses ☐ 3. Active implantable cardiac devices and electrophysiological devices ☐ 4. Structural interventions and new devices (e.g. LAA/PFO occluders, heart failure devices) ☐ 5. Cardiac surgery including extracorporeal membrane oxygenation, cardiopulmonary bypass devices, artificial hearts and left ventricular assist devices
☐	**Neurology**	☐ 1. Central and peripheral nervous system devices ☐ 2. Implants for hearing and vision (sensory recovery) ☐ 3. Neurosurgical devices
☐	**Respiratory, anaesthesiology, intensive care**	☐ Respiratory and anaesthetic devices
☐	**Endocrinology and diabetes**	☐ Endocrinology and diabetes devices
☒	**General and plastic surgery Dentistry**	☒ 1. Surgical implants and general surgery ☐ 2. Plastic surgery and wound care ☐ 3. Maxillofacial surgery & Devices for dentistry e.g. oral surgery, implantology, dental materials etc.
☐	**Obstetrics and gynaecology including reproductive medicine**	☐ Devices for obstetrics and gynaecology

☐	**Gastroenterology and hepatology**	☐ Devices for gastroenterology and hepatology
☐	**Nephrology and urology**	☐ Devices for nephrology and urology
☐	**Ophthalmology**	☐ Devices for ophthalmology

PART 2 – SCIENTIFIC OPINION OF THE THEMATIC EXPERT PANEL/SUB-GROUP

2.1 Information on panel and sub-group

Date of opinion	06/10/2022
Expert panel name	General and plastic surgery and dentistry
Sub-group of expert panel (where relevant)	Surgical implants and general surgery

2.2 Summary of expert panel opinion

- **Device description**

[redacted] is a fully resorbable mesh with a resorbable hydrogel coating. It is a sterile mesh device designed for the reinforcement and reconstruction of soft tissue deficiencies. It has been developed to reinforce areas where weakness exists in adults while minimizing the variability of resorption rate (loss of mass) and strength to provide support throughout the expected healing period. Preclinical implantation studies indicate that resorption of the poly(4-hydroxybutyrate) (P4HB) fibres is minimal throughout the 12-week expected healing period and up to 26 weeks post implantation. The fascial side of the mesh allows for a prompt fibroblastic response through the interstices of the mesh, allowing for complete tissue ingrowth, similar to P4HB mesh alone. The visceral side of the mesh is a resorbable hydrogel coating, separating the mesh from underlying tissues and organ surfaces to help minimize tissue attachment to the mesh. Shortly after hydration in saline, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days. The clinical use is to reconstruct soft tissue deficiencies, to provide immediate short-term support and to provide a scaffold that enables tissue ingrowth as the mesh resorbs over time.

[redacted] current clinical purpose is the reinforcement of abdominal soft tissue, where weakness exists, in hiatal hernia repair procedures in adult patients.

- **Novelty**

None of the elements of [redacted] are new or considered novel. The novelty part for this procedure is the extension of the intended purpose of the device to ventral hernia repair. However, surgical meshes are commonly used for ventral repair, so the interface between the patient and device for this indication is not considered novel.

- **Adequacy of clinical evidence assessment by notified body**

The clinical evaluation report (CER) and related documents used for the assessment of clinical evidence by the notified body provide sufficient data for the intended use. It has to be noted that the intended use will be extended to ventral hernia repair. Literature and registry data are collected from a relatively low number of patients but so far without evidence of decreased benefit or increased risk. The importance of PMCF Plan to record more clinical data is emphasized by the notified body (NB).

- **Sufficiency of clinical evidence**

The literature review was well structured and conducted, and it confirmed that device-related complications for patients treated with the [redacted] for open ventral and hiatal hernia repair are consistent with

complications associated with current standards of care. Clinical data is sufficient to support both uses of the [redacted] for hiatal hernia repair and open ventral hernia repair indications.

- **Adequacy of benefit-risk determination**

Outcomes discussed in the literature included hernia recurrence, reoperation rates and rates of adverse events. In the literature reviewed to assess the state-of-the-art for hernia repair, the use of meshes was demonstrated to lower the risk of hernia recurrence compared with the use of suture alone. For ventral hernia repair, synthetic and biologic mesh had similar complication rates and variable recurrence rates which may relate to differences in patient populations and follow-up times. For hiatal hernia, there were mixed results for recurrence and complications based on limited evidence comparing mesh to suture cruroplasty. Overall, state-of-the-art discussion shows that [redacted] has a comparable benefit-risk profile compared to other treatment options for use in ventral hernia repair and hiatal hernial repair.

