ERNs & HCPs Evaluation FAQ

Acronyms

Healthcare Provider Centres (HCPs)

European Reference Networks (ERNs)

Independent Evaluation Body (IEB)

IDOM Consulting, Engineering, Architecture (IDOM)

Andalusian Agency for Healthcare Quality (ACSA)

European Union (EU)

Board of Member States (BoMS)

Network Coordinators (NC)

Online Exchange Information Tool (OEIT)

Measurable Elements (ME)

Project Managers (PM)

Not Applicable (NA)

European Foundation for Quality Management (EFQM)

Improvement Plan (IP)

General Process of the Evaluation

1. Key dates of the evaluation process.

According to the Evaluation Manual, the evaluation process will be implemented in four stages:

1. Preparatory steps, which started on 11th November 2022
2. Self-evaluation, which started on 19th December 2022 and finishes on 19th February 2023 for Healthcare Provider Centres (HCPs) and on 26th February 2023 for European Reference Networks (ERNs)
3. Technical evaluation will start after the self-evaluation. This stage includes performing virtual interviews for the ERNs level and onsite audits in some HCPs
    a. Virtual interviews will be carried out between 27th February 2023 and 27th March 2023
    b. Onsite audits will be conducted between 9th March 2023 and 18th May 2023
4. Evaluation results, from the end of May until the beginning of September 2023

These key tasks and dates were presented in the Webinar (12th December 2022). However, the deadlines and timeline are subject to change at the discretion of the European Commission and the Independent Evaluation Body (IEB).

2. Composition of the IEB and profile of the auditors.

The Consortium consisting of IDOM Consulting, Engineering, Architecture (IDOM) and the Andalusian Agency for Healthcare Quality (ACSA) has been appointed by the European Union (EU) Commission as the IEB to perform the technical evaluation of the ERN and their Members. The pool of experts to perform the evaluation has over 200 evaluators. In general, most of them are senior healthcare professionals with:

- Over 10 years of professional experience
- Experience in quality or healthcare management

3. Did the National Authorities also receive the information about this evaluation? Will the evaluation results be shared with the respective Ministries of Health?

The representatives on the ERNs Board of Member States (BoMS) are aware and periodically informed by the Commission about the different stages of the ERNs evaluation.

Some examples of their implication are:

- The BoMS approved the Operational Criteria for the ERNs evaluation in February 2022, and afterwards, Network Coordinators (NC) were informed
- As well, the members of the BoMS were informed about the beginning of the ERNs evaluation by the Commission
- The BoMS will receive the final reports of the ERNs evaluations

4. How could we discuss the revision of the current deadline for the submission of the self-evaluations?

The Commission has analysed the external factors which could affect the self-evaluation (such as the current hospital pressure or parallel ERNs processes) and the estimated time to fulfil the self-evaluation form. In consequence, the deadline for the submission of the self-evaluation has been already extended to **19th February for the HCPs and 26th February for ERNs**.

5. **How and when will all ERN members to be evaluated receive formal communication from the Commission on the evaluation? Will the respective hospital managers also receive formal communication from the Commission?**

The formal announcement of the beginning of the ERNs evaluation process was done by the Commission on 15th November 2022. This communication was emailed to all the contacts included on the ERNs directorate list kept by the Commission services. If hospital managers teams are included on this list, they would have received the communication at the same time as the HCP representatives.

6. **In the Evaluation Manual it is stated that the procedure starts with the request of the NC, is it established what will happen if the NC does not request to be evaluated?**

The evaluation procedure starts for two different reasons, according to the Implementing Decision 2014/287/EU:

- NC request or
- automatically at least every five years from the initial assessment

7. **In paragraph 6.1 of the Evaluation Manual it is stated that the evaluation is not intended to obtain a "positive or negative" result, could you explain how this fits with the flowchart of the evaluation process where it is shown that the procedure could terminate with the termination of the ERN or membership of ERN members?**

As it is stated in the Implementing Decision 2014/287/EU, the BoMS is responsible for the termination of ERNs and loss of memberships.

As the evaluation of ERNs and their Members is carried out independently, the results will be considered by the BoMS to decide about the termination of an ERN or a loss of membership.

According to Articles 11 and 12 of the Implementing Decision 2014/287/EU an ERN shall be terminated in the case of a negative evaluation report of the ERN has been drawn up according to Article 14, and a Member of an ERN may lose membership if the Member refuses to be evaluated under Article 14 or if a negative evaluation report on the Member has been drawn up according to Article 14.

