THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

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European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Introduction to preparing a revision application

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Basic principles for maintaining a CEP

- Any change must be reported to EDQM for approval
- **The dossier must always be kept up-to-date**

Holder to:

- ✓ **inform customers of changes made following each revision**
- ✓ **send revised CEP** to customers as soon as a revised CEP has been issued

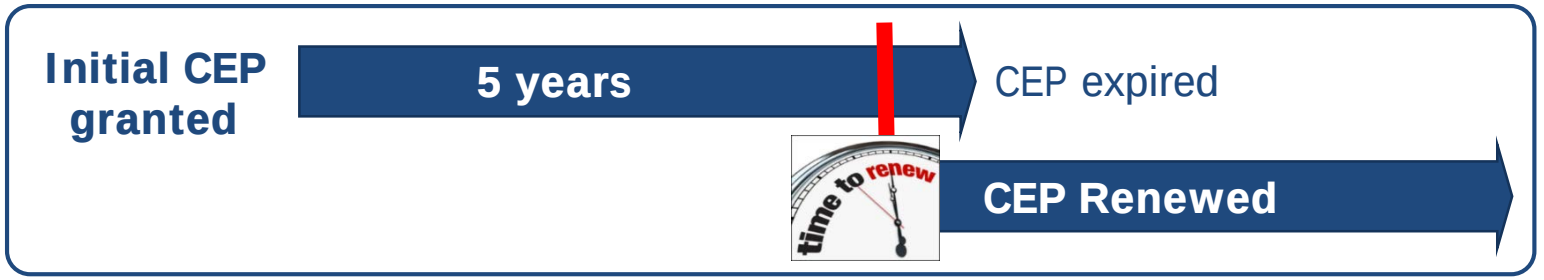
Refer to the EDQM document:

CEP holders responsibilities towards their customers (PA/PH/CEP (21) 57, January 2022)

Validity of CEP:

- Limited to **5 years** from the first issued date
- **Unlimited <u>after</u>** completion of the **Renewal procedure**

Provided that the dossier is always **kept up-to-date**



Overview of the types of Revision applications

- **Revisions depending on the classification of changes:**
  - Notifications (IN or AN) and the possibility of grouped revisions
  - Minor revisions (incl. minor by default)
  - Major revisions
  - Sister file application

- **Other types of applications**
  - Transfer of holdership
  - Renewal (to be completed before the initial CEP expiry date)
  - Following a revision of Ph. Eur monograph

Revisions of CEPs: Background

Based on EU Regulations on Variations to Marketing Authorisations

Specific EDQM guidelines for revisions of CEPs, available on the EDQM website:

- **Guideline on Requirements for Revision / Renewal of CEPs**

  (PA/PH/CEP (04) 2, 7R corr, September 2018)

- EDQM guidance on **Applications for "Sister Files"**

  (PA/PH/CEP (09) 141, 2R, November 2018)

- **Management of applications** for new Certificates of Suitability, Requests for Revision or Renewal of Certificates of Suitability and applications using the 'sister files' procedure (PA/PH/CEP (13) 110, 3R, November 2021)

Timelines for revision applications

Refer to the EDQM document:

Management of applications for new Certificates of Suitability, Requests for Revision or Renewal of Certificates of Suitability and applications using the 'sister files' procedure (PA/PH/CEP (13) 110, 3R, November 2021)

Type of application	EDQM Timelines for assessment of initial application	Applicant Timeline to reply to first request for additional information	EDQM Timelines for assessment of reply to request for information	Applicant Timeline to reply to second request for additional information	EDQM Timelines for assessment of reply to request for information
New	115 WD °	180 CD* 30 CD #	92 WD* 23 WD #	90 CD * 30 CD #	92 WD * 23 WD #
Sister file	46 WD	30 CD +	23 WD	30 CD	23 WD
Minor revision(s)	23 WD	30 CD	23 WD	30 CD	23 WD
Major revision	46 WD	30 CD	23 WD (TSE or Herbal:46 WD)	30 CD	23 WD (TSE or Herbal:46 WD)
Monograph revision	69 WD	30 CD	23 WD (TSE or Herbal:46 WD)	30 CD	23 WD (TSE or Herbal:46 WD)
Renewal	69 WD	30 CD	23 WD (TSE or Herbal: 46 WD)	30 CD	23 WD (TSE or Herbal:46 WD)

* if the request from EDQM relates to significant information required to address the issues identified

EDQM Timeline for the assessment of the initial application	
• **Notification** • **Minor Revision**	23 Working Days
• **Major Revision** • **Sister file application**	46 Working Days
Renewal procedure	69 Working Days

The EDQM timelines depend on the type of revision

Outcome of the assessment of a CEP revision

Update
CEP 2.0

When are CEPs revised?

