EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Checklist for Initial Notifications for Parallel Distribution

Guidance for industry

The European Medicines Agency (hereinafter 'the Agency') asks its applicants to use this checklist in advance of submission of an initial notification for parallel distribution. You should be able to answer "Yes" to every item listed below unless a specific point is not applicable ("n/a") to the application in question. In order to improve the quality of submissions, it is recommended to include the checklist with your submission.

Upon receipt of an initial notification for parallel distribution, the procedure manager proceeds to validate the documentation submitted in accordance with the checklist included below.

Updates to the information included in the IRIS form after submission of any notification for parallel distribution are only possible in exceptional cases, so the applicants should review the information included in the form carefully before submitting. Changes impacting fees would not be possible after submission. Only changes requested by the assessor would be possible and only by exception when properly justified.

Reference documents for further information:

- Parallel distribution: Regulatory and procedural guidance:

  https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/parallel-distribution-regulatory-procedural-guidance

- Frequently Asked Questions (FAQs) about parallel distribution:

  https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Regulatory check	Comments	Yes	N/A
1. Valid authorisations	Provide reference number of the relevant Wholesale Distribution Authorisation (WDA) as well as of the Manufacturing and Importation Authorisation (MIA) for the company responsible for re-labelling / re-packaging. MIAs and WDAs can be found in EudraGMDP: http://eudragmdp.ema.europa.eu/ In case the relevant MIA or WDA is not available in EudraGMDP, please include colour copies in your IRIS submission.	☐	
2. Latest version of Annexes to Marketing Authorisation	**Human medicines:** In order to determine the correct version of the annexes to the relevant marketing authorisation: • Check the **EMA website**: (https://www.ema.europa.eu/en/medicines) • and **European Commission (EC)**website : (https://ec.europa.eu/health/documents/community-register/html/index_en.htm) To determine the correct annex date, please refer to the date next to the procedure number (e.g. 04/06/2020, IB/49). As a rule of thumb, please use the most recent approved annexes. Please note, that published **yearly updates may not** include the latest approved variation (i.e. the variation published above the yearly update on the EC website does not contain "updated with the decision of ABCD of DD/MM/YYYY"). In those cases, please refer to the information published on the European public assessment report (EPAR), which should contain the latest approved variation. **Veterinary medicines:** In order to determine the correct version of the annexes to the relevant marketing authorisation: • Check the Veterinary Medicines Information website: https://medicines.health.europa.eu/veterinary/en To determine the correct annex date, please search for your product. Once on the product page, scroll down to the header "Documents". Here you will find the product information. Please download the annex in the correct	☐	

Regulatory check	Comments	Yes	N/A
	language and determine the annex revision date from the naming convention of the downloaded PDF. The naming convention is as follows: ema-combined-vXX-PRODUCT NAME-vraXXX-YYYY-MM-DD-language code. The highlighted date is the correct annex date that should be used for your submissions.		
3. Change of pack size	Indicate whether the sourced EU presentation number is different from the distributed EU presentation number. In general, the sourced and distributed EU presentations should be identical except in pack size.	☐	☐
4. Member State of Origin and Member State of Destination	As parallel distribution is the distribution across European borders, it is not possible to source a product from one Member State and parallel distribute it in the same Member State. In case only one Member State of Destination (MSD) is selected, ensure that it is not included also as Member State of Origin (MSO).	☐	
5. Specific mechanism (if applicable)	Ensure that if the specific mechanism applies, a prior notice letter containing, at least, the following details has been sent to the MAH **at least 30 days before submission**: • Parallel Distributor name • Product Name / Active Substance • Member States of Origin • Member States of Destination The prior notice letter is to be signed and sent either by the parallel distributor or by another company on behalf of the parallel distributor. Further information on the specific mechanism can be found on the FAQs on parallel distribution published on the EMA website.	☐	☐
6. Re-packagers	Enter all re-packagers involved in the re-packaging of your product presentations. If they are not available in the list, liaise with your re-packagers to register themselves in OMS: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration_en.pdf	☐	
7. Re-labelling vs Re-boxing	Clearly indicate the method of re-packaging and its details, providing supporting documents as follows:		

