

# CHECKLIST: HOW TO SUCCESSFULLY COMPLETE YOUR ANSM SUBMISSION STRESS-FREE

PUBLISHED BY PYRAMIDALE COMMUNICATION, MEDICAL COMMUNICATIONS AGENCY

## 01

### Identify the key messages of the campaign

- **Identify** the key messages you want to communicate.
- **List** the key messages as a storyline using bullet points.

## 02

### Check that the messages are consistent with regulatory content

- **Check** the Marketing Authorization (MA): ensure that promotional messages comply with the terms of the MA and/or the Transparency Commission's opinion (if published), and with clinical studies in line with the MA.
- **Gather** the mandatory legal notices.
- **Collect** scientific references: all clinical claims or benefits must be supported by published and valid scientific studies.

## 03

### Select a medical communications agency with expertise in this field

- **Select** a medical communications agency that has expertise in ANSM submissions and understands the pharmaceutical regulatory environment. They will help you prepare all the necessary documents for submission.
- **Provide** your agency with a systematic briefing. Its expertise could prove invaluable at this important stage.

## 04

### Anticipate and plan the submission

- **Establish** a detailed timeline, allowing buffer time for unforeseen issues.
- **Adjust** the timeline in real time according to the project's progress.
- Your agency, if experienced with ANSM submissions, can provide effective support.

## 05

### Create compliant materials

- **Check** for clarity and accuracy: the message must be precise, clear and not exaggerated.
- **Ensure** balanced product communication, including both efficacy and safety information.
- **Respect** comparative advertising rules, without disparagement.
- **Diverse communication materials:** **prepare** all intended communication materials (brochures, posters, emails, digital banners) for submission.

## 06

### Coordinate with internal teams

- **Collaborate** with regulatory teams from the document conception stage to validate the compliance of materials and planned content.
- **Involve** medical teams as early as possible to ensure compliance with available clinical data.
- **Involve** your communications agency in discussions with the various internal departments. If your agency has good regulatory expertise, it will be able to provide you with advice and benchmarks.

## 07

### Submit the complete folder to the ANSM

- **Compile** the required documents: prepare a complete folder with all promotional materials, clinical studies, references, and legal statements.
- **Comply** with the required format: ensure that all documents meet the format requested by the ANSM.
- **Ensure** proper data referencing. An agency with proven expertise in ANSM submissions can provide valuable support in this area.
- **Plan** for timelines: make sure your document review timeline does not end too close to the submission deadline. Allow sufficient buffer time for last-minute changes.

## 08

### Ensure post-submission follow-up

- **Monitor** ANSM feedback: pay close attention to any feedback or requests for modifications, which may include minor or more substantial adjustments.
- **Respond** promptly to requests: in the event of a request for clarification or adjustment, ensure a timely response.
- **Choose** a responsive agency that can quickly implement the requested changes, in order to avoid delays or deferral to a subsequent submission period.

## 09

### Anticipate the unexpected at the ANSM

- Plan B in case of refusal: **prepare** a contingency plan in case the ANSM requests significant modifications or rejects your submission, including alternative messaging or timeline adjustments.
- **Integrate** your agency into your submission strategy. It can advise you on the potential risks involved in adjusting your strategy based on your challenges and deadlines.

## 10

### Carry out rigorous archiving and systematic feedback

- **Archive** all approved communications: keep a folder of materials approved by the ANSM for use in future submissions or audits.
- **Keep a history** of submissions: track past submissions to anticipate any new campaigns or corrective actions.
- Systematically **provide** feedback on the submission with the internal departments involved and your communications agency. Each experience contributes to improving expertise and workflow efficiency.

✉ CONTACT



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