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Human Medicines Division

# Q&A Document following the Webinar on Submissions of Parallel Distribution Notifications for CAPs held on 9th June 2022

| Question | Answer |
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| Why do we have to send separate mock-up for outer and inner packaging with initial notification and not combined in one file? | We are currently developing an IT tool to support with the assessment of cases. It is a technical requirement of the tool to have 2 separate files for the mock-up (one for outer and one for inner). Therefore, parallel distributors are prompted to submit their outer packaging, inner packaging, and package leaflet as separate files during the submission phase.<br><br>Please refer to the Parallel Distribution FAQ page, Question 3. How to apply for a PD notice? for more details on the requirements for case documentation |
| Question on presentation: Why did it say in your presentation regarding Mock-ups and Labelling that for Labelling the parallel importer must submit a file containing images of the outer carton (in case of reboxing) or fully labelled original outer carton (in case of relabelling)? Isn't labelling concerned only with putting a new label over the secondary packaging of the product, which has nothing to do with reboxing? | According to the current naming convention, the file naming should be **mock-up** for mock-ups of the inner and outer packaging, and **labelling** for images of reboxed and/or relabelled packaging (depending on the selected repackaging method). The name of the file 'labelling' refers to product labelling (package labelling in general). The term 'labelling' was used as an overarching term that can include both the repackaging methods of relabelling and reboxing. |

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| In your presentation of the annual update you did not select any notices. Is it possible to abstain from selecting any notices? | The presentation was done from the IT test environment. In reality, the system will automatically select ALL active notices which the applicant holds, and which meet the search criteria: product+pharmaceutical form+country of destination. |
| Could we submit new sourced presentation through Annual update, if EU number differ by blister type, for example PVC/PE/PVDC/Alu and Aclar/PVC/alu?<br>-------<br>Can a parallel distributor who has submitted Initial Notice of Parallel Distribution for a product with a particular EU number distribute in the destination member state identical product (the same active substance, concentration, pack size, same primary packaging) but with a different EU number (because only the material of the primary packaging is different - for example the blister is made from material X that is different from the material of the blister of the product subject to the Notice -Y? | The composition of the blister is part of the terms of marketing authorisation and is detailed in the List of all authorised presentations document on the EPAR website. Please note that blisters with different compositions cannot be used interchangeably. For example, an EU-number with a blister composition PVC/PE/PVDC/Alu cannot be sourced and subsequently distributed as an EU-number with a blister composition of Aclar/PVC/alu. Each EU number corresponds to a specific blister type. |

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| About relabelling: what happens if the language of the product is already in language of country of destination? | The product on the images supporting initial notification must contain a label (re-labelled outer packaging and relabelled inner packaging) with all required text as per annex. This is a requirement since the initial notice cannot be issued based on a single product packaging where most, if not all, original text can be used for the new end market. When releasing the product, in case the original packaging already features the language of the member state of destination, you can use the information on the original packaging provided that it is in line with the latest Marketing Authorisation. You have to however add the supplementary mandatory information on the outer, optionally also on the inner (parallel distributor / repackager details etc). See Frequently asked questions about parallel distribution \| European Medicines Agency (europa.eu)for more information. |
| If we already submit a mock up how the packaging will look like with all information of the annex with the initial notification (including EXP and Lot) why do we have to submit a mock up again with all information of the annex with the annual update again? | A Marketing Authorisation is subject to a lot of variations and changes over the years which can impact the packaging material. During the annual update procedure, we request to see the product the way it was last released on the market, which is why we ask for a mock-up file with each annual update submission. |
| Should repackager address details on our labels now show UK(NI) if relevant? | The printing of the full address of the repackager on the packaging material is optional. In case the PD chooses to do so, it is recommended to indicate UK(NI) or XI, similarly to the recommendations listed in Questions and answers to Stakeholders on the implementation of the Protocol on Ireland/Northern Ireland (europa.eu) for OMS or other databases. |
| When EMA closing the Annual Update which was submitted with Safety Update, that means that SU is also approved? Is there any corresponding information in AU document? Thank you. | When an annual update is completed including product safety related updates, there is no need to submit a separate safety update notification.<br><br>The notice letter for the annual update does not contain reference to the fact that the completed |