In addition, considering Article 14, the BoMS may request an Improvement Plan (IP) from those Members/ERNs whose evaluation has not been satisfactory and offer the Member/ERN in question one year to remedy the shortcomings identified before carrying out a new evaluation.

8. **Will the evaluators take into account the national/hospital administrative procedures (e.g., subcontracting - delay of grant signature - mono beneficiary grant) delaying the achievement of the ERN goals?**

The impact on the achievement of the ERN goals due to unexpected or out-of-control variables will be properly assessed by the evaluation team. However, if the implementation of the objectives has been interrupted, an explanation of the activities that have been planned to overcome the unforeseen events that have delayed the achievement of the objectives, should be attached in the comments area.

9. **COVID impacted significantly HCP activities from March 2020 up to end 2021. How will this be considered by the evaluators? The impact of the pandemic was different depending on the country, how is this aspect considered?**

Of course, COVID-19 impact will be considered. However, an explanation of the impact on the results will be expected.

10. Some ERN Members extended their area of expertise recently (in April 2022). Can you confirm that the new departments of these HCPs also will not be included in the evaluation?

The evaluation period covers from the initial assessment of the ERN/HCP until the end of 2021. This entails that, those areas of expertise that have been extended recently are not included in the current evaluation process.

11. If we are currently in the process of evaluating our reference centres, are there gateways with your procedure or shall we do it again for the Commission?

Unfortunately, no. All the HCPs that went through an assessment in 2017 are required to go through this evaluation process.

12. In the case of an ERN counting two multidisciplinary teams in the same hospital, dealing with different groups of diseases, should they submit a common evaluation or two separate ones?

If each multidisciplinary team submitted separate assessments in 2017, then each team will have to deal with separate evaluation processes. Therefore, two self-evaluations should be submitted.

13. Will the HCP representative be involved in a double evaluation procedure? such as NC and such as an HCP.

HCP representatives will only be involved in their own evaluation process. However, if that person is also acting as the NC, they could be involved in a double procedure: one concerning the ERN and other concerning the HCP that they represent.

14. Where can we find Manuals and other forms before having access to the Online Exchange Information Tool (OEIT)?

Both, the Evaluation Manual and the Technical Toolbox were published in February 2022.

A summary with the explanation of the evaluation process has been uploaded in the Commission's website (https://health.ec.europa.eu/european-reference-networks/overview/evaluation-european-reference-networks_en).

Also, those documents are available on the website of some ERNs as well (such as ERN-CRANIO, Endo-ERN or ERKNet).

Additionally, these support documents have been sent to the participants after the webinar, uploaded to the OEIT (https://www.ern-assessment.com/) , and, if requested, may be sent by the helpdesk.

Communication

15. Which is the contact point for queries during the evaluation process?

An Evaluation Coordinator will be allocated to each ERN and each HCP. These Evaluation Coordinators can be contacted through two different channels:

- For any internal communication or information related to the evaluation methodology, the communication area of the OEIT may be used
- For any technical problems, suggestions, or logistical issues, via email or telephone: helpdesk@ern-evaluation.eu, phone number: +34 946 89 73 45

16. How can we contact the evaluators?

For any internal communication with the evaluators, the communication area of the OEIT may be used.

The role of the NC

17. There are criteria that cannot be formally checked by the NC and the NC can just trust the information provided by the HCP What are the legal aspects related to the acknowledgment process related to the NC?

The NC only must acknowledge that each HCP has submitted its self-evaluation through the OEIT. There is no need for a review or analysis of the information contained in the HCPs' self-evaluation. It is simply a verification that they have done it. Therefore, the NC has no legal responsibility for the information provided by the HCP.

18. Will NCs have a training session to make sure the acknowledgment is done in a harmonised way for all the ERNs in parallel to what is being done for the AMEQUIS evaluators that will need to be trained and oriented to their role to assure consistency of the scoring of the criteria between different evaluators?

No training session is expected. The OEIT user guide contains explanations about how to perform the "validation", which is only an acknowledgment of the self-evaluation submission by each Member of an ERN.

19. Will the NC or its team be able to do the acknowledgment directly through the OEIT?

The NC should only carry out the acknowledgement of their Members' submissions. This can be done through the OEIT.