- After any change which **impact the content of the CEP or its annexes**, resulting of a Notification, Revision or Renewal

- In the other cases, an **approval letter** is sent by EDQM:

APPROVAL OF REQUEST
CEP REMAINS VALID

What to do with a revised CEP ? → Mandatory step

- Holder to provide a copy to their customers
- MAH to update relevant Marketing Authorisation Applications (variation)

What to do when a change is approved but CEP is not revised ? → Mandatory step

- Holder to inform customers, but there is no variation of Marketing Authorisation Application

Refer to the EDQM document:

CEP holders responsibilities towards their customers (PA/PH/CEP (21) 57, January 2022)

Overview of the types of Revision applications

- **Revisions depending on the classification of changes:**
  - Notifications (IN or AN) and the possibility of grouped revisions
  - Minor revisions (incl. minor by default)
  - Major revisions
  - Sister file application

- **Other types of applications**
  - Transfer of holdership
  - Renewal (to be completed before the initial CEP expiry date)
  - **Following a revision of Ph. Eur monograph**

CEP and Revision of the Ph. Eur. monograph

CEP holder responsibility:

(EU Directive 2001/83/EC)

ensure compliance to the current version of the Ph. Eur. monograph.

When a revised Ph. Eur. monograph is published:

- CEP Holder is informed by the EDQM via a letter about the classification:

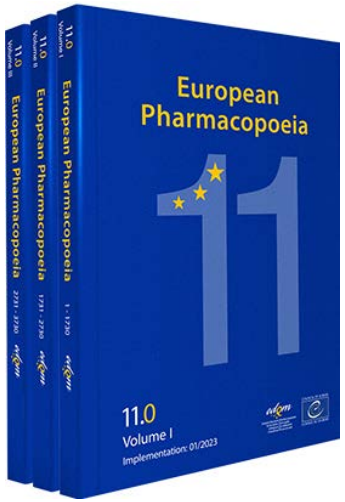
Case A

The changes (e.g. updated specification) should be implemented and should be included in the next request for revision.

Case B

The CEP holder is asked to:

- ✓ provide sufficient data to demonstrate suitability of the monograph
- ✓ clarify whether all related substances are controlled by the method of the revised monograph
- ✓ Whether the final substance contains additional impurities



Timeline for assessment :

3 months

How to apply for revision: different types of revision

- **Revisions depending on the classification of changes:**
  - **Notifications (IN or AN)** and the possibility of grouped revisions
  - **Minor revisions (incl. minor by default)**
  - **Major revisions**
  - **Sister file application**

- **Other types of applications**
  - Transfer of holdership
  - **Renewal** (to be completed before the initial CEP expiry date)
  - Following a revision of Ph. Eur monograph

How to apply for revisions

Module 1

- **Cover letter**
- Complete **application form**, including:
  - **Comparative table** of the changes
    Refer to: Annex 7 of the application form
  - Updated declarations if needed
    Annexes 3 to 6 of the application form

Module 2: Not required but may be submitted and **should be in line with Module 3**

Module 3

- Update of **all impacted section(s)** of the CTD dossier

Data supporting the request for revision

Applicants should use and refer to the:
EDQM **Guideline on requirements for revisions and renewal** (PA/PH/CEP(04)2,7R corr)

How to apply for revisions: the Application form

since June 2023

Application Form

REQUEST FOR REVISION OR RENEWAL OF A CERTIFICATE OF SUITABILITY

(to be completed for each request for revision or renewal of a Certificate of Suitability to the monographs of the European Pharmacopoeia, in accordance with Resolution AP-CSP (07) 1)

1.2 **Type of application** *(please tick one application box only)*

☐ Notification *(may include several changes)*

☐ Minor revision *(may include several changes including notifications)*

☐ Major revision (*may include notifications and minor changes)*

☐ Renewal

☐ *without changes* ☐ *with changes (notifications and/or minor changes – no major change)*

☐ Transfer of holdership

☐ Grouped revision *(several dossiers affected by the same change[s])*

Please list the dossier numbers and substances below:

NB: if needed, an annex with list of all affected dossiers may be provided

CEP	[Substance name]

Always use the **latest version**

(application form, declarations, Holder's commitment)

It is the **CEP holder's responsibility** to:

- carefully **choose the type of revision**
- by **taking into account all the changes** declared, in line with the EDQM Guideline for Revision (PA/PH/CEP(04)2,7R corr)

How to apply for revisions: the Comparative table

- Key element for the **declaration of changes**
- For any request for revision (including Notification or Renewal with changes and also NDSF)

⚠ Changes must be **individually classified <u>and</u> declared** in the comparative table ⚠

IF NOT, change(s) considered as: not declared = not assessed = **not approved**

4. COMPARATIVE TABLE

The comparative table should highlight the differences between the approved and proposed text of module 3, together with the correct classification of each change according to the EDQM Guideline for revisions.
The justification for the changes should be fully developed in the cover letter.