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| | procedure included new product safety information. |
| Why do we have to provide labelling how it would look like in case there is no German text with the Annual update, although it has already been provided with the initial notification? | The annual update should show colour copies of the product the way it is currently marketed. Please note however that the annual update is assessed on a case-by-case basis and that you may be requested to provide additional documents. |
| Regarding re-labelling: Could the foreign language (original) package leaflet removed from the package by the PD and could they replace it with package leaflet of destination country language? Or both should be kept in the package? | The original package leaflet should be removed and replaced with the leaflet in the language of the member state of destination. |
| In case of safety updates, the changes in products have to be implemented also in the three months we have to notify them, or they can be made in more time? | The implementation time for safety annexes is also three months. |
| Why do we have to confirm that we will not mix and match batches? It is a matter of course, that we do not so. Maybe you can add a box to click and confirm this in the form. | In the interest of the patient's safety and for traceability purposes, we ask you to confirm that you do not mix and match batches. Thank you for the suggestion to add it as a tick box on the form during submission, it has been noted. |
| What happens if we exceptionally do not manage to submit an Annual update in its month of birth due to illness for example? | It can still be submitted at the earliest opportunity. It is strongly recommended to submit before its 'birth-date' or as close as possible. |
| would it be possible to implement the "annual update scope of change" to the "annual update"-process | Thank you for your suggestion, it has been noted. |
| Is there any guidelines regarding when we have to separate packaging materials to old/new versions? For example, when the storage requirements change from 96 hours to 24 hours. Can we overwrite the previous | This is very product-specific and should be determined on a case-by-case basis. A change in storage conditions could be a result of a change to the composition of the product or it could be a result of new stability studies. We kindly ask you |

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| packaging materials, or do we have to write via Ask EMA about the change? | to continue to contact us through Ask-EMA so we can assess your case individually. |
| Would it be possible to only publish the annexes on one website? Only showing the ones that are valid. | The European Commission is the authorising body for all CAPs, who takes a legally binding decision on the authorization of centralized products. Commission decisions are published in the Community Register of medicinal products for human use. Variation procedures which do not affect the Commission Decision granting the marketing authorisation (including its annexes) are no longer reflected in the Union Register of medicinal products since 1 April 2011. EMA publishes its own European public assessment report (EPAR) for each medicine and this one is updated every time a variation impacts the annexes, even if the procedure does not require a new Commission Decision. |
| I would like to inquire whether we are obligated to implement packaging materials that were employed to Annual Update or we are allowed to implement new packaging materials 6 months counted from the date of annex. My query results from the fact that we should prepare documentation for AU according to the latest annex however the annexes are often released just before our submission deadline. Thus in such case we would be forced to discard all packaging materials from our stock. | The requirement to show documentation in line with the latest annex only applies to the initial notification procedure. For the annual update procedure, six months (regular variation) or three months (safety-related variation) implementation rules apply. |
| Dear Sir or Madam,<br><br>For Example Pelmeg, in preference we find a Product information with the last updated date October 15th, 2021,<br><br>then I changed back a few weeks later to July 8th, 2021. We noticed this happened in more Product informations before, like Lyrica.<br><br>At this time my question is why is this | Please refer to the presentation slides for more information on identifying the correct annex. Please also note that the "last updated" date on the EPAR website should never be used in determining the correct marketing authorisation, since it refers to the date when the website was updated, not the date of the Annex. |

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| happening and should we adapt the newest date or the last updated date.<br><br>I appreciate any feedback you might have. | |
| How would be parallel distributions impacted by the implementation of PMS (positive and negative impact) and how would the impact be if any with the upcoming DADI webforms. Would the process changed? Would IRIS be in sync with PMS and OMS and how it would support parallel distribution? | PD procedures are simple processes with low data dependencies. IRIS is in sync with OMS and PMS integration routine is currently undergoing improvements. It is unlikely that there is a major impact on Parallel Distribution submissions, but companies will be informed in advance if that is the case. |
| In the Animal Health sector, what are the main differences between Parallel Distribution for CAPs and Parallel Trade for non-CAPs (latter introduced by Regulation 2019/6) | Parallel trade of non-CAPs is regulated at a national level and falls outside the remit of the EMA. |
| How should parallel distributors update their packaging material if annexes between EC and EMA differ, in the case where a safety update requires updating according to an older date than what the other website states, even if the older date contains newer information?<br><br>The case I am thinking about is Lyrica where EMA and safety update list state annex dated 2021-10-28 with new information and EC website states PSUSA Modification with annex dated 2021-11-12 containing older information. | We always advise to follow the annex mentioned in the monthly safety update list as this annex contains safety changes. If a later annex is published shortly after and also includes the safety change, then this annex may also be used. It may not be the case for the annexes published later. In case of doubt, please submit a query through Ask-EMA.<br><br>The Lyrica case was an exceptional case where an annex was published that did not include all previous variations. When exceptions like this occur, the Agency does its best to notify the parallel distribution network. |
| Regarding the updating of package leaflets, I see that amendments are frequently uploaded on the EMA website. Some are minor changes to the labelling or package leaflet, not connected with the SPC. In these cases, should the date of the package leaflet be updated to the date of the latest version, even if these changes do not affect | Yes. The revision date in the package leaflet should always reflect the date of the annex used. In case of an initial notification this should be the date of the latest annex available to you. In case of an annual update, you have six months to implement a new annex (regular variation) or three months (product safety-related variation), and the revision date should reflect this accordingly. |

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| the leaflet of the medicinal product of the country of destination? | |
| In the FAQ's a color copy is described as a scan "of all sides of the re-labelled and/or re-packed outer packaging, as well as the re-labelled inner packaging, as they will be marketed in the Member State of destination compiled in a single document". Why does the mock up file must contain everything from the annex text? So, the "labelling-file" will not show you how it will be produced by EurimPharm in the future and will not correspond to any annual update picture we will send you. | In cases where multiple member states of origin are selected amongst which MSOs that do not feature German as an official language, we kindly ask you to show us a mock-up showing full labelling text as per the marketing authorisation. Please note that the Agency cannot approve an application for an initial notice based on the example of one particular batch. |
| Immediate contact option in exceptional cases:<br>Orifarm is aware of the possibility to submit questions or inquiries via the ASK-EMA service desk, but the waiting time in some seldom cases is too long. Example: Some EU numbers or products are not in the EMA submission database (e.g. this was the case with Jyseleca). We sometimes face very short tender deadlines and in seldom cases need fast support as otherwise we cannot attend the tender. | In cases of technical issues, please submit a ServiceDesk ticket and we will respond as soon as possible. When planning for tenders we also kindly ask you to bear in mind the 35 days handling time for the Agency to process parallel distribution notifications. |
| Some assessors request to update with using the specific annex mentioned in the safety list – even if this one is already outdated. Why can't we update against the latest annex? (NOC update is included in latest annex, plus sometimes difficult to find the prior (already outdated) NOC annex via EMA website) | On occasions the latest published annex does not always include the safety update. In these cases you will be asked to use the annex as per the safety update list. |
| Is there an option to increase user-friendliness of the IRIS-portal?<br>1. Some EU numbers are not (yet) part of IRIS-portal with possible commercial impact for us<br>2. Choosing the MSD and MSO – you | 1. If EU numbers are missing, please contact ServiceDesk.<br><br>2. Noted as a potential improvement to allow 'select all'. |

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| cannot "select all" and it is displayed on several pages. Moreover IRIS allows to choose the same MSD and MSO. Can this option be deactivated?<br>3. Scope of change: option to search for EU-nr and company at the same time would be very beneficial<br>4. Option to choose several managers as once | 3. Thank you for the suggestion, noted.<br>4. Thank you for the suggestion, noted. |
| Mistakes are often not tolerated by EMA, but the whole fee must be paid in case a submission is withdrawn due to a mistake made, wouldn't it be possible, e.g., to only take an administrative cost into account instead of the whole amount that needs to be paid (especially in case of initial notifications)? | Noted. |
| I hope this webinar includes the submission of veterinarian medicines.<br><br>- What are the differences? | The submission process in IRIS for notifications for parallel distribution of veterinary medicines is identical to the submission process for human medicinal products. The differences in the product information (packaging/package leaflet) result from the veterinary legislation (e.g. absence of a blue box or safety features). |