20. Will the acknowledgment at the ERN level and at the HCP team level happen at the same time?

There is no acknowledgment of the ERN level self-evaluation.

The self-evaluation of the ERNs is open for one more week to allow all HCPs to complete their self-evaluation and for the NC to make its acknowledgment. Therefore, the self-evaluation for the ERNs and HCPs has different deadlines, 19th February 2023 for the HCPs and 26th February 2023 for the ERNs.

21. Will the measurable elements (MEs) be supplemented with standards?

An Evaluation Manual and a Technical Toolbox have been developed based on internationally recognised practices. For additional information, please refer to section 2.1 of the Evaluation Manual or sections 1 and 2 of the Technical Toolbox.

22. At this time point can HCPs make comments concerning some ME?

The methodology of the evaluation process has been developed with representatives of different ERNs in several working groups. At this point, no changes can be introduced.

The Operational Criteria were approved by the ERNs BoMS in February 2022, and the NCs were informed soon afterwards.

OEIT

23. Will the HCPs receive direct emails with the login details for the OEIT? Is the username and password the same as the access to ERN?

All the contacts included on the ERNs directorate list provided to the IEB will receive an email with their login details to access the platform on 19th December 2022, date on which the self-evaluation will start for ERNs and HCPs.

If any representative has not received it, a request can be sent through the helpdesk to add it to an evaluation project.

24. When will the OEIT be available to ERN Members and ERN Coordination Teams?

The platform is available for ERNs and HCPs from 19th December 2022.

25. Will the OEIT enable HCPs to save draft versions of their evaluation responses?

Draft version of the self-evaluation can be saved to allow the HCPs/ERNs complete and edit their answers.

All users have access to the information of the ERN/HCP process in which they are involved. The OEIT can save the information and changes made by the users throughout the evaluation process. This includes comments, documents, scoring, and messages exchanged to and from users and the IEB.

26. How many people will be allowed to access the OEIT for each HCP/ERN Coordination Teams?

All the contacts on the ERNs directorate list provided by the Commission will be able to access their respective evaluation, if any other representative need access credentials they can be requested.

27. Who will have access to the evaluation reports of the ERN and of the individual Member?

Each HCP representative and sub-representative will have access to their own evaluation report and each NC and Project Managers (PMs) will have access to their evaluation report. Only the NC will have access to all HCPs evaluations from their ERN.

28. Is there a maximum number of signs you can use for the comments?

The limit of characters in the comment area is 4,507.

Self-evaluation

29. What kind of evidence should be included in the self-evaluation?

ERNs/HCPs need to add any document that support the explanation related to their compliance with each ME's requirements.

This evidence can adopt different formats:

- Documents that describe how the HCP carries out different processes, activities, etc.

- List of indicators, guidelines, and protocols, list of patient associations, etc. In both cases, the document or the link that allows the evaluator to access the document should be attached
- List of documents to be prepared by ERNs and their Members also facilitates information regarding the evidence that can be provided

For additional information, please refer to section 6 of the Technical Toolbox "List of documents and other evidence suggested being prepared by the ERN and their Members".

30. What language should the evidence and self-evaluation form be written in?

The self-evaluation form must be filled in English. All the documents provided by the ERNs and the HCPs as evidence should be in English or in the original language with a summary in English.

31. If a document has not been created before the evaluation. Can we create it and submit it?

Those documents which have not been created yet should be elaborated to be submitted as evidence.

32. Is it mandatory to complete each of the MEs and evidence to close the self-evaluation?

It is mandatory to complete **ALL** MEs. However, some ME do not require the attachment of supporting documentation. In these, explanations can be added in the comments area.

33. Should the evidence documents be uploaded on the OEIT in a specific file format? (. word, .pdf, etc.).

The evidence documents can be uploaded in any format (Word, PDF or Excel, among others).

34. The Excel template with the questions can be filled in and then uploaded on the OEIT, or information needs to be filled in directly on the OEIT?

The excel template must be filled in and then uploaded on the OEIT.

Self-evaluation and ME for HCPs

35. In the OEIT, will it be possible to submit one document for multiple MEs or an individual document must be uploaded for each ME?

Documents that have been already uploaded to provide evidence for other ME can be re-used. To re-use evidence, the document in question can be selected from documentation that has been already uploaded or simply refer to the document in question in the area for comments.