Annexes	Yes	N/A
7) Comparative table	☐	

Comparative table

- Key element for the **declaration of changes**
- For any request for revision (including Notification or Renewal with changes)

Changes must be **individually classified and declared** in the comparative table

IF NOT, change(s) considered as: not declared = not assessed = **not approved**

- Format of the comparative table available as **Annex 7 of the application form:**

CTD section reference	Approved text of the dossier[1]	Proposed text of the dossier[2,3]	Classification[4] of the change(s) and brief justification

[1, 2] specify the precise approved and proposed wording of the CTD section

[3] underline or highlight the changes in the text

[4] classification according to current version of EDQM Guideline for revisions/renewals PA/PH/CEP (04) 2, including a brief description and justification of the changes, if necessary a complete justification should be provided in the cover letter

Comparative table: expectations

CTD section reference	Approved text of the dossier	Proposed text of the dossier	Classification of the change(s) and brief justification.
3.2.S.2.1	-	No change	-
3.2.S.2.2	**Step 1:** In a clean reactor charge solvent **toluene** (**100 L**), SM 2 (50 kg), acid (**1 L**). Heat and maintain the reaction mass at **80 to 85°C** for **40** hours. Cool reaction mixture and stir for **2 to 3 hours** at 0-5°C. Filter the reaction mass through a Nutsche Filter. Wash the cake with **10L** chilled solvent 1. …	**Step 1:** In a clean reactor charge solvent **methanol** **(910 L)**, SM 2 (50 kg), acid **(1.3L)**. Heat and maintain the reaction mass at **85 to 90°C** for **25** hours. Cool reaction mixture and stir for **2 hours** at 0-5°C. Filter the reaction mass through a Nutsche Filter. Wash the cake with **8L** chilled solvent 1. …	**Major change:** replacement of solvent toluene by methanol and optimisation of the manufacturing process. Refer to module 1 pages xx and xx for discussion on impact of the change and discussion on carry-over , along with analytical data
3.2.S.2.3	**Process water** Description : clear colourless liquid pH: 5.00 to 7.00 Conductivity : NMT 1,30µS/cm (at 25°C) Total organic carbon: NMT 500 ppb Nitrates: **NMT 0.2 ppm**	**Process water** Description : clear colourless liquid pH: 5.00 to 7.00 Conductivity : NMT 1,30µS/cm (at 25°C) Total organic carbon: NMT 500 ppb Nitrates: **NMT 0.1 ppm**	**Notification :** tightening of specification for nitrates in process water

Comparative table: expectations

Changes should be:

- **easily identifiable**

- and **highlighted** (*e.g.* in bold)

Copy **as much information as needed**

to ensure:

- an **easy overview of the change**

- while remaining in a **legible format**

(e.g. Route of synthesis / Flowcharts copied in the table)

CTD section reference	Approved text of the dossier	Proposed text of the dossier	Classification of the change(s) and brief justification.
3.2.S.2.1	-	No change	-
3.2.S.2.2	**Step 1:** In a clean reactor charge solvent **toluene** (**100 L**), SM 2 (50 kg), acid (**1 L**). Heat and maintain the reaction mass at **80 to 85°C** for **40** hours. Cool reaction mixture and stir for **2 to 3 hours** at 0-5°C. Filter the reaction mass through a Nutsche Filter. Wash the cake with **10L** chilled solvent 1. …	**Step 1:** In a clean reactor charge solvent **methanol** **(910 L)**, SM 2 (50 kg), acid (**1.3L**). Heat and maintain the reaction mass at **85 to 90°C** for **25** hours. Cool reaction mixture and stir for **2 hours** at 0-5°C. Filter the reaction mass through a Nutsche Filter. Wash the cake with **8L** chilled solvent 1. …	**Major change:** replacement of solvent toluene by methanol and optimisation of the manufacturing process. Refer to module 1 pages xx and xx for discussion on impact of the change and discussion on carry-over , along with analytical data
3.2.S.2.3	**Process water** Description : clear colourless liquid pH: 5.00 to 7.00 Conductivity : NMT 1,30µS/cm (at 25°C) Total organic carbon: NMT 500 ppb Nitrates: **NMT 0.2 ppm**	**Process water** Description : clear colourless liquid pH: 5.00 to 7.00 Conductivity : NMT 1,30µS/cm (at 25°C) Total organic carbon: NMT 500 ppb Nitrates: **NMT 0.1 ppm**	**Notification :** tightening of specification for nitrates in process water

The **last column of the table** is dedicated to the **classification and justification of the change**:

- Provide a brief description of the change and explain some context
- Classification justified in line with the EDQM Guideline for Requirements for Revision/Renewal (PA/PH/CEP (04) 2)
- If applicable, describe where corresponding **supportive information** is available (for instance: Module 1, page x/x)

How to apply for revisions: the classification of changes

- By referring to the EDQM guideline for the classification of changes:

GUIDELINE ON REQUIREMENTS FOR REVISION/RENEWAL OF CERTIFICATES OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA MONOGRAPHS

(PA/PH/CEP (04) 2, 7R corr)

Divided in several parts :

1. **Administrative changes**
2. **Quality changes: apply to chemical/double and herbal CEPs**
3. **TSE changes**
4. **Use of CEP in an application for another CEP**
5. **Renewal**
6. **Transfer of holdership**