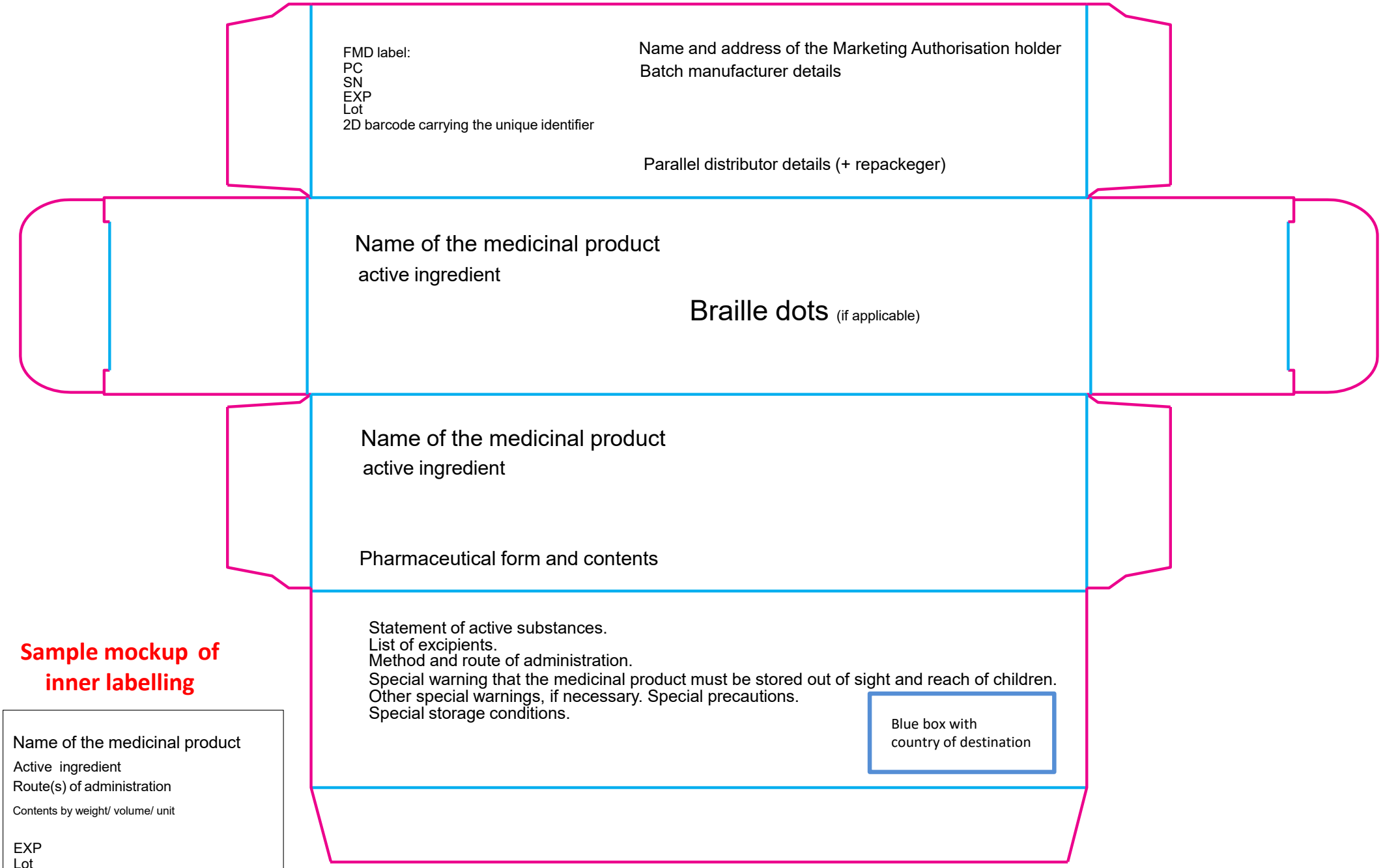
Regulatory check	Comments	Yes	N/A
(correct nature of repackaging is used, and this refers to the outer packaging with blue box)	• Re-boxing: – colour images of the new outer packaging and images of the re-labelled inner packaging in a single file; – Mock-ups in case of reboxing: please provide two separate documents: one document containing a mock-up of the outer carton and another one of the inner label (not combined in one file). The text on the mock-up should be identical to the text on the colour copies and in compliance with the annex. Please refer to Annex I at the end of this checklist for more information. • Re-labelling: – colour images of the relabelled original outer packaging and images of the re-labelled inner packaging in a single file; – Mock-ups in case of relabelling: please provide two separate documents: one document containing a mock-up of the outer label and another one of the inner label (not combined in one file).The text on the mock-up should be identical to the text on the colour copies and in compliance with the annex. Please refer to Annex I at the end of this checklist for more information. • Re-boxing and re-labelling = both of the above activities, therefore 2 x sets of colour copies are required as well as two sets of mock-ups. Mock-ups are also acceptable provided that they comply with EMA requirements as laid down in the FAQs on parallel distribution published on the EMA website. **Multipacks with intermediate packaging**: the outer packaging containing the blue box has to be looked at when defining the repackaging method.	☐	
8. Outer and inner labelling	Ensure that the images correspond to the product presentation indicated in IRIS and that the text is in the language of the MSD. The text on the labelling should match the information in the Annexes with the exception of:		