36. Is evidence required for each and every item? Even for those which are validated as part of the onsite audit?

Evidence is not required for each ME.

Even for those MEs which are validated as part of the onsite audit, provision of evidence may still be required to show compliance with the ME.

37. Will document links/webpage links be sufficient as an evidence format?

Document/webpages links will only be sufficient if the link allows the evaluators to access a document or relevant information supporting the ME.

38. When we ask the HCPs to do the self-evaluation, do they need to gather all the documentation, or will it be enough to confirm the existence of the beforementioned documentation and that they have it available upon request?

The HCP will need to gather all the information and documentation used as evidence before submitting the self-evaluation and uploading it to support the ME.

39. Question A.9 of Part A requests: "Please indicate the research activities and clinical trials, at both national and international levels, within the ERN's area of expertise in which the HCP has participated in the framework of the ERN": Do the HCPs have to report only the research activities that were reported in the ERN Monitoring Indicator or is a broader list accepted? (The monitoring indicators are already asked in the following questions A.10 of the same form).

In this question of section A of the self-evaluation, a broader list is accepted (whatever is easier for HCPs).

40. Why is some data requested from the past 3 years, and other data is requested from the past 5 years?

Some of the sections that require the HCP to provide information on the last three years of activity refer to the monitoring indicators that were published in 2019.

41. ME 1.6.1: How the term "comprehensive" in ME 1.6.1 will be measured? (This concerns some other MEs; it is advisable to clarify all these misleading terms).

Comprehensive information should include everything that is needed or relevant about the treatment and diagnosis. Therefore, the information that patients and families receive must be integral, holistic and consistent.

42. ME 1.9.1: In the scoring guidelines, there is the same score for 1 and 2, is it a clerical error?

The scoring guide in this particular ME is dichotomic.

43. ME 3.1.3: This ME requires as evidence a list of educational activities organized by the HCP and makes reference to the ERN monitoring indicator 4.1 and 4.2. Could you please specify whether this list should be restricted only to the ERN monitoring indicators reported or if it can include also some activities that were not reported in the monitoring but that fall into the scope of the ERN? (This question applies to all the ME that are linked to an ERN monitoring indicator).

Extended information will be useful for the evaluator to better understand the performance of ERNs and HCPs. However, it should be clearly indicated the information that is directly related to the monitoring indicators.

44. ME 3.2.1. evidence says, "Include your answer in table 11 of the application form." Does it need to be replicated in the answer to 3.2.1. or only appear in Table 11?

Please note ME 3.2.1 refers to table 9 of the HCPs self-evaluation instead of table 11.

Documentation already provided in other sections of the self-evaluation can be referred to, it does not need to be replicated.

45. Section A, III, 8: in EpiCARE we cover more than 120 diseases and conditions, how could HCPs list all the rare epilepsy that they have encountered in the last 5 years?

Please, just list a selection of the conditions you treat. If the ERN/HCP considers some diseases to be more relevant for the evaluator to carry out the technical evaluation, those should be added to the list.

46. For the self-evaluation exercises (featuring as part of the evaluation of the ERN and HCPs) - In some cases (where relevant) we are informed in the manual that a fourth scoring category is introduced (such as NA). In other cases, the scoring is dichotomous (0 or 2). Will this be clear to participants when filling out the form online? This is not clear from the (offline) version we have already.

The scoring options are clearly indicated in the OEIT for each ME. A Not Applicable (NA) option is included where needed, according to the scoring guide specified in each ME in section 2 of the Technical Toolbox.

47. ME 6.1.4: "list activities of working groups of the network in which you have participated": should members of the coordination team be included in the list? e.g ERN project manager working with a work package leader on completing several tasks?

They do not need to be included, only the activities and the working groups of the ERN in which the HCP has participated must be indicated.

Self-evaluation and MEs for ERNs:

48. ME 1.4.4: which sustainability are we speaking about? financial, scientific, other? And for ERNs.

The concept "long-term sustainability" refers to the need to safeguard the future sustainability of ERNs both from an economic point of view and in the interest of patients and Member States. This can be achieved through the various paths of research and promotion of patient accessibility.

It is further defined in the guidelines of criterion 1.4 (on page 12 of the Technical Toolbox).

