



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 March 2021  
EMA/HMPC/84827/2021  
Human Medicines Division

## Committee on Herbal Medicinal Products (HMPC)

### Draft Agenda for the meeting on 1-3 March 2021

Chair: E van Galen, Vice-Chair: E Svedlund

1 March 2021, 10:00 – 17:00, virtual meeting

2 March 2021, 09:00 – 17:00, virtual meeting

3 March 2021, 09:00 – 16:00, virtual meeting

#### **Disclaimers**

Some of the information contained in this set agenda is considered commercially confidential or sensitive and therefore not disclosed.

Of note, this agenda is a working document primarily designed for HMPC members and the work the Committee undertakes.

#### **Note on access to documents**

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## Table of contents

<b>1.</b>	<b>Introduction</b>	<b>5</b>
<b>1.1.</b>	<b>Welcome and declarations of interest of members, alternates and experts</b>	<b>5</b>
<b>1.2.</b>	<b>Adoption of agenda</b>	<b>5</b>
<b>1.3.</b>	<b>Adoption of the minutes</b>	<b>5</b>
<b>2.</b>	<b>EU herbal monographs and list entries for adoption</b>	<b>5</b>
<b>2.1.</b>	<b>Status of HMPC/MLWP activities</b>	<b>5</b>
2.1.1.	Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in March 2021	5
2.1.2.	Appointment of Rapporteurs and Peer-reviewers	5
<b>2.2.</b>	<b>Revised EU herbal monographs and list entries for final adoption</b>	<b>6</b>
<b>2.3.</b>	<b>Revised EU herbal monographs and list entries for public consultation</b>	<b>6</b>
2.3.1.	Monograph on Hyperici herba and supporting documents	6
2.3.2.	Monograph on Trigonellae foenugraeci semen and supporting documents	6
<b>2.4.</b>	<b>Reviewed EU herbal monographs and list entries for decision on revision</b>	<b>6</b>
2.4.1.	Monograph on Cinnamomi corticis aetheroleum and supporting documents	6
2.4.2.	Monograph on Cinnamomi cortex and supporting documents	6
<b>2.5.</b>	<b>EU herbal monographs, list entries and public statements for final adoption</b>	<b>6</b>
<b>2.6.</b>	<b>EU herbal monographs, list entries and public statements for adoption for release for public consultation</b>	<b>7</b>
2.6.1.	Public statement on Saccharomyces cerevisiae CBS 5926 and supporting documents	7
2.6.2.	Monograph on Species digestivae and supporting documents	7
2.6.3.	Monograph on Taraxaci officinalis radix and supporting documents – postponed	7
2.6.4.	Monograph on Vaccinii macrocarpi fructus and supporting documents	7
<b>2.7.</b>	<b>EU herbal monographs, list entries and public statements - post finalisation</b>	<b>7</b>
<b>3.</b>	<b>Referral procedures</b>	<b>7</b>
<b>4.</b>	<b>Guidelines and guidance documents</b>	<b>7</b>
<b>4.1.</b>	<b>Non-clinical/clinical safety and efficacy and multidisciplinary</b>	<b>7</b>
4.1.1.	Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs (EMA/HMPC/893108/2011 Rev. 1)	7
<b>4.2.</b>	<b>Quality</b>	<b>7</b>
4.2.1.	Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)	7
4.2.2.	Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)	8
4.2.3.	Nitrosamines and Herbal MPs	8
4.2.4.	Change of assay methods in Ph. Eur. monographs	8
<b>4.3.</b>	<b>Regulatory / Procedural</b>	<b>8</b>

4.3.1.	Regulatory Q&A on herbal medicinal products .....	8
<b>4.4.</b>	<b>Report on HMPC Drafting Groups activities.....</b>	<b>8</b>
4.4.1.	Quality DG.....	8
4.4.2.	ORGAM DG .....	8
<b>5.</b>	<b>Organisational, regulatory and methodological matters</b>	<b>8</b>
<b>5.1.</b>	<b>Mandate and organisation of the HMPC .....</b>	<b>8</b>
5.1.1.	Strategic Review and Learning Meetings.....	8
5.1.2.	HMPC membership.....	9
5.1.3.	Election of Co-opted member (paediatrics) .....	9
5.1.4.	Preparation of Election of Co-opted member (Clinical pharmacology).....	9
5.1.5.	HMPC meeting dates 2022-2024 .....	9
<b>5.2.</b>	<b>EMA Scientific Committees or CMDh-v .....</b>	<b>9</b>
5.2.1.	Scientific Coordination Board Meeting .....	9
5.2.2.	Update on PSUSA Menthae piperitae aetheroleum .....	9
<b>5.3.</b>	<b>Coordination with EMA Working Parties/Working Groups/Drafting Groups .....</b>	<b>10</b>
5.3.1.	Public statement on the use of herbal medicinal products containing estragole.....	10
<b>5.4.</b>	<b>Cooperation within the EU regulatory network.....</b>	<b>10</b>
5.4.1.	Coordination with European Pharmacopoeia.....	10
5.4.2.	Coordination with the European Commission.....	10
<b>5.5.</b>	<b>Cooperation with International Regulators.....</b>	<b>10</b>
5.5.1.	IRCH – WHO 12th annual virtual meeting .....	10
<b>5.6.</b>	<b>Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee .....</b>	<b>10</b>
5.6.1.	AESGP .....	10
5.6.2.	EUCOPE .....	10
<b>5.7.</b>	<b>Work plan .....</b>	<b>11</b>
5.7.1.	HMPC work plan 2021 .....	11
<b>5.8.</b>	<b>Planning and reporting .....</b>	<b>11</b>
5.8.1.	Big Data Training Signpost .....	11
<b>5.9.</b>	<b>Legislation and regulatory affairs .....</b>	<b>11</b>
<b>5.10.</b>	<b>Questions from members.....</b>	<b>11</b>
<b>6.</b>	<b>EU herbal monographs and list entries in preparation</b>	<b>12</b>
<b>6.1.</b>	<b>Revision of EU herbal monographs and list entries in preparation for adoption after public consultation .....</b>	<b>12</b>
<b>6.2.</b>	<b>Revision of EU herbal monographs and list entries in preparation for public consultation.....</b>	<b>12</b>
6.2.1.	Monograph on Foeniculi amari fructus and supporting documents .....	12
6.2.2.	Monograph on Foeniculi amari fructus aetheroleum and supporting documents .....	12
6.2.3.	Monograph on Foeniculi dulcis fructus and supporting documents .....	12

6.2.4.	Monograph on Juniperi pseudo-fructus and supporting documents - postponed .....	12
6.2.5.	Monograph on Lavandulae aetheroleum and supporting documents .....	12
6.2.6.	Monograph on Pelargonii radix and supporting documents - postponed .....	12
6.2.7.	Monograph on Agropyri repentis rhizoma and supporting documents .....	12
<b>6.3.</b>	<b>Review of EU herbal monographs and list entries in preparation for decision on revision .....</b>	<b>12</b>
6.3.1.	Monograph on Colae semen and supporting documents .....	12
6.3.2.	Monograph on Fucus vesiculosus and supporting documents - postponed .....	13
6.3.3.	Monograph on Fumariae herba and supporting documents .....	13
6.3.4.	Monograph on Mate folium and supporting documents .....	13
6.3.5.	Monograph on Plantaginis lanceolatae folium and supporting documents .....	13
6.3.6.	Monograph on Rosmarini aetheroleum and supporting documents .....	13
6.3.7.	Monograph on Rosmarini folium and supporting documents .....	13
6.3.8.	Monograph on Sabalis serrulatae fructus and supporting documents .....	13
6.3.9.	Monograph on Solidaginis virgaureae herba and supporting documents - postponed .....	13
6.3.10.	Monograph on Urticae folium and supporting documents .....	13
6.3.11.	Monograph on Urticae herba and supporting documents .....	13
6.3.12.	Monograph on Viola tricoloris herba and supporting documents .....	14
6.3.13.	Monograph on Zingiberis rhizoma and supporting documents .....	14
<b>6.4.</b>	<b>EU herbal monographs and list entries in preparation for adoption after public consultation .....</b>	<b>14</b>
6.4.1.	Monograph on Menyanthes trifoliata folium and supporting documents .....	14
<b>6.5.</b>	<b>EU herbal monographs and list entries in preparation for adoption for release for public consultation .....</b>	<b>14</b>
6.5.1.	Monograph on Andrographidis paniculatae folium and supporting documents – postponed	14
6.5.2.	Monograph on Centellae asiaticae herba and supporting documents – postponed .....	14
6.5.3.	Monograph on Cisti cretici folium and supporting documents .....	14
<b>7.</b>	<b>Any other business</b>	<b>14</b>
<b>7.1.</b>	<b>Topics for discussion .....</b>	<b>14</b>
7.1.1.	Overview of WebEx - new virtual meetings platform .....	14
7.1.2.	Update on HMPC Opinion for Allii sativii bulbus .....	14
<b>7.2.</b>	<b>Documents for information .....</b>	<b>15</b>
7.2.1.	HMPC .....	15
7.2.2.	ARSP .....	15
7.2.3.	EU herbal monographs, list entries and public statements – on hold .....	15
7.2.4.	Other .....	15

## 1. Introduction

### 1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the HMPC plenary session to be held on 1-3 March 2021. See March 2021 HMPC minutes (to be published post May 2021 HMPC meeting).

### 1.2. Adoption of agenda

HMPC agenda for 1-3 March 2021.

Time schedule for 1-3 March 2021.

### 1.3. Adoption of the minutes

HMPC minutes for 11-13 January 2021.

## 2. EU herbal monographs and list entries for adoption

### 2.1. Status of HMPC/MLWP activities

#### 2.1.1. Overview of HMPC/MLWP assessment work including the Rapporteurship distribution – Status in March 2021

---

Report: HMPC Chair

**Action:** for discussion

Document: Overview

#### 2.1.2. Appointment of Rapporteurs and Peer-reviewers

---

Report: HMPC Chair

**Action:** for adoption

New Rapporteur and Peer-Reviewer:

Reappointments

- Aloysiae citriodorae folium
- Hyperici herba
- Mate folium
- Rosmarini aetheroleum
- Rosmarini folium
- Solidaginis virgaureae herba
- Trigonellae foenugraeci semen

New assessments to start in 2021

- Cnici benedicti herba
- Cimicifugae rhizoma/ Hyperici herba

New substance for decision on prioritisation

- Tribulus terrestris herba

Documents: Proposal (CZ), Summary of proposals  
Periodic reviews to start in 2021

- Cucurbitae semen
- Levistici radix
- Juglandis folium

## **2.2. Revised EU herbal monographs and list entries for final adoption**

None

## **2.3. Revised EU herbal monographs and list entries for public consultation**

### **2.3.1. Monograph on Hyperici herba and supporting documents**

---

**Action:** for adoption

Documents: MO, AR, LoR, Reader's Guidance; References: 03/822

### **2.3.2. Monograph on Trigonellae foenugraeci semen and supporting documents**

---

**Action:** for adoption

Documents: MO, AR, LoR, Readers Guidance; References: 67/126

## **2.4. Reviewed EU herbal monographs and list entries for decision on revision**

### **2.4.1. Monograph on Cinnamomi corticis aetheroleum and supporting documents**

---

**Action:** for adoption

Document: Review report, Readers Guidance, Vigilyze overview; References: 00/02

### **2.4.2. Monograph on Cinnamomi cortex and supporting documents**

---

**Action:** for adoption

Document: Review report, Readers guidance, Vigilyze overview; References: 00/12

## **2.5. EU herbal monographs, list entries and public statements for final adoption**

None

## 2.6. EU herbal monographs, list entries and public statements for adoption for release for public consultation

### 2.6.1. Public statement on *Saccharomyces cerevisiae* CBS 5926 and supporting documents

---

**Action:** for information

Document: PS

### 2.6.2. Monograph on *Species digestivae* and supporting documents

---

**Action:** for adoption

Documents: MO, AR, LoR, email communication; References: 00/21

### 2.6.3. Monograph on *Taraxaci officinalis radix* and supporting documents – postponed

---

### 2.6.4. Monograph on *Vaccinii macrocarpi fructus* and supporting documents

---

**Action:** for adoption

Documents: MO, AR, LoR; References: 459/249

## 2.7. EU herbal monographs, list entries and public statements - post finalisation

None

## 3. Referral procedures

None

## 4. Guidelines and guidance documents

### 4.1. Non-clinical/clinical safety and efficacy and multidisciplinary

#### 4.1.1. Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) including recommendations regarding contamination with PAs (EMA/HMPC/893108/2011 Rev. 1)

---

**Action:** for discussion

Documents: [Draft PS](#), OoC

### 4.2. Quality

#### 4.2.1. Guideline on quality of herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)

---

**Action:** for information

Documents: [Draft Guideline](#), OoC

- 4.2.2. Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)
- 

**Action:** for information

Document: [Draft Guideline](#), OoC

- 4.2.3. Nitrosamines and Herbal MPs
- 

**Action:** for discussion

Documents: CMDh practical guidance for Marketing Authorisation Holders

- 4.2.4. Change of assay methods in Ph. Eur. monographs
- 

**Action:** for discussion

### 4.3. Regulatory / Procedural

- 4.3.1. Regulatory Q&A on herbal medicinal products
- 

**Action:** for discussion

Documents: Proposals for Q&A on use combination monographs; [Regulatory Q&A on herbal medicinal products](#), Proposal modification Q18 Non-European Reg Q&A, [Q&A on the EU framework for \(T\)HMP, including those from a 'non-European' tradition](#)

### 4.4. Report on HMPC Drafting Groups activities

- 4.4.1. Quality DG
- 

None

- 4.4.2. ORGAM DG
- 

None

## 5. Organisational, regulatory and methodological matters

### 5.1. Mandate and organisation of the HMPC

- 5.1.1. Strategic Review and Learning Meetings
- 

Portugal Presidency virtual meeting – 17-18 March 2021

Report: A P Martins

**Action:** for information

Document: Agenda



### 5.1.2. HMPC membership

---

New membership:

- Ireland, Jacqueline Masterson (alternate) as of 14 January 2021
- Luxembourg, Jane Murray (alternate) as of 17 February 2021
- Spain, Olga Maria Palomino (member) as of 21 February 2021

End of membership:

- Spain, Adela Nunez Velazquez (member) as of 22 February 2021
- Lithuania, Audronis Lukosius (alternate) as of 1 March 2021

### 5.1.3. Election of Co-opted member (paediatrics)

---

Report: HMPC Chair

**Action:** for adoption

Documents: Call for nominations dated 21 January 2021, [Procedure for the nomination and appointment of co-opted members of the CHMP, CVMP and HMPC](#), Candidature

### 5.1.4. Preparation of Election of Co-opted member (Clinical pharmacology)

---

Report: HMPC Chair

**Action:** for discussion

Documents: Expertise of HMPC members

### 5.1.5. HMPC meeting dates 2022-2024

---

**Action:** for adoption

Document: Meeting dates

## 5.2. EMA Scientific Committees or CMDh-v

### 5.2.1. Scientific Coordination Board Meeting

---

Report: HMPC Chair

**Action:** for information

Documents: Draft Minutes 14 December 2020, Minutes 1 February 2021

### 5.2.2. Update on PSUSA *Menthae piperitae aetheroleum*

---

**Action:** for discussion

Documents: Presentation, MO, Email communication, [Menthae piperitae aetheroleum](#)

## 5.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

### 5.3.1. Public statement on the use of herbal medicinal products containing estragole

---

**Action:** for adoption

Documents: Questions to SWP, Final PS, OoC

## 5.4. Cooperation within the EU regulatory network

### 5.4.1. Coordination with European Pharmacopoeia

---

- EDQM 13B expert group meeting  
Report: M Bald  
**Action:** for information  
Document: SoD
- EDQM TCM expert group meeting  
Report: M Bald  
**Action:** for information  
Document: SoD

### 5.4.2. Coordination with the European Commission

---

- Cannabis for medicinal use  
Report: HMPC Chair, EC representative: M Leon Grzymkowska  
**Action:** for adoption
- New draft EC Regulation amending Annex III of Reg 1925/2006 regarding HADs  
Report: EC representative: M Leon Grzymkowska;  
**Action:** for information  
Documents: Draft regulation; Email correspondence, [EP ENVI agenda January 2021](#)

## 5.5. Cooperation with International Regulators

### 5.5.1. IRCH – WHO 12th annual virtual meeting

---

Report: HMPC Chair

**Action:** for information Documents: Report, Agenda, Participants list

## 5.6. Contacts of the HMPC with external parties and interaction with the Interested Parties to the Committee

### 5.6.1. AESGP

---

Report: HMPC Chair

**Action:** for adoption Document: AESGP hearing report held on 18 November 2020

### 5.6.2. EUCOPE

---

- Hearing to be held in May 2021

Report: HMPC Chair

**Action:** for discussion

Document: Draft Agenda, Request for hearing

- Digital Conference on the European Health Economy  
Report: HMPC Chair  
**Action:** for information  
Documents: Questions on BW Event Session on Health claims; List of participants

## 5.7. Work plan

### 5.7.1. HMPC work plan 2021

---

Report: HMPC Chair, HMPC Vice Chair

**Action:** for information

Documents: Work plan 2021, Annex 1, Annex 2

- PhV data and experiences in national assessments  
Report: R Laenger, HMPC Vice Chair  
**Action:** for discussion  
Document: Updated summary on national experiences with HMPC monographs and during MRP/DCP procedures; References: 29/29
- Forward planning and prioritisation  
Report: HMPC Vice Chair  
**Action:** for adoption  
Documents: Draft New Template
- Use of real-world data and requirements for the safe use of herbal substances in children  
Report: HMPC Vice Chair, H Pinto Ferreira, M Petrikova; EMA: W Peschel  
**Action:** for information  
Document: Presentation
- Development of training on assessment of applications for herbal medicinal products  
Report: HMPC Vice Chair, C Purdel  
**Action:** for information  
Documents: Course description template

## 5.8. Planning and reporting

### 5.8.1. Big Data Training Signpost

---

**Action:** for discussion

Document: Presentation

## 5.9. Legislation and regulatory affairs

None

## 5.10. Questions from members

None

## 6. EU herbal monographs and list entries in preparation

### 6.1. Revision of EU herbal monographs and list entries in preparation for adoption after public consultation

None

### 6.2. Revision of EU herbal monographs and list entries in preparation for public consultation

#### 6.2.1. Monograph on *Foeniculi amari fructus* and supporting documents

---

**Action:** for discussion

Document: See 6.2.3; References: 00/00

#### 6.2.2. Monograph on *Foeniculi amari fructus aetheroleum* and supporting documents

---

**Action:** for discussion

Document: See 6.2.3.; References: 00/00

#### 6.2.3. Monograph on *Foeniculi dulcis fructus* and supporting documents

---

**Action:** for discussion

Document: Presentation; References: 00/00

#### 6.2.4. Monograph on *Juniperi pseudo-fructus* and supporting documents - postponed

---

#### 6.2.5. Monograph on *Lavandulae aetheroleum* and supporting documents

---

**Action:** for discussion

Documents: Reader's Guidance

#### 6.2.6. Monograph on *Pelargonii radix* and supporting documents - postponed

#### 6.2.7. Monograph on *Agropyri repentis rhizoma* and supporting documents

---

**Action:** for discussion

Documents: Draft MO, AR, LoR, Readers Guidance; References: 74/67

### 6.3. Review of EU herbal monographs and list entries in preparation for decision on revision

#### 6.3.1. Monograph on *Colae semen* and supporting documents

---

**Action:** for discussion

Documents: Review report; References: 164/53

### 6.3.2. Monograph on *Fucus vesiculosus* and supporting documents - postponed

---

### 6.3.3. Monograph on *Fumariae herba* and supporting documents

---

**Action:** for discussion

Documents: Review report, Reader's guidance; References: 00/16

### 6.3.4. Monograph on *Mate folium* and supporting documents

---

**Action:** for discussion

Documents: Review report, email correspondence ; References: 00/34

### 6.3.5. Monograph on *Plantaginis lanceolatae folium* and supporting documents

---

**Action:** for discussion

Document: Review report; References: 00/09

### 6.3.6. Monograph on *Rosmarini aetheroleum* and supporting documents

---

**Action:** for discussion

Documents: Review report, Presentation; References: 05/05

### 6.3.7. Monograph on *Rosmarini folium* and supporting documents

---

**Action:** for discussion

Documents: Review report, Presentation; References: 08/08

### 6.3.8. Monograph on *Sabalis serrulatae fructus* and supporting documents

---

**Action:** for discussion

Document: Review report; References 52/37

### 6.3.9. Monograph on *Solidaginis virgaureae herba* and supporting documents - postponed

---

### 6.3.10. Monograph on *Urticae folium* and supporting documents

---

**Action:** for discussion

Document: Review report; References: 28/11

### 6.3.11. Monograph on *Urticae herba* and supporting documents

---

**Action:** for discussion

Document: Review report; References: 28/06

#### 6.3.12. Monograph on *Violae tricoloris herba* and supporting documents

---

**Action:** for discussion

Documents: Review report, email correspondence; References: 28/25

#### 6.3.13. Monograph on *Zingiberis rhizoma* and supporting documents

---

**Action:** for discussion

Document: Readers Guidance, Presentation; References: 137/25

### 6.4. EU herbal monographs and list entries in preparation for adoption after public consultation

#### 6.4.1. Monograph on *Menyanthes trifoliata folium* and supporting documents

---

**Action:** for discussion

Documents: Draft MO, AR, LoR; References: 77/73

### 6.5. EU herbal monographs and list entries in preparation for adoption for release for public consultation

#### 6.5.1. Monograph on *Andrographidis paniculatae folium* and supporting documents – postponed

#### 6.5.2. Monograph on *Centellae asiaticae herba* and supporting documents – postponed

---

#### 6.5.3. Monograph on *Cisti cretici folium* and supporting documents

---

**Action:** for discussion

Documents: Draft MO, AR, LoR, Readers Guidance, Presentation; References: 00/86

## 7. Any other business

### 7.1. Topics for discussion

#### 7.1.1. Overview of WebEx - new virtual meetings platform

---

**Action:** for discussion

Document: Presentation

#### 7.1.2. Update on HMPC Opinion for *Allii sativii bulbus*

---

**Action:** for discussion

Documents: Presentation, Opinion, [HMPC RoP](#)

## 7.2. Documents for information

### 7.2.1. HMPC

---

Table of Decisions from HMPC meeting held on 11-13 January 2021

Overview of expertise of members HMPC and subgroups

[Inventory of herbal substances for assessment work](#)

[Abbreviations in HMPC agendas/minutes](#)

Common names of herbal substances in all languages

Final Monograph Overview

HMPC plenary Best Practice Guide with annexed Reader's Guidance template

### 7.2.2. ARSP

---

### 7.2.3. EU herbal monographs, list entries and public statements – on hold

---

None

### 7.2.4. Other

---

- Draft Agenda for the PCWP/HCPWP Joint meeting on 2-3 March 2021
- [Guideline on good pharmacovigilance practices \(GVP\)](#)  
Public consultation on revision 3 of GVP Module XVI on risk minimisation measures and on its new Addendum II from 3 February 2021  
Documents: 26 GVP Introductory Cover Note - M XVI Rev 3 with ADD II for public consultation, 2-01 GVP Module XVI Addendum II - Evaluation, 09 GVP Module Risk Minimisation Measures Rev 3