Regulatory check	Comments	Yes	N/A
	• Manufacturer responsible for the release of the sourced product batch • Parallel Distributor and/or re-packager details • Blue box, which should bear the name of the MSDs and any other information required by the Member State of Destination In case of change of pack size, the sourced EU number on the packaging has to be **fully covered** in case of relabelling. Ensure that the product presentation corresponds to the description of the approved EU presentation in its Marketing Authorisation (e.g. if according to the Marketing Authorisation, a product comes in a bottle without outer carton, an outer carton should not be created). Even if not included in the Annex, it is recommended to adhere to the colour scheme of the packaging of the sourced product (e.g. warning text or colour code per strength). For requirements on labelling, please refer to the regulatory check section on the FAQs on parallel distribution published on the EMA website. https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution	☐	
9. Annex IV (educational material & controlled distribution system), Patient alert cards and Biological products specifics	Ensure that any particular conditions for distribution of the product are met before placing the product on the market, liaising with the relevant National Competent Authorities in the EU/EEA, as needed. Sale version of the Patient Alert Card or other Educational Material (if included in the Annex) need to be enclosed in the submission to show the Agency how the product will be presented to users In cases where labelling information is amended as a result of national requirements but not included in the Annexes, please provide justification for such inclusion within the submission. It is noted that for pharmacovigilance reasons and traceability purposes, it may not be possible to deviate from the revision date on sourced Risk Minimisation	☐	☐

Regulatory check	Comments	Yes	N/A
	Measures material.		
10. Package leaflet	Ensure that the revision date of the package leaflet matches the date of the Annexes and the date indicated in IRIS. Ensure that the relevant manufacturer is mentioned and matches the one mentioned on the outer packaging. In case of discrepancies between the latest Annex and the package leaflet of the sourced product, please follow the advice provided on the FAQs on parallel distribution and provide justification for such discrepancy in your submission. Ensure that the colour scheme of the Annexes is correctly reproduced in the package leaflet. Ensure that the reference to Appendix V is replaced with the current contact information of the reporting system in the Member State(s) of Destination.	☐	

This checklist is published for transparency purposes and does not preclude that, during the actual validation of the submitted application, the Agency may identify other issues to be addressed by the applicant.

Sample mockup of outer packaging - computer-readable text, i.e. separate text parts can be highlighted



Sample mockup of inner labelling

Name of the medicinal product

Active ingredient

Route(s) of administration

Contents by weight/ volume/ unit

EXP

Lot