- **Consistency of clinical evidence with purpose / medical indication(s)**

Although based on a small number of patients included in observational studies and with limited follow-up, the evidence provided is consistent with the purpose and medical indication(s).

- **Consistency of clinical evidence with the PMCF plan**

The PMCF plan for [redacted] specifies the PMCF activities that will be conducted to continue to acquire clinical data on the device. PMCF activities include collecting registry data for hernia repair from two registries, a manufacturer sponsored PMCF clinical study (retrospective trial with prospective follow-up), two Investigator Sponsored Studies (ISS), and Real-World Data analyses of the clinical data reported in Rognoni, 2020[1]. The PMCF plan will serve to gather additional longer-term data through a 5-year follow-up to confirm the safety and performance of the device throughout its expected lifetime and to ensure the continued acceptability of the benefit-risk ratio in all indications.

- **Overall conclusions and recommendations on clinical evaluation**

From the analysis provided, this expert panel agrees with the NB's assessment on the benefit-risk ratio of this device for the clinical indications currently under scrutiny in the early postoperative period. Further long-term studies with appropriate follow-up strategies are needed to draw definitive conclusions.

[1] Rognoni C, Cuccurullo D, Borsoi L, Bonavina L, Asti E, Crovella F, Bassi UA, Carbone G, Guerini F, De Paolis P, Pessione S, Greco VM, Baccarini E, Soliani G, Sagnelli C, Crovella C, Trapani V, De Nisco C, Eugeni E, Zanzi F, De Nicola E, Marioni A, Rosignoli A, Silvestro R, Tarricone R, Piccoli M. Clinical outcomes and quality of life associated with the use of a biosynthetic mesh for complex ventral hernia repair: analysis of the "Italian Hernia Club" registry. Sci Rep. 2020 Jul 1;10(1):10706. doi: 10.1038/s41598-020-67821-w. PMID: 32612131; PMCID: PMC7329869.

2.3 Detailed aspects of the opinion as required by MDR Annex IX Section 5.1

Opinion of the expert panel on the specific aspects of the clinical evaluation assessment report of the notified body (CEAR)[2]
1. Overall opinion on the NB's assessment of the adequacy of the manufacturer's clinical evaluation report
The notified body (NB) performed a thorough and sufficiently detailed assessment of the manufacturer's clinical evaluation report (CER) and all the clinical evidence presented. The clinical evaluation assessment report (CEAR) is considered adequate and detailed.
2. Opinion on the NB's assessment of the sufficiency of the clinical evidence provided by the manufacturer
The clinical evidence provided by the manufacturer in the CER and associated documents, namely the PMCF Report, were analysed extensively by the NB and evidence of that exercise was extensively provided in the CEAR. Some shortcomings were identified, namely the relatively low number of patients enrolled in the studies and registries, especially for the extended indication of ventral hernias and the relatively short follow-up period. In our opinion, this requires a stricter surveillance strategy as the one proposed by the manufacturer and agreed by the NB. Data used to assess the clinical evidence provided by the manufacturer was summarized in the CER. The device has been tested clinically in 596 patients, 360 for hiatal hernia repair and 236 for open ventral hernia repair. Outcome data were provided for each hernia type: • For hiatal hernia repair, clinical data were collected from published peer-reviewed clinical literature (3 studies, 162 patients), manufacturer-held unpublished data (180 patients) and the Herniamed registry (18 patients). • For open ventral hernia repair, clinical data were analysed from 1 published case report (1 patient), Real-World Data provided by the Abdominal Core Health Quality Collaborative (ACHQC) registry (66 patients), the Herniamed registry (65 patients), and Real-World Data analysed in the Charleux-Muller study[3] (104 patients). In our opinion, the data analysis for both indications were thoroughly performed by the manufacturer including clinical safety and performance outcomes. The follow-up period is relatively limited (not beyond 2 years), although an extended observation period of 5 years is foreseen, with data being acquired at specific time points. Regarding some specific outcomes, the following is highlighted: <u>Recurrence</u> Rates varied according to the number of patients included in the study or the length of the follow-up period. For hiatal hernia, recurrence rates in the clinical literature were 3.2% – 8.0% at 12 – 17 months of follow-up. In the Herniamed data, the recurrence rate was comparable with 11.1% (2/18) at 12

[2] According to Annex IX Section 5.1 of Regulation (EU) 2017/745 - Assessment procedure for certain class III and class IIb devices.