49. ME 2.1.1, 2.1.3, and 2.1.4: could you please be precise about the difference between the three ME?

As it is defined in the Technical Toolbox, each MEs from criterion 2.1 concerns different aspects:

- 2.1.1: it refers to the clinical guidelines used to standardise the particular clinical procedure/diagnosis
- 2.1.3: it refers to clinical pathways. It is a broader concept and comprises the whole patient journey

- 2.1.4: it refers to examples of how to improve cross-border care

Further information can be found on pages 13 and 14 of the Technical Toolbox.

50. ME 3.1.1 Would it be possible to define a little bit more precisely "Quality and Safety for Patients"?

To better understand the 3.1 criterion referring to ERNs, it is important to understand how the concept of Quality and Safety affects the HCPs that are members of each ERN. For this, please refer to the HCP Operational Criteria, in section 5, criterion 5.1 guidelines (Technical Toolbox, page 65) as it is well defined.

The concept of Quality refers to the different strategies that are implemented in the analysis and processing of patient data for the management of HCPs. These strategies must be aligned with the objectives of the ERN.

Examples of preventive activities to manage Patient Safety risks may include prevention and control of healthcare related infection, ensuring safe surgery, unequivocal identification of patients, analysing and learning from adverse effects, among others.

51. ME 7.3.1: Should the documents, e.g., a Description of the communication and dissemination strategy, describe the years 2017-2021 and achievements, or the strategy for the future activities of the Network?

In this case, it refers to the activities and achievements regarding the strategy defined for the period 2017-2021.

Interviews for ERNs and ePAGs:

52. In the document review, it is said that ERN will have to provide monitoring indicators collected in the last three years: There is discrepancy of information in the manual: will the data be provided by the EC or by the members/ERN coordination?

As it is stated in the Evaluation Manual in page 16, the ERN monitoring indicators will be provided by the Commission.

53. How will ePAGs be selected? How will the patient's representatives involved in the ERNs will be selected for the interview?

The IEB will select the patient representatives to be interviewed from a list provided by the ERN.

As the IEB will conduct interviews with the coordinators and chairs of the ERNs' groups, it is considered interesting the patient representatives who have been in the ERNs since their launch and who sit on the ERN Board, Executive Committee or Co-Chairs of the Sub-Thematic ERNs would be relevant.

54. Can ePAGs from the UK be interviewed?

ePAGS from the UK cannot be interviewed as the UK is no longer a Member State.

Onsite audits

55. For the audit, you will need the authorization of the local administration. How did you plan to get it?

If an authorization of the local administration is required, it is expected that the HCP obtains that approval. The IEB will facilitate any information, if needed.

56. How are the HCPs for onsite audits selected? Is it dependent on your self-evaluation or is it at random? When the HCPs selected for onsite audits will be informed?

The IEB will propose the Commission of the HCPs to visit, based on the sampling methodology included in the Technical Toolbox (see pages 111 and 112).

HCPs selected for onsite audits will be communicated by 13th January 2023.

57. The centres that already passed an individual audit five years ago can be audited again?

Assessment and evaluation are different processes. Therefore, those HCPs which were audited five years ago are not excluded from being selected to be visited for evaluation purposes.

The sample will be randomly selected as it is stated in section 7 of the Technical Toolbox.

58. Could you clarify which items/elements of the operational criteria will be assessed as part of the HCP audit? (Patient interviews/professional interviews/medical documentation review). As far as we can see, there are a few mismatches in the evaluation manual.

After an in-depth review of the section 2 of the Technical Toolbox (*"Operational Criteria for Healthcare Providers"*), those MEs to verify during the visit are shown below in Table 1:

Table 1: ME to be evaluated in the onsite audit.

MEs to be evaluated during the interview with patients	1.1.1
	1.1.2
	1.6.1
	1.6.3
MEs to be evaluated during the interview with professionals	1.6.2
	1.6.4
	1.9.1
	4.2.2
	4.2.4
	5.1.2
	5.1.6
	5.1.7
	7.1.2
MEs to be evaluated during the medical record review	1.2.2
	1.5.1
	1.5.3
	1.6.5
	1.7.1
	2.2.2
	2.3.1

	2.5.2
	3.2.2
	7.2.2

59. Some HCPs have restrictions imposed by their Ethical Committee for patients to be approached by third parties. Providing a list of patients to be interviewed by the IEB may therefore represent a challenge. How long in advance will the HCPs receive the notification from the IEB to provide the list of patients?