How to make best use of the EDQM Guideline for Revisions

4.II.1.1 Change in the manufacturer of a starting material used in the manufacturing process of the final substance	Conditions	Specific documentation	Type of change
a) The proposed manufacturer of the starting material is part of the same group as the currently approved manufacturer	1, 2	1, 2, 3, 4	IN
b) The proposed manufacturer of the starting material is not part of the same group as the currently approved manufacturer	1,2	1, 2, 3, 4	MIN
c) The proposed manufacturer of the starting material uses a different route of synthesis or manufacturing conditions which impact the specifications of the starting material		1, 3, 4	MIN
d) The proposed manufacturer of the starting material uses a different route of synthesis or manufacturing conditions which impact the specifications of the final substance			MAJ (*)
e) The proposed manufacturer of the starting material is used in the manufacturing process of a biological substance		1, 3, 5	MAJ

Conditions	
1.	The specifications of the starting material are identical to those already approved.
2.	The final substance is not a biological substance or a sterile substance.
Documentation	
1.	A declaration from the Certificate holder that the specifications of the final substance are the same as those already approved.
2.	A declaration from the Certificate holder that the specifications and the quality control procedures of the starting material are the same as those already approved. If a different route of synthesis is retained for the new supplier, the synthetic flowchart of how the starting material is obtained should be provided.

List of changes classified as:

- Notification:
  - Immediate (**IN**)
  - Annual notification (**AN**)
- Minor change (**MIN**)
- Major change (**MAJ**)

Non-classified changes are:

Minor changes by default

How to apply for revisions: Example of the **Renewal application**

GUIDELINE ON REQUIREMENTS FOR REVISION/RENEWAL OF CERTIFICATES OF SUITABILITY TO THE EUROPEAN PHARMACOPOEIA MONOGRAPHS

PA/PH/CEP (04) 2, 7R corr, current version

5. Renewal of the certificate of suitability	Conditions	Specific documentation	Type of change
a) No change has been made since the last CEP was granted or last revision approved	1	1, 2, 3	Renewal
b) Changes are included in the request for renewal	1	2, 3, 4, 5, 6	Renewal

Conditions

1. No major changes to the content of the CEP application are introduced.

Documentation

1. A statement that no changes that may affect the quality, safety or efficacy of the final substance have been made.
2. Certificates of analysis from at least two recent production batches.
3. Updated declarations as annexes to the application form.
4. An updated dossier in CTD format and/or updated sections affected by the changes.
5. List of changes introduced in the format of a comparative table (i.e. approved text vs proposed text).
6. Relevant data supporting each change as described in this guideline.

Condition:

- No Major change

Documentation depending on:

- Renewal without changes (**5a**)
- Renewal with changes (**5b**)

Type of change:	**Renewal**
Notification (**AN** or **IN**)	✖
Minor change (**MIN**)	✖
Major change (**MAJ**)	⊘

How to apply for revisions: **Renewal application**

*Updated application form since **June 2023***

Application Form
REQUEST FOR REVISION OR RENEWAL OF A CERTIFICATE OF SUITABILITY

(to be completed for each request for revision or renewal of a Certificate of Suitability to the monographs of the European Pharmacopoeia, in accordance with Resolution AP-CSP (07) 1)

1.2 **Type of application** *(please tick one application box only)*

☐ Notification *(may include several changes)*

☐ Minor revision *(may include several changes including notifications)*

☐ Major revision (*may include notifications and minor changes)*

☐ Renewal
☐ *without changes* ☐ *with changes (notifications and/or minor changes – no major change)*

☐ Transfer of holdership

☐ Grouped revision *(several dossiers affected by the same change[s])*
Please list the dossier numbers and substances below:
NB: if needed, an annex with list of all affected dossiers may be provided

CEP	[Substance name]

Type of change:	**Renewal**
Notification (**AN** or **IN**)	✖
Minor change (**MIN**)	✖
Major change (**MAJ**)	⊘

Renewal procedure

Upcoming **update CEP 2.0**

Initial CEP granted → **5 years** → CEP expired

6 months before

the expiry date of the CEP

CEP Renewed

Specific procedure to obtain the **Renewed** CEP:

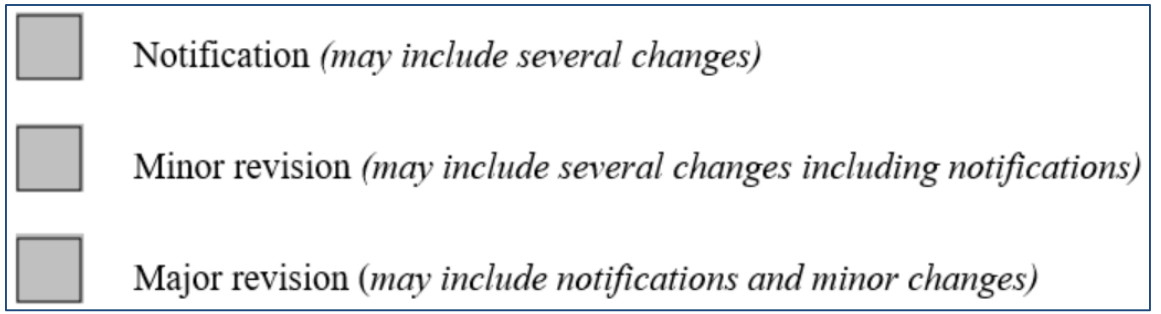
- **A initially granted CEP is valid 5 years**
- Renewal assessment focuses on compliance with: Ph. Eur. GM 2034, recent European quality guidelines (e.g. **Nitrosamines risk assessment**)