[3] Charleux-Muller D, Hurel R, Fabacher T, Brigand C, Rohr S, Manfredelli S, Passot G, Ortega-Deballon P, Dubuisson V, Renard Y, Romain B. Slowly absorbable mesh in contaminated incisional hernia repair: results of a French multicenter study. Hernia. 2021 Aug;25(4):1051-1059. doi: 10.1007/s10029-020-02366-5. Epub 2021 Jan 25. PMID: 33492554.

months of follow-up. Both results did not reflect a difference from standard of care results. However, for open ventral hernia, a recurrence rate of 18.3% (mean follow-up of 25.0 months +/- 17.6) from the Real-World Data analysis of the Charleux-Muller study[3] have to be noticed but may be explained by their occurrence predominantly in contaminated or highly contaminated fields. The ACHQC registry reports recurrencies for ventral hernia in 11.8% at 12 months. The recurrence rate from the Herniamed data was 9.3% (10/108) for ventral hernia at 12 months of follow-up. It must be noted that none of the registries analyses differentiated open from laparoscopic approach.

Postoperative Complications

For open ventral hernia, a surgical site occurrence (SSO) rate of 30.7% was reported in the Charleux-Muller study[3] that complies with the specified acceptance criteria for SSOs (25% +/- 8.5%). The SSO rate must be interpreted cautiously because many of the meshes were implanted in contaminated or highly contaminated fields. The ACHQC and Herniamed registries' analysis also reported SSOs for ventral hernia repair within the acceptance criteria: as extracted from ACHQC surgical site infection (SSI) was 6.3% at 30 days, and other SSOs were 11.0% (including seroma, hematoma, and infection). From the Herniamed data, pain was reported in 12.0% of the patients within 1 year for all patients with ventral hernia repair thus within the acceptance criteria rate of 17.6% for chronic pain at 1 year postoperatively.

In summary, the recurrence rates and postoperative complication rates are comparable to the standards of care. Data collection and analysis is clearly presented in the CER and the CEAR.

We agree with the NB's conclusion that there is sufficient clinical evidence to support the current indication of hiatal hernia repair and the extended indication for open ventral use. In addition, data collection for both hiatal and open ventral use will be ongoing by the defined PMCF Plan.

3. Opinion on the NB's assessment of the adequacy of the manufacturer's benefit-risk determination

The benefit-risk determination was based on data provided by published studies, registry data (ACHQC and HerniaMed) and manufacture's own data. The two indications were analysed separately:

- Hiatal hernia: 351 patients included (180 from manufacturer's data, 9 from HerniaMed and 162 from the literature review). Recurrence and complication rates are at standard level.
- Ventral hernia: 226 patients included (66 from ACHQC, 65 from HerniaMed and 105 from the literature review). Acceptable recurrence rates. In addition, a very recent publication (Van Rooijen, 2022[4]) gathered data from 84 additional patients. In this study, with a 2-year follow-up, the recurrence rate and surgical site occurrences were both acceptable. Because the study also had a low number of patients and a short observation time, the authors main recommendation was to have longer periods of follow-up in order to make clearer recommendations regarding the use of the product.

Based on the cited data, we agree with the NB's benefit-risk-determination. In addition, we have the following comments:

[4] Van Rooijen MMJ, Tollens T, Jørgensen LN, de Vries Reilingh TS, Piessen G, Köckerling F, Miserez M, Windsor ACJ, Berrevoet F, Fortelny RH, Dousset B, Woeste G, van Westreenen HL, Gossetti F, Lange JF, Tetteroo GWM, Koch A, Jeekel J. Slowly resorbable biosynthetic mesh: 2-year results in VHWG grade 3 hernia repair. Hernia. 2022 Feb;26(1):131-138. doi: 10.1007/s10029-021-02453-1. Epub 2021 Jul 19. PMID: 34282506; PMCID: PMC8881263.