The evaluators will suggest the criteria to select the patients to be interviewed at least one month in advance.

Please note that HCPs will contact patients, not the IEB.

Information about the purpose of the interview might be sent to the patients from the HCP, and those who voluntarily want to participate must sign a written consent before the interview.

A template of both documents will be facilitated by the IEB in advance to be approved by the Ethical Committee of the HCP.

60. Do we have official material to be shared with the patients to explain to them what their role will be in the evaluation, they could be scared of being interviewed, so maybe a set of few sample questions?

Standardised information about the entire process will be provided to the HCP for the recruitment of patients to be interviewed. This information will include the purpose of these interviews and a few sample questions.

61. Can we have a template of the patients' consent to allow them to participate in the evaluation interview, should it be in English? Do you have informed consent forms for the patients in all European languages?

To facilitate the interview with patients the IEB can provide an informed consent template. Please note, this template will be in English and will be sent if required.

62. We are concerned about GDPR when it comes to contacting patients and accessing patient files. How would you proceed to protect patient's confidentiality? What about GPDR issues involving interpreters?

All the evaluators/interpreters participating in the evaluation process must sign a confidentiality agreement, as established on page 151 of the Technical Toolbox.

Also, HCPs should keep patient information as anonymous as possible.

63. Who is expected to authorize interviews of patients by the IEB?

HCPs should look for volunteers among their patients to participate in the interview as part of the onsite audit.

Each patient must authorise their participation by signing a written consent requested by the HCP, as stated on page 120 of the Technical Toolbox.

64. Would it be possible to have online interviews with patients?

The online alternative is suggested as the most advisable, due to the difficulty of bringing patients together and because it will facilitate the inclusion of cross-border patients.

65. What happens if a HCP administration refuses to authorize such a practice?

Interviews with patients treated are part of the methodology to perform audits in HCPs, as stated on page 120 section 11 of the Technical Toolbox.

The organization of interviews with patients is not mandatory, however, if they are not conducted, the IEB will not be able to evaluate some MEs which need to be verified during the visit in the session with patients. Therefore, these specific MEs will be scored "0: No activity / Not developed". It is important to take into consideration that some of these MEs are classified as "core", and, according to section 12 of the Technical Toolbox, only three core MEs can be scored "0" to obtain a "satisfactory" result.

66. It is stated, on page 120, that the interviews of the patients "will be contacted in English, so the presence of an interpreter (with no conflict of interest with the hospital) may be necessary".

a. Who covers the expenses of the interpreter?

This is not specified in the evaluation manuals. However, as a general practice of other similar evaluation processes carried out by organizations like Joint Commission International or the European Foundation for Quality Management (EFQM), it is expected the HCP to be evaluated to cover the expenses of an interpreter. This is to ensure the evaluation is conducted in English.

b. What do we need to understand by "no conflict of interest with the HCP"?

As the patient's answers could be conditioned by the presence of a HCP team professional, the conflict of interest would apply to any professional of the HCP involved.

To ensure the session is conducted in English (as stated in section 11 of Technical Toolbox) it is suggested that any patient relatives or representatives from patient associations who are fluent in English and the language(s) used at the hospital could do the translation.

67. Isn't this request for face-to-face interviews in contradiction with what is requested in Section 11 section 1 (Group interview with patients) and section 3 (Medical records review) as numbered: "In NO case the name of the patient be included. A code will be agreed between …"

No, it is not contradictory

Section 11 of the Technical Toolbox proposes that the interviews with patients can be performed virtually so that evaluators do not need to meet them in person, nor have access to their identity.

Medical records or any other document regarding patient information will be always provided by the HCP team to the evaluators and can be anonymised before.

Results of the evaluation

68. An Improvement Plan (IP) must be submitted for all core MEs that have been scored "1" or "0": What is the responsibility of the Coordinator/Coordination team in the preparation of this document?

In the ERN case, the NC must develop the IP with the work packages' leaders' help and will be responsible to send it to the IEB for its review. Likewise, in the HCP case, their representative has to develop the IP with the HCP team's help and will be responsible to send it to the IEB.

69. Could you specify what will be the outcome of the evaluation in case of a negative evaluation?

Those ERN/HCP whose evaluation has not been satisfactory will have a period of one year to implement the IP and remedy the shortcomings identified before carrying out a new evaluation.