Documentation:

- **Updated declarations for each manufacturing site** (Annex 3a and Annex 4 of the AF)
- **Recent** batch data (≤18 months)

Overview of the types of Revision applications

- **Revisions depending on the classification of changes:**
  - **Notifications (IN or AN)** and the possibility of grouped revisions
  - **Minor revisions** (including minor changes by default)
  - **Major revisions**
  - **Sister file application**



Classification of changes – Types of application

Do & Tell	Tell & Do	
Notification (IN / AN)	**Minor changes (MIN)**	**Major changes (MAJ)**
Possible only if: ➢ **<u>All</u> the conditions** listed in the guideline **are met** ➢ Changes **without any impact** on the quality of the final substance ➢ Cover all **administrative changes**	➢ **Minor changes** listed in the guideline ➢ **Minor changes by default** (e.g. non-classified changes)	➢ **Potential impact** on the quality of the final substance ➢ In some cases, the need for a separate application should be considered *(Sister file procedure)*

Notifications

☒ Notification *(may include several changes)*

- It should be formally **confirmed** that **all the conditions are met, as listed in the EDQM guideline on Requirements for Revision / Renewal of CEP**
- **The corresponding documentation listed in the guideline should be provided** (for instance declarations or batch analysis data)

4.II.1.6 Change in test procedure for in-process tests or limits applied during the manufacture of the final substance or specification limits for a starting material /reagent/intermediate	Conditions	Specific documentation	Type of change
a) Tightening of the limits of in-process tests applied during the manufacture of the final substance or specification limits for a starting material /intermediate / reagent used in manufacture	1, 2, 3	1	AN

Conditions	
1	The change does not result from unexpected events arising during manufacture.
2	Any change should be within the range of currently approved limits.
3.	The test procedure remains the same (e.g. a change in column length or temperature, but not a different type of column or method), or changes in the test procedure are minor.

Documentation	
1.	Comparative table of approved and proposed in-process tests or limit in starting material/intermediate/reagent.

Minor changes

☒ Minor revision *(may include several changes including notifications)*

- **Typical changes are listed** in the guideline

Examples: addition of a new starting material manufacturer when there is no impact on the final substance specifications, addition/extension of a **re-test period**, ...

- Revised discussions on **impurities** should be submitted as **minor revisions**:

Examples: Risk assessment on Elemental impurities, **Nitrosamine impurities**, Mutagenic impurities, ...

- **All changes** that are **neither listed as a notification** nor as a **major change** in the guideline **are considered as « minor by default »**

Major changes

☒ Major revision (*may include notifications and minor changes)*

- Any substantial change to the process or to the specifications of the final substance/intermediate that **<u>may potentially</u>** impact the quality of the final substance.

The type of submission depends on the **<u>potential impact on the quality</u>** of the final substance, and not necessarily on the final result

- It is CRUCIAL to discuss the impact of the change on the quality and control strategy for the final substance.

Science-based argumentation and relevant analytical data are expected !

Reminders on the type of revision: examples of changes

NOTIFICATION

- Change of the name of an approved intermediate manufacturer
- Tightening of a specification limit (*e.g.* **4.II.1.6.a**)

MINOR revision

- Introduction of an intermediate manufacturer who is **using a different solvent** in the manufucturing process, **when** this solvent is already used elsewhere in the process of the final substance **and** is still demonstrated absent in the final substance (*e.g.* **4.II.1.4.b**)

MAJOR revision

- Introduction of a **new solvent in the penultimate step** of the manufacturing process of the final substance, when **this solvent has been demonstrated** absent in the final substance

Sister file application

Reminders on the type of revision

Classification of changes depends on the **potential impact** on the quality of the final substance, and **not only** on the final result

Each change should be **individually classified**

Most common types of revision :

- ☐ Notification *(may include several changes)*
- ☐ Minor revision *(may include several changes including notifications)*
- ☐ Major revision (*may include notifications and minor changes)*

Appropriate type of revision according to the proposed changes:

Type of change:	Type of Revision:		
	Notification	Minor revision	Major revision
Notification (**AN** or **IN**)	✖	✖	✖
Minor change (**MIN**)	⊘	✖	✖
Major change (**MAJ**)	⊘	⊘	✖

Technical Advice Meeting possible in case of doubt for questions:

