



Title: Marketing status reporting and sunset clause monitoring		
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1. Purpose

To describe:

- the handling of the marketing status reporting provided by Marketing Authorisation Holders (MAHs) and the monitoring of the sunset clause period/timer by the EMEA based on the marketing data, for medicinal products for human use whether authorised before or after 20 November 2005.
- the handling of subsequent information received on cessation of placing the product on the market which may be of public health concern, whether temporary or permanent, and the granting of an exemption to the application of the sunset clause by the European Commission.
- the procedure for managing the end of the 3-year period without marketing and notifying this situation to the European Commission.

2. Scope

This SOP applies to the Human Pre- and Post-authorisation Evaluation of Medicines for Human Use Units.

3. Responsibilities

It is the responsibility of each Head of Unit and Head of Sector to ensure that this procedure is adhered to within their own unit and sector. It is the responsibility of the PTL to monitor the overall sunset time. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedure**.

4. Changes since last revision

Revised number of the marketing of the product subfolder in EDMS and update of the links provided in section 6.

5. Documents needed for this SOP

The following templates can be found in (X:\Templates\Others\Sunset clause) and can be generated from SIAMED:

- Template letter to the MAH for confirmation of the expiry of the 3-year period without marketing
- Template notification to the Commission of the expiry of the 3-year period without marketing

6. Related documents

- Letter addressed to all MAHs for initiating marketing status reporting (dated February 2006)
- Questions and Answers on the notification to the EMEA of actual marketing and cessation of placing on the market for centrally authorised medicinal products (EMEA/180078/2005) -

- <http://www.emea.europa.eu/htms/human/postguidance/q95.htm>
<http://www.emea.europa.eu/htms/human/postguidance/q96.htm>
- Questions and Answers on the application of the so-called “sunset clause” to centrally authorised medicinal products (EMEA/180079/2005)-
<http://www.emea.europa.eu/htms/human/postguidance/q105.htm>
 - Template table of Marketing Status reporting
<http://www.emea.europa.eu/htms/human/postguidance/q100.htm>
 - EMEA Post-Authorisation Guidance (sections “Marketing & Cessation notification” and “Sunset clause monitoring”)
<http://www.emea.europa.eu/htms/human/postguidance/list.htm>

7. Definitions

Marketing Status reporting:

An overview at one time point of the various presentations/pack-sizes of a specific product marketed or not in each country of the European Economic Area (EEA). Marketing and cessation are indicated with a date.

Sunset clause:

A three-year period without marketing of the medicinal product leads to the invalidity of the Marketing Authorisation (MA). This period starts counting from the granting of the MA or from the last cessation of placing the product on the market.

Sunset timer:

The tool used to monitor the overall sunset clause period.

Sunset timer ON:

The so-called “sunset timer” is qualified as “ON” when the counting of the 3-year period is running i.e. when none of the medicinal product presentations are available on the market in any of the countries of the EEA.

Sunset timer OFF:

The so-called “sunset timer” is qualified as “OFF” when the counting of the 3-year period is not running i.e. when there is at least one of the medicinal product presentations available on the market in at least one of the countries of the EEA.

Marketing / placing on the market:

The release of the medicinal product into the distribution chain i.e. out of the direct control of the MAH.

Cessation of placing on the market:

Cessation of release into the distribution chain with the consequence that the concerned product is no longer available for supply to the patients.

The date of cessation is the date of the last release into the distribution chain.

Where the MAH identifies that there may be a public health concern with a cessation, the MAH should inform the EMEA (via their Product Team Leader (PTL)) in writing, 2 months in advance of the interruption or in exceptional circumstances as soon as considered likely or known. The MAH should provide detailed information for the Agency to assess the impact of such cessation. This should include e.g. grounds, expected length of cessation period, Members State(s) concerned, company’s intention to provide information to prescribers and patients, etc. The Rapporteur and Committee for Medicinal Products for Human Use (CHMP) will be involved as appropriate in the evaluation of the information received.

Furthermore, the MAH should provide the updated Marketing Status reporting table, in line with the template.