1. There is a very limited number of patients included in the published studies and the registries: looking at the complications. The only concern that could be raised at present concerns the SSO rate of 30.7% that was reported in the Charleux-Muller study[3]. However, this meets the specified acceptance criteria for SSOs (25% +/- 8.5%), in particular considering that many of the meshes were implanted in contaminated or highly contaminated fields. The ACHQC and Herniamed registries reported safety outcomes for ventral hernia repair and, though not differentiated by open or laparoscopic approach, the rates for SSOs are also within the acceptance criteria.
2. The limited number of evaluated patients so far is not a striking argument to question the NB's risk assessment, since the degree of novelty of the device can be classified as low. The device itself shows no novelty. The extension of the intended use to ventral hernia repair has been shown to be an acceptable indication for similar products.
3. Most data cover a follow-up period of 2 years that must be regarded as relatively short. A follow-up of 5 years would be more adequate to detect recurrence and long-term risks (e.g., adhesions, bowel obstruction, fistula).
4. To address the issues raised in points 1 to 3, the PMCF Plan is recognized as having the potential to generate more reliable clinical data over a longer follow-up period.

4. Opinion on the NB's assessment of the consistency of the manufacturer's clinical evidence with the intended purpose, including medical indication(s)

The evidence provided by the manufacturer comes from observational studies with a low number of patients and relatively short follow-up period of observation. This low number of patients could be related to a limited adoption of this device in clinical practice due to its intrinsic characteristics. Apart from these limitations, the available data for the device, for the cited indications, was consistently assessed by the NB in what regards safety and performance of the device in the early postoperative period. Some doubts could be raised also in terms of long-term effectiveness since no defined postoperative follow-up protocol has been shown in the present studies (radiology, clinical examination, blinding of the assessors) and the follow-up rate looks suboptimal in the registry studies. Accordingly, the data should be confirmed in further studies in controlled environment and extended follow-up.

5. Opinion on the NB's assessment of the consistency of the manufacturer's clinical evidence with the PMCF plan

The PMCF plan is correct and consistent with the evidence provided by the manufacturer, as assessed by the NB.

In terms of abdominal wall and hiatal hernias, the studies presented are a valuable source of postoperative data and overall mesh performance and the investigators responsible for these studies are well-known experts in the field. Unfortunately, most of the studies will not enrol patients in a prospective way with defined inclusion criteria, clear endpoints and follow-up plan. For hiatal hernia only retrospective series will be available for evaluation thus introducing possible bias in performance evaluation. Nevertheless, the comparison of mesh to sutured repair for cruroplasy is of interest. For incisional hernia, the limited expected number of enrolled patients will be mitigated by the data coming from Herniamed and ACHQC registries that are potentially comprehensive and, hence, able to provide relevant Real-World Data.

2.4 Overall conclusions and recommendations

In the screening phase the reasons were identified for why it should be provided an opinion by the expert panels on this device: "It is clearly seen in surgical practice, supported by the literature, that complications after the use of this device occur over time. Current scientific data shows no sufficient follow-up to appropriately assess the device's safety."

This expert panel agrees with the assessment made by the NB regarding the adequacy and sufficiency of the clinical data presented by the manufacturer, as well as with benefit-risk ratio assessment.

A new multicentre study has been recently published and it adds 84 more patients with a 24-month follow-up to the data already analysed (Van Rooijen, 2022[4]). Overall, there is no evidence of increased recurrence or complication rate with this device compared to accepted standard procedures. Still, the number of patients enrolled in the different studies and registries is relatively low und the follow-up period relatively short.

The acquisition of more clinical data is foreseen in the PMCF Plan and this was also considered adequate to generate more clinical data and detect long-term adverse events like the ones caused by device-tissue interaction. Additionally, the device will be followed in two quality registries (HerniaMed and ACHQC) to further increase the available clinical evidence and to monitor the device throughout its expected lifetime.

2.5 Stakeholder information, where available

Relevant information provided by stakeholders, if applicable[5]
Has the Secretariat provided information from stakeholders?
☐ Yes ☒ No
Summary of the information that was taken into account and how it was taken into account.
Not applicable

2.6 Divergent positions in case no consensus was reached

Summary of divergent positions
There were no divergent views in the panel.

Please indicate how many of the experts of the panel or sub-group had divergent views
Not applicable

[5] According to Article 106.4 of Regulation (EU) 2017/745, expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions.