

COVID 19 – FAQ

Scope : Marketing authorization, Variations, Renewal, Sunset Clause

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INTRODUCTION

The current COVID-19 pandemic is currently having a huge impact on citizens, patients and businesses.

The ANSM is mobilized on a daily basis in close collaboration with the Ministry of Solidarity and Health and all health stakeholders in the exceptional context of the COVID-19 pandemic. As a public service and with regards to its mission towards public health, the ANSM has organized itself to meet its essential missions, in particular to ensure the availability and safety of health products and treatments for patients with COVID-19.

This questions and answers document (Q/A) should be read as an addendum of **the recommendations from European authorities**:

- From European Commission (***Notice to stakeholders - Questions and answers on regulatory expectations during the COVID19 pandemic***)
 - ✓ https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf
 - ✓ <https://www.ema.europa.eu/en/news/guidance-regulatory-requirements-context-covid-19-pandemic>
- And the Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (CMDh) :
 - ✓ https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/COVID-19/CMDh_418_220_Rev0_04_2020_-_PG_on_COVID-19_crisis.pdf

This document provides guidance to applicants and marketing authorizations holders for medicinal products for human use on regulatory expectations as well as possible adaptations during the COVID-19 pandemic in line with to those already provided at European level and which is applicable for national procedures.

If needed, this document will be updated to answer new questions and to adapt the content to the evolution of the pandemic. This document remains valid until further notice.

1. Handling applications

Q1.1. Will all applications be handled by the ANSM?

Answer:

The ANSM, a public service and health safety agency, has adapted its processes to meet its obligations during containment measures due to COVID-19 and until resumption of normal activity; it has also adapted its activities to the needs of the field, in particular to guarantee access to essential health products for the care of COVID patients at hospital level.

Therefore, if all applications will be handled, such as:

- Application type : Marketing authorization / Variation / Renewal / Translation / Sunset Clause / Marketing discontinuation / Abrogation
- Procedure type: European (MRP/DCP) and national procedures.

For the ANSM, priority will be given to applications for marketing authorization and variations concerning:

- COVID related medicines,
- a risk of shortage of an essential drug involved in the care of patients with COVID-19
- a risk of shortage of other essentials drugs.

In this context, the ANSM will comply European guidelines mentioned in the introduction.

It is recommended, as far as possible, **to delay other non-priority applications until the end of confinement.**

In addition, it is appropriate for each holder to prioritize their filings, taking into account in particular their own ability to deal with Agency questions within regulatory deadlines for files that are not related to COVID.

Q1.2. Are non-priority applications accepted?

Answer:

It is recommended as far as possible to postpone the submission of non-priority applications. These will however be accepted but may not be processed immediately or within the usual regulatory deadlines.

For marketing authorization applications in MRP / DCP for which France would be chosen as Reference Member State (RMS), slot requests should be submitted, as usual, in accordance with the instructions published on the ANSM website:

[https://www.ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Attribution-des-slots-Timeslots-allocation/\(offset\)/3](https://www.ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Attribution-des-slots-Timeslots-allocation/(offset)/3)

2. Submission processes

Q2.1. Have submission way/format been changed?

Answer:

Only electronic applications are accepted.

The submission methods may vary depending on the priority nature:

- Priority applications related to COVID or risks of essential medicine shortage
 - ✓ Submissions of applications as usual on CESP; you will be asked in particular for national procedures and European procedures for which France is acting as RMS (FR-RMS) to:
 - clearly identify in the comment field of the CESP repository: "**COVID**" or "**risk of essential medicines shortage**"
 - clearly identify in the subject of your cover letter the priority nature of the application, specifying at the beginning of the subject "**COVID**" or "**risk of essential medicines shortage**"
 - provide the reasons justifying the priority in the cover letter.
 - ✓ Requests for exemptions (see dedicated sections)
- Non-priority applications as usual without further notice.

3. 3. Deadlines - calendars

Q3.1. Can I postpone my renewal application?

Answer :

Yes.

Partial submission provided that conditions and timelines described in the European guidelines are fulfilled (cf. European guidelines)

Q3.2. Are the ANSM processing timelines affected?

Answer:

The agency guarantees the processing of all requests.

- The regulatory deadlines could be reduced when it comes to priority requests.
- The regulatory deadlines will be respected for the following processes:
 - ✓ All national variations ; it is reminded :
 - that a start date (D0) will be systematically sent for types IB and types II; if on the theoretical start date, no D0 is sent, a D0 will be sent before the end of the 1st theoretical evaluation round (D30 or D60) to confirm the start of the procedure on the theoretical date of D0;
 - in the absence of any formal decision at the regulatory deadlines, an implicit decision applies.
 - ✓ All variations in MRP / DCP France acting as Concerned Member State (CMS)
 - ✓ as well as the management of national phase for translations / notifications at the end of the European phase of Marketing Authorization / Variation applications;
- The deadlines could be adapted for the following requests:
 - Non-priority national marketing authorization MA applications
 - Non-priority MRP/DCP marketing authorization applications for which France is RMS,
 - Non-priority MRP/DCP variations applications for which France is RMS,Thus, apart from priority requests, the agency may delay the (re-) start of the procedure, in accordance with European guidelines.
- Requests for cancellation of marketing authorization and declarations relating to the launch or cessation of marketing of medicines will be treated as usual.

Q3.3. Can I request for clock-stop extensions during the validation phase?

Answer:

Apart from specific exemptions for priority submissions linked to COVID or linked to risks of essential medicine shortage, for national procedures, it is not authorized to extend the response timelines for the validation issues.

Q3.4. Can I request for clock-stop extensions during assessment phase?

Answer:

Please refer to European guidance for details.

- For all MA applications : yes
- For all renewal applications : yes

- For variation applications: yes, for type II variations when duly justified.

4. Dossier content

Q4.1. Can some requirements be waived/adapted for application? Process : MAA

Answer:

In general, in place of the original signatures, only the surname, first name and function of the person who in principle signs the document can be accepted.

In the event that certain documents are not submitted in support of the applications, this should be duly justified and this will be examined by the ANSM on a case by case basis.

A commitment may be proposed to provide certain documents not available at the time of the application due to COVID (such as GMP certificates) during the procedure and in any case before the end of the 1st assessment round.

(cf. European guidance).

Q4.2. Can some requirements be waived/adapted for applications? Process : Variations

Answer:

- In general, in place of the original signatures, only the surname, first name and function of the person who in principle signs the document can be accepted.
- In the event that certain documents are not submitted in support of the applications or for groupings that do not comply with EC Regulation No 1234/2008, this should be duly justified and this will be examined by the ANSM on a case by case basis.
- Transfer and/or change of so called “Exploitant” (responsible for placing the product on the market in France) application have been simplified and the updated requirements will be published soon on ANSM website.
- Other adaptations/waiver for requests concerning medicines intended to be used for the treatment of COVID-19 patients: please refer to European recommendations : https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/COVID-19/CMDh_418_220_Rev0_04_2020_-_PG_on_COVID-19_crisis.pdf
- ✓ The « **exceptional change management process (ECMP)** » may be applied for implementing new starting materials/reagents/active substance/intermediate/finished product manufacturing/packaging sites/suppliers or control sites. Refer to guidance for details of submission.
- ✓ For the implementation of this exceptional procedure, a request should be submitted by the MA holder to the ANSM or to the competent authority who acts as RMS. An answer from the authorities will be transmitted within 2 working days.
- ✓ Provided that the request for the ECMP procedure has been accepted, the corresponding variation applications should be submitted within 6 months of implementation.

- ✓ It is however, reminded that without response from the authorities within 2 working days, the ECMP procedure is considered accepted.
- ✓ Requests should be sent to the following mailboxes:

Procedures	Mailboxes to be used	Subject of email
National	e-recevalibilite@ansm.sante.fr	COVID-ECMP – name of medicine – CIS/NL identification No.
European	Ueurop@ansm.sante.fr	COVID-19, ECMP - procedure number (e.g. FR/H/nnnn/001) – name of medicine

Q4.3. Can some requirements be waived/adapted for applications? Process: Renewal

Answer:

Cf. Q3.1

In general, in place of the original signatures, only the surname, first name and function of the person who in principle signs the document can be accepted.

When the complete submission will be filed, in the event that certain documents are not submitted in support of the applications, this must be duly justified and this will be examined by the ANSM, on a case by case basis.

Q4.4. Does the COVID situation constitute a reason for sunset clause waiver?

Answer:

Yes, the COVID situation can cause a delay in the launch of certain medicines.

The European recommendations remind companies of the need to apply for the Sunset clause waiver as usual.

These waiver requests linked to COVID context should be submitted to the ANSM; they will be examined as usual. A justification should be provided in the usual form.

Requests should be sent to the following mailbox:

Procedures	Mailboxes to be used	Subject of email
National	dajr@ansm.sante.fr	Dérogation à la caducité – nom spécialité – CIS/NL

Q4.5. ASMF: is it possible to apply the principle of mutual recognition if the ASMF has already been assessed by the agency for another application or by another European authority?

Answer:

Any information concerning an ASMF evaluation by another Member State of the EU can usefully contribute to the evaluation conducted by the ANSM and speed up processing.

It is recommended to mention it in the cover letter with the following information and to provide a copy of the approval of the corresponding competent authority in the annex to the cover letter:

- DCI / ASMF No./ version No.,
- Approval date for the ASMF / Competent Authority,
- Specialty (name, dosage, pharmaceutical form) for which the ASMF has been approved by the Member State.

5. Notification of the decision

Q5.1. How national decisions are sent to MAH?

Answer:

Until further notice, the ANSM will deliver its decisions electronically (pdf and word version) for all of its processes.

These electronic documents will not be duplicated by paper mail during or after the pandemic. Likewise, all correspondence during the processing of these files will be carried out by email.

Q5.2. Who are the decisions addressed to?

Answer:

All correspondence will be sent as much as possible to the generic email addresses that each applicant has provided to the “Comité d’interface” and which is mentioned in the filing with a copy to the designated person in charge of the file in the eAF; for some letters (invalidation, request for additional information, intended refusal or refusal), it will be requested to acknowledge receipt by return email.