MAHs are advised that such reporting is without prejudice to other procedures. Where cessation is due to efficacy, safety and/or quality related issues for which particular procedures are established, the specific related procedure should be followed in addition (e.g. quality defect, pharmacovigilance issues, etc.)

Exemption:

Through a specific legal provision, the Commission may grant, in exceptional circumstances and on public health grounds, an exemption to the application of the sunset clause provision.

Exemptions can apply at any time of the marketing authorisation life cycle (i.e. at the time of the marketing authorisation, during the marketing authorisation life, or approaching the expiry of the sunset clause period).

Where the MAH informs the EMEA that the sunset timer should not be started (i.e. sunset timer 'off'), the PTL should liaise with the Regulatory Affairs (RA) PTM to check whether the Commission should be consulted to grant an exemption.

It will be up to the MAH to justify why an exemption should apply based on public health grounds and in exceptional circumstances. A request for an exemption including a justification should be notified to the Commission and each justification will be considered on a case-by-case basis. A copy of such request should also be addressed to the EMEA.

Chrono mailbox 'Marketing status' (in Chrono In/Workflow):

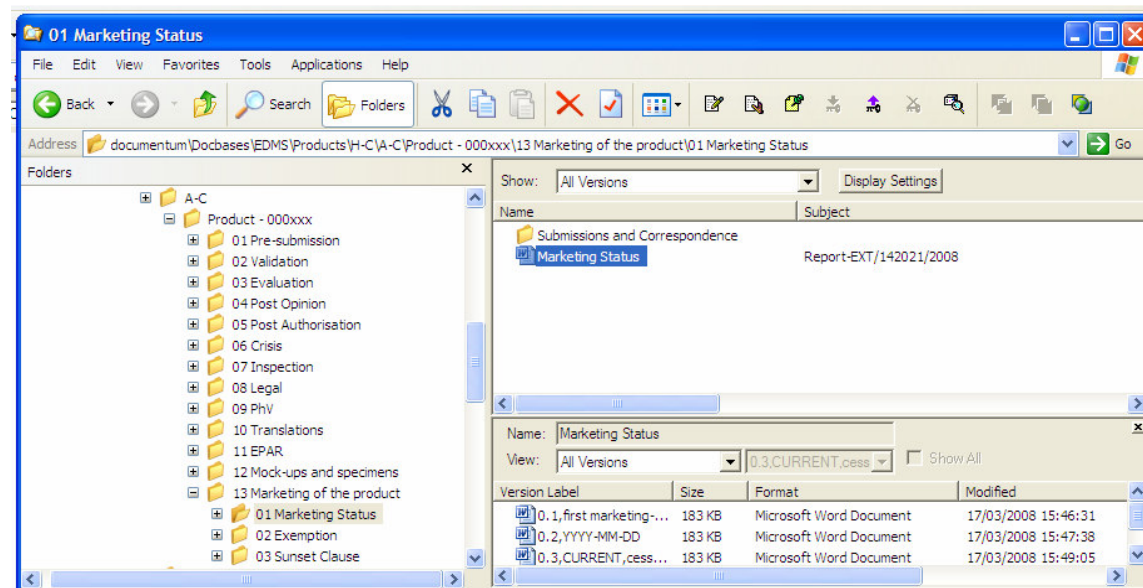
All marketing status reportings either relating to the first marketing, updates or cessation, should be sent by the MAH to the mailbox address (marketingstatus@emea.europa.eu) and should be copied to the PTL for the first marketing and for cessations.

- First marketing reporting: should be sent within 30 days of the initial placing on the market of the product within the Community;
- Updated reporting: should be sent at time of PSUR submission and after renewal, annually in accordance with anniversary of the Commission Decision date;
- Cessation: should be sent 2-month before the interruption, otherwise as soon as the interruption is considered likely or known.

The chrono box will be checked on a regular basis by the Specialised Group Assistant (SGA) for any actions as appropriate. When processed, the e-mail will be moved and kept under the sub-folder "Processed".

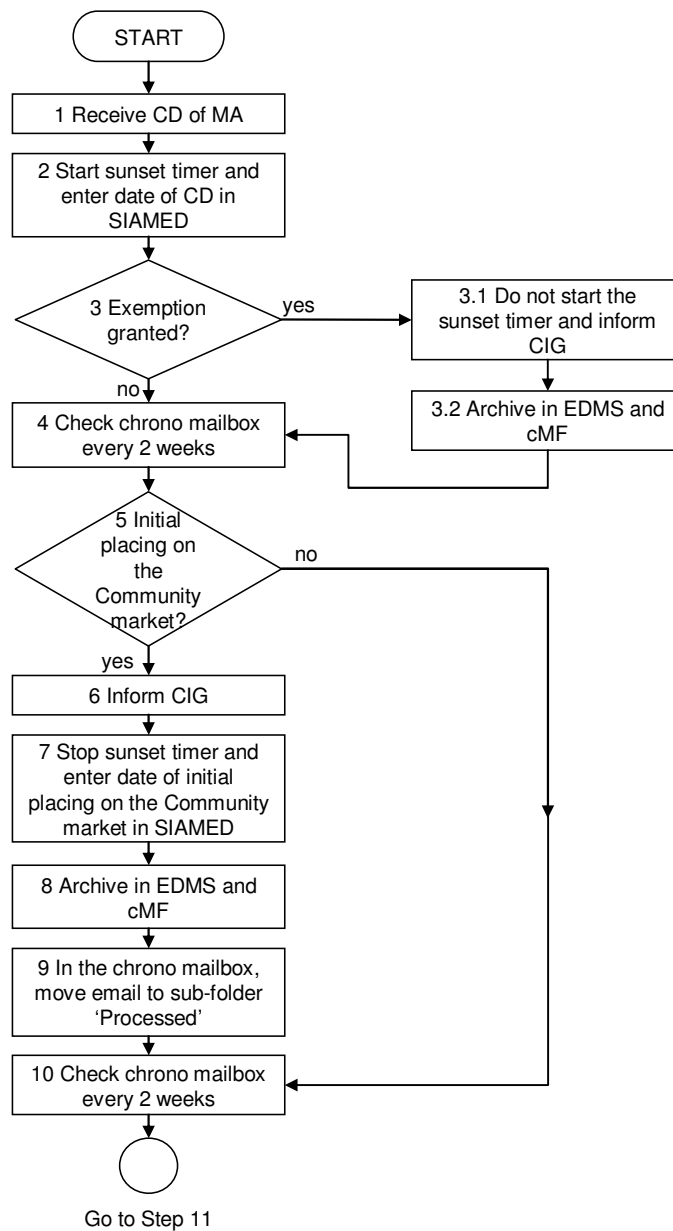
Tree organisation of the 'Marketing of the product' folder and its subfolders in EDMS

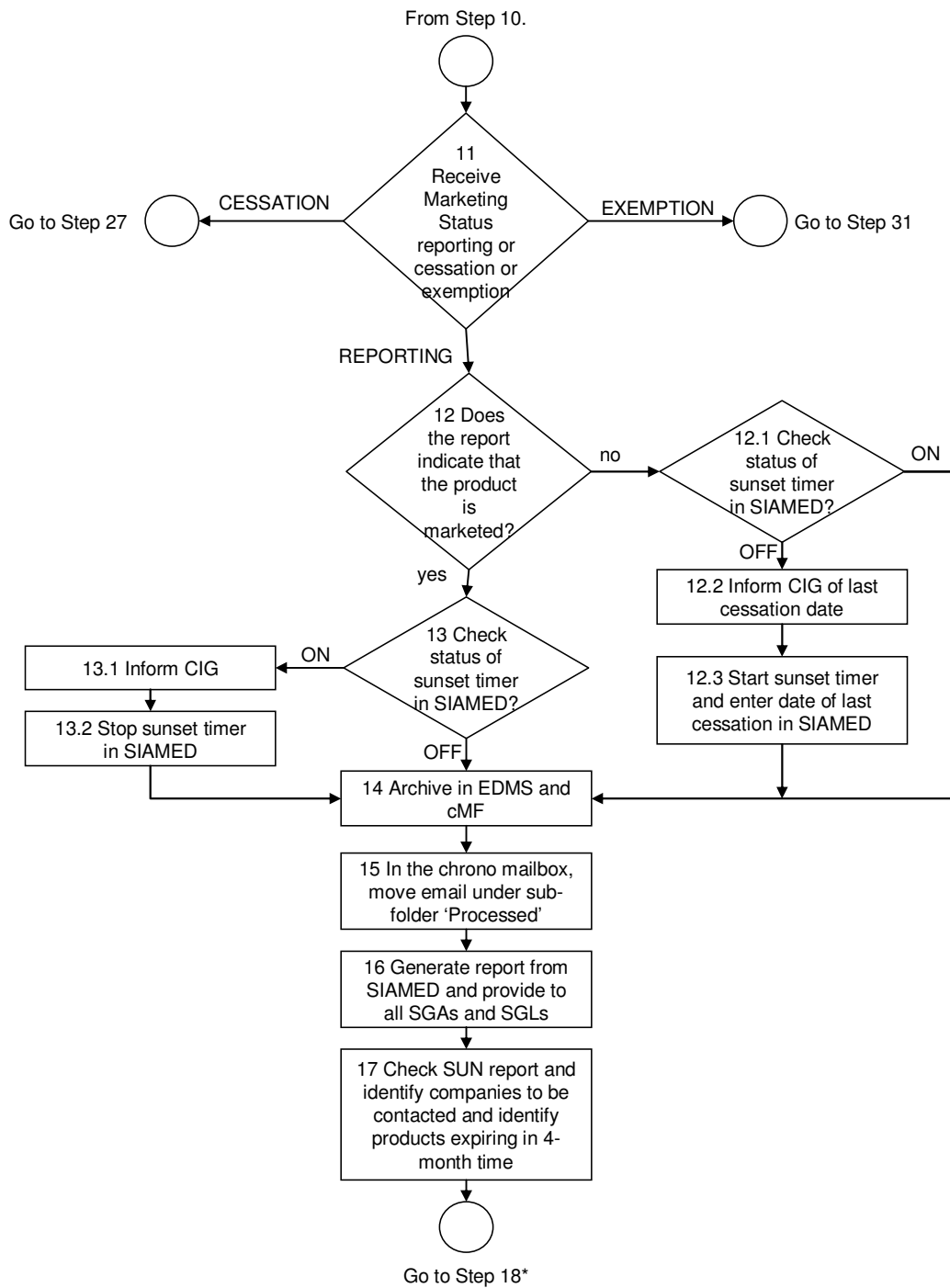
The 'Marketing of the product' folder is located under the product folder. The folder structure will have to be created manually by the SGA for all existing products. For new authorised products, the folder structure will be created automatically.



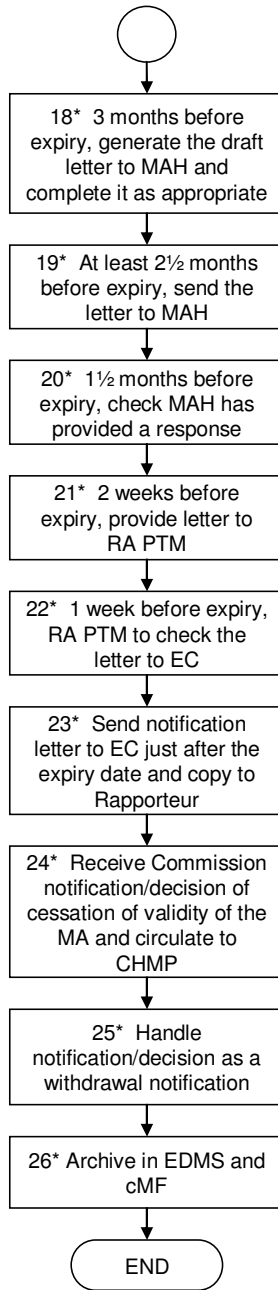
CD: Commission Decision granting marketing authorisation
CIG: Central Information Group
cMF: Core Master File
EC: European Commission
EEA: European Economic Area
EDMS: Electronic Document Management System
MA: Marketing Authorisation
MAH: Marketing Authorisation Holder
MS: Member State
PTL: Product Team Leader
PTM: Product Team Member
RA: Regulatory Affairs
SGA: Specialised Group Assistant
SGL: Specialised Group Leader

8. Process Map(s)/ Flow Chart(s)

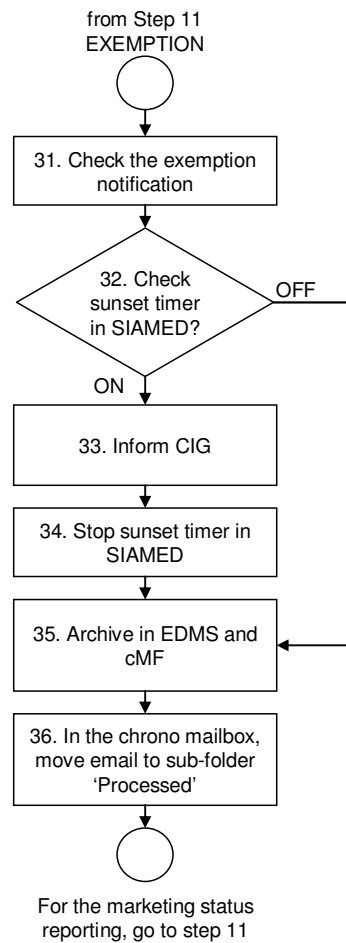
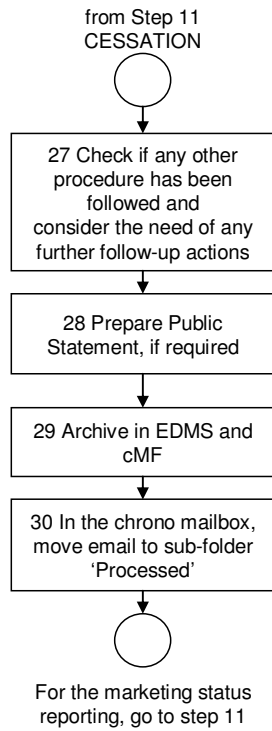




From Step 17



** These steps will take place as of July 2008*



Step	Action	Responsibility
	“Processed”	
10	Check the chrono mailbox “ Marketing status” every 2 weeks	SGA
11	After the receipt of the initial placing on the Community market, the following documents can be received: <ul style="list-style-type: none"> - Updated marketing status reporting, go to step 12. - Cessation of placing on the market, go to step 27. - Exemption granting, go to step 31. 	SGA PTL PTL
12	Verify if the product is marketed (i.e. at least one presentation/pack-size available in one country of the EEA). If no, go to step 12.1. If yes, go to step 13.	SGA
12.1	Check if the sunset timer is ON or OFF. If the sunset timer is OFF, go to step 12.2. If the sunset timer is ON, go to step 14.	SGA
12.2	Inform CIG, via the H-SIAMED e-mail address (copy PTL), of the last cessation date. The last cessation date will be the start date for the counting of the sunset period. If an exemption is already granted, do not inform CIG of the last cessation date.	SGA
12.3	Start the sunset timer in SIAMED as follows: <ul style="list-style-type: none"> - Select “SUN”. - Enter the due date. The due date should be calculated as follows: date of last cessation + 3 years. - Enter a comment in the field “Administrative”: “<i>start date = DD/MM/YYYY (last cessation date)</i>”. Go to step 14.	CIG
13	Check if the sunset timer is ON or OFF. If the sunset timer is ON, go to step 13.1. If the sunset timer is OFF, go to step 14.	SGA
13.1	Inform CIG, via the H-SIAMED e-mail address (copy PTL), to stop the sunset timer.	SGA
13.2	Stop the sunset timer in SIAMED as follows: <ul style="list-style-type: none"> - Select “SUN”. - Close the timer but do not suppress the SUN procedure and enter the date of re-marketing. Go to step 14.	CIG
14	<ul style="list-style-type: none"> - Create a subfolder “YYYY-MM-DD” (i.e date of receipt) under the folder “Submissions & Correspondence” and save in this subfolder the related information/e-mails (See folder structure, p.3). Extract the Marketing Status reporting table and save it as a new version of the Marketing status Excel file*. In the section <u>label</u> of the file EDMS properties, mention: “ YYYY-MM-DD ” (i.e. date of ‘version updated’ mentioned in the reporting table). <p>* Marketing status Excel file is located directly under “Marketing Status” folder (see folder structure, p.3)</p>	SGA

Step	Action	Responsibility
	<ul style="list-style-type: none"> - Provide CIG with the original notification from the MAH if not already received by them. - File the document in the cMF of the concerned product. 	CIG
15	In the chrono mailbox, move the e-mail to the folder "Processed"	SGA
16	<ul style="list-style-type: none"> - Until June 2008, generate through SIAMED a "SUN" report of products (i.e. only those with the sunset timer is ON) bi-annually until June 2008 and monthly as from June 2008. Please see the Working Instruction WIN/H/3165 for further instructions regarding the timelines and the content of the SIAMED "SUN" report. - Provide the report to all SGAs and SGLs by e-mail. 	CIG
17	<ul style="list-style-type: none"> - Review the bi-annual SUN report and identify which companies need to be contacted as per the instructions provided in the Working Instruction WIN/H/3165 . - As of June 2008, review the monthly SUN report and identify products for which the 3-year period without marketing is going to expiry in 4-months time and inform PTL for action as below. 	SGA with support of PTL
18*	<ul style="list-style-type: none"> - 3 months before the expiry of the sunset period, generate the draft letter (use template available in SIAMED) to be sent to the MAH requesting confirmation of the sunset period. - complete the draft letter with the appropriate wording i.e. either referring to the CD date or the last cessation date. <p>In case of doubt when checking this letter, liaise with the RA PTM.</p>	PTL
19*	Send the letter to the MAH at least 2½ month before the expiry date of the sunset period.	PTL
20*	<p>1½ month before the expiry of the sunset period, check that the MAH has provided a response. If not, send a reminder.</p> <p>In case of discrepancy with the MAH in terms of counting the 3-year period, clarify with the MAH as appropriate.</p>	PTL
21*	2 weeks before the expiry of the sunset period, provide to the RA PTM, in a signature book with a transmission slip, the draft notification letter to the European Commission on the expiry of the sunset period (use template available in SIAMED) and the confirmation letter from the MAH.	PTL
22*	1 week before the expiry of the sunset period, check the notification letter to the Commission.	RA PTM
23*	<p>The day after the expiry of the sunset period, send the notification letter to the Commission with the confirmation letter from the MAH and a copy to the Rapporteur and the MAH.</p> <p>If not a working day, send it the next working day.</p> <p>Circulate, for information, this letter in the next CHMP pre-mail.</p>	PTL
24*	<p>Receive the notification/decision of cessation of validity of the MA from the Commission.</p> <p>Circulate a copy of the notification/decision in the CHMP pre- or post-mail.</p>	CIG/PTL PTL
25*	Handle the notification/decision as for MA withdrawal notified by	PTL

* These steps will take place as of July 2008

Step	Action	Responsibility
	<p data-bbox="380 191 1149 243">[*organisation tree in EDMS: <i>documentum\Docbases\EDMS\Products\H-CD-F\Product-000XXX\13 Marketing of the product\02 Exemption</i>]</p> <ul style="list-style-type: none"> <li data-bbox="380 254 1062 285">- Provide CIG with the original of the exemption document. <li data-bbox="380 296 1127 327">- File the original document in the cMF of the concerned product. 	<p data-bbox="1175 317 1232 348">SGA</p> <p data-bbox="1175 359 1232 390">CIG</p>
36	<p data-bbox="380 401 1138 432">In the chrono mailbox, move the e-mail under the folder “Processed”</p> <p data-bbox="380 443 1081 508">To follow-up on any actions with regard to the marketing status reporting, go to step 11.</p>	SGA

10. Records

Information regarding marketing status, cessation, exemption and expiry of the sunset period are stored in EDMS in the product folder (electronically) and in the cMF (paper).