REQUEST FOR TECHNICAL ADVICE MEETING FOR CERTIFICATION OF SUITABILITY

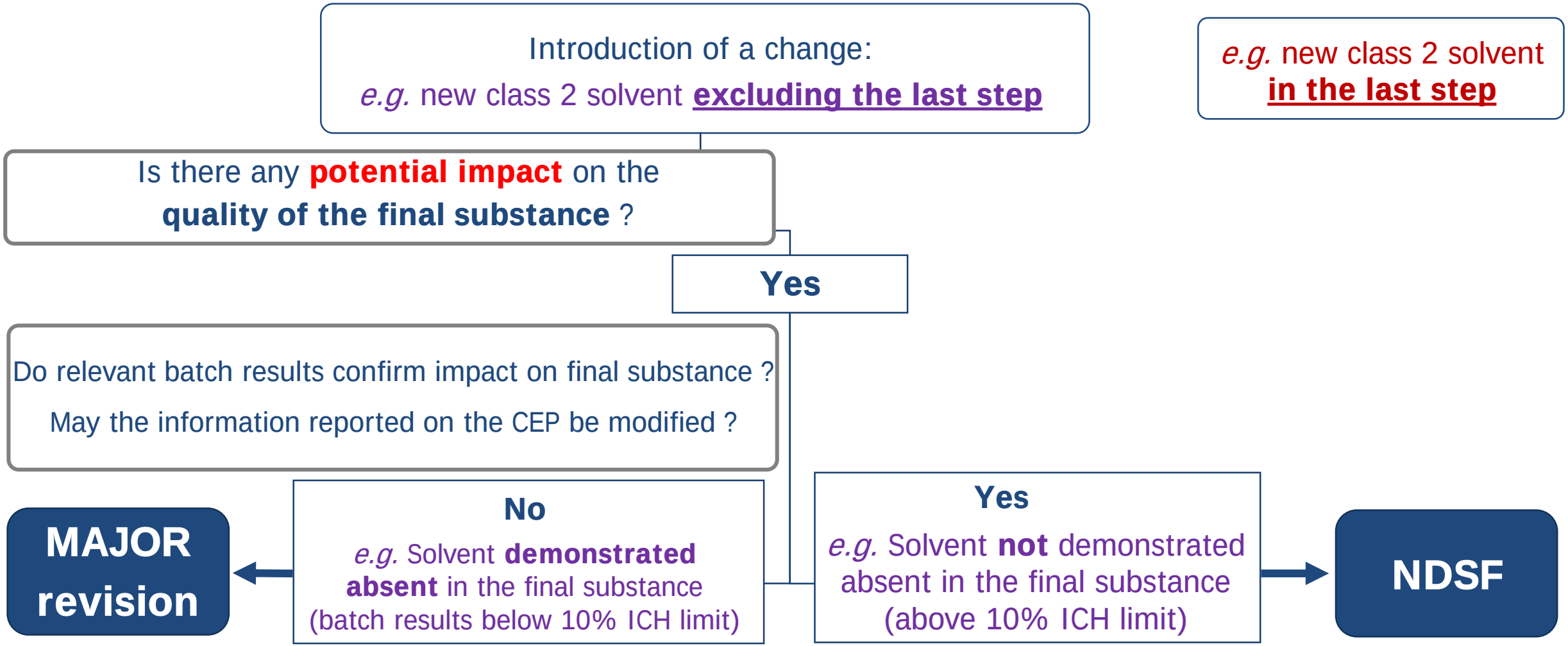
to be filled in for each request for a Technical Advice meeting related to the procedure for Certificate of Suitability to the monographs of the European Pharmacopoeia AP-CSP (07) 1

- of technical nature, on matters concerning the content of an application
- or related to the requirements for the submission of revision / renewal with **complex or multiple changes**

The **need for the change and the associated risks** as well as the **impact of the change** on the control strategy for the manufacturing process should always be **properly justified**

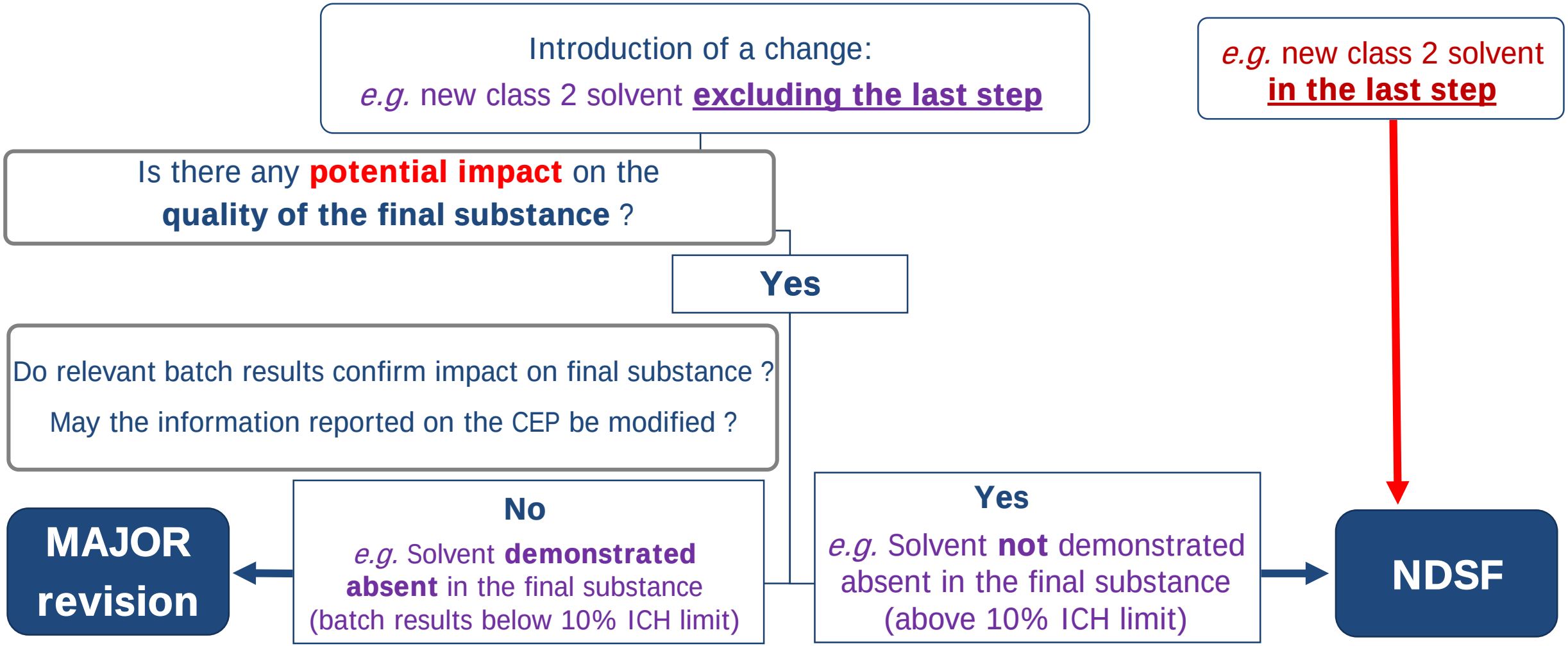
Classification of changes: Major revision vs Sister File (NDSF)

Depending on the change, a ‘sister file’ (NDSF) submission might be needed instead:



Classification of changes: Major revision vs Sister File (NDSF)

Depending on the change, a ‘sister file’ (NDSF) submission might be needed instead:



CEP via the ‘Sister file’ Procedure (NDSF)

In certain cases, it may not be possible to apply for a revision of the initial CEP, and a **new application** should be requested via the ‘**Sister file**’ procedure

The ‘Sister file’ procedure is a **fast track procedure**: same timeline as for a Major revision

Consult the EDQM guidance on applications for “Sister Files”
(PA/PH/CEP (09) 141, 2R, November2018)

- ✓ **Facilitates the treatment of similar dossiers**
- ✓ **Applicable to chemical / herbal applications only**
- ✓ Substance is the same as for parent file for which the CEP is valid
- ✓ Holder is the same (or belongs to the same group) in both applications
- ✓ **Differences with parent file could be classified as a revision**

CEP via the ‘Sister file’ Procedure (NDSF)

In certain cases, it may not be possible to apply for a revision of the initial CEP, and a **new application** should be requested via the ‘**Sister file**’ procedure

The ‘Sister file’ procedure is a **fast track procedure**: same timeline as for a Major revision

Consult the EDQM guidance on applications for “Sister Files”
(PA/PH/CEP (09) 141, 2R, November2018)

To apply:

- The **specific application form**
- The **comparative table** to indicate the differences between the existing CEP (Parent file) and the new application proposed via the Sister file procedure
- a **complete dossier** in eCTD format

Application Form
REQUEST FOR
A CERTIFICATE OF SUITABILITY
VIA THE ‘SISTER FILES’ PROCEDURE

CEP via the ‘Sister file’ Procedure (NDSF)

Cases where a separate CEP application is needed:

- Addition of a **new manufacturing site of the final substance** that **does not belong to the same group** and even when a qualified contract manufacturer
- The **solvents used in final purification steps** have been changed
- A new solvent is introduced that **cannot be demonstrated absent**
- **Substantially different route of synthesis**?
  - Different starting materials
  - Different intermediates
  - Use of different catalysts/reagent

This applies even when the impurity profile of the final substance is unchanged

CEP via the ‘Sister file’ Procedure (NDSF)

Documentation needed:

Module 1

- ✓ **Application form** (for sister files)
- ✓ Cover letter – Number of parent file indicated and overview of differences between parent/sister file (and **subtitle** to be included)
- ✓ **Comparative table:**
  - as included in the application form, is a **key document for acceptability of sister file**
  - **should include all sections** and be **sufficiently detailed** to easily understand the differences between the “Parent” and the “Sister” CEPs.

Module 2

- ✓ Quality overall summary (QOS), which **should be in line with Module 3**

Module 3

- ✓ Full technical documentation according to current procedures (as for standard new CEP application)
  - → **Complete dossier given,** not substituted by references to parent file

More information available regarding:

➢ Revision applications

Refresher on How to submit a revision application and gain rapid acceptance of proposed changes: Reminders and Updates!

CERTIFICATION OF SUITABILITY | ON-DEMAND WEBINAR | 22/11/2022

This webinar is aimed at holders of a Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP). Experienced EDQM CEP Assessors explain how to maintain the validity of a CEP once it has been granted, and attendees are advised on what to include in a revision application...

➢ CEP 2.0

Upcoming **updates for CEP 2.0**

The CEP 2.0 – Webinar for CEP holders and CEP users

CERTIFICATION OF SUITABILITY (CEP) | PDF PRESENTATION | 16 MAY 2023

In 2020, the European Directorate for the Quality of Medicines & HealthCare (EDQM) launched the "CEP of the future" project to design a "new-look" CEP to better meet the current needs of stakeholders, offer enhanced user-friendliness and provide greater information transparency. This project is...

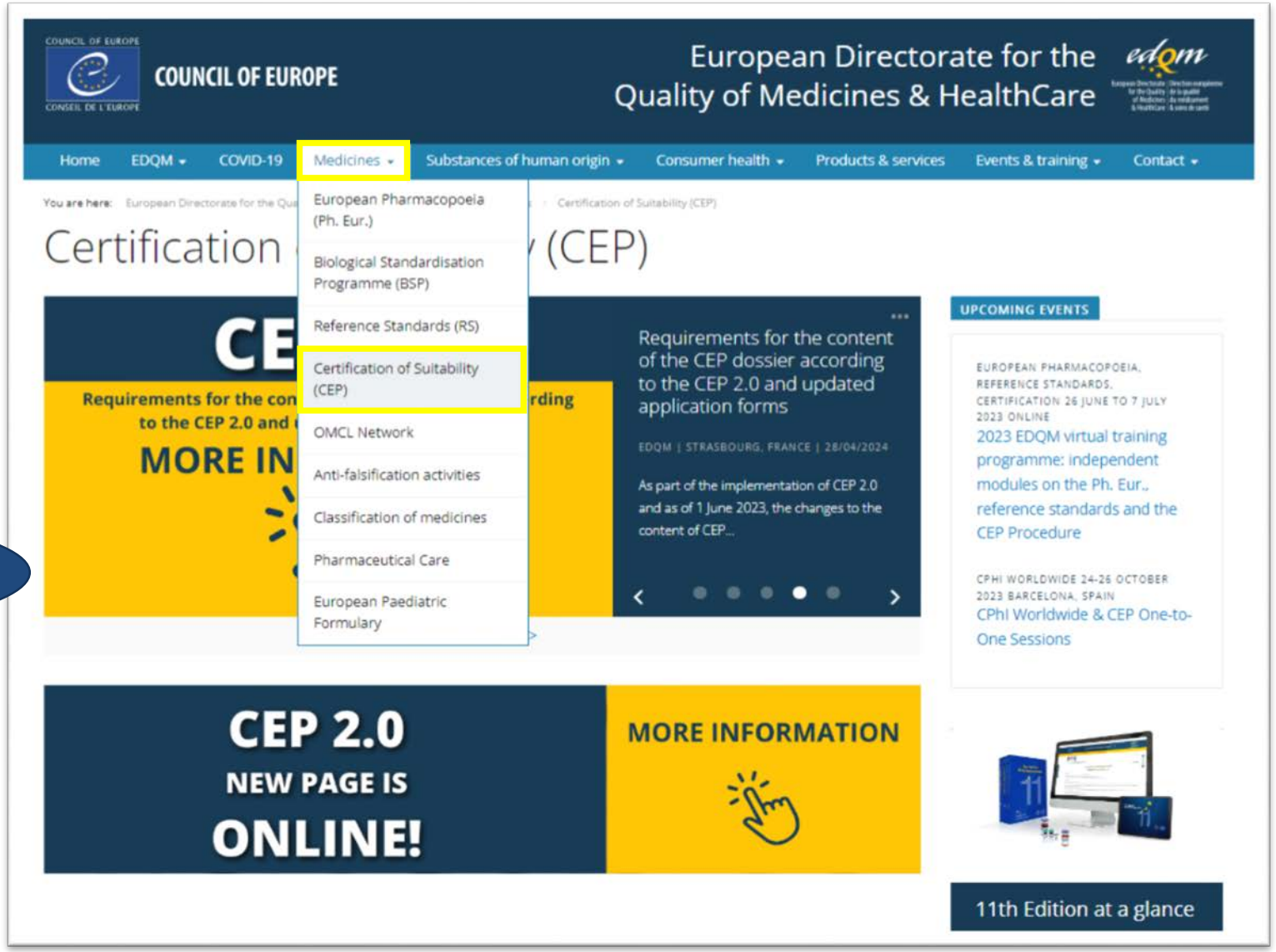
Regularly consult EDQM website !

CEP 2.0

Requirements for the content of the CEP dossier according to the CEP 2.0 and updated application forms

MORE INFORMATION

- 3.2.S.2.1 Manufacturer(s)
- 3.2.S.2.2 Description of Manufacturing Process and Process Controls
- 3.2.S.4.1 Specification
- 3.2.S.4.2 Analytical Procedures
- 3.2.S.7 Stability



Take home messages

For your submission of Revision / Renewal, make sure to:

- **Classify changes in line with the EDQM guideline** on requirements for Revision/renewal (PA/PH/CEP (04) 2, 7R corr)
- Submit a **consolidated comparative table**
- Facilitate a **quick and clear understanding of the changes**

The **need for the change and the associated risks** as well as the impact of the change on the control strategy for the manufacturing process should always be **properly justified**

Any question, doubts on classification?

Consult EDQM website for supportive guidance documents

- The Certification Department provides support through the EDQM helpdesk for general questions, or on the account communicated by EDQM for specific dossiers
- Technical advice meetings are also possible (fees)
- One-to-one meetings during conferences/CPHIs

Thank you for your attention

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