25 February 2022
EMA/CVMP/ERA/768241/2021
Committee for Veterinary Medicinal Products (CVMP)

Overview of comments received on the "Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6" (EMA/CVMP/ERA/622045/2020)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	Access VetMed (former EGGVP)
2	German Environment Agency
3	NextraResearch S.r.l.
4	Federation of Veterinarians of Europe (FVE)
5	AnimalhealthEurope

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1. General comments – overview

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
1	We welcome the CVMP reflection paper on the interpretation of Article 18(7) of regulation 2019/6. We are pleased with the pragmatic approach and generally support the underlying principles in the paper. However, this is a reflection paper, not a guideline, and so criteria are not (yet) defined, and the "may" provision is still too broad. As such it is still wide open to interpretation from each NCAs ("at discretion") and will lead to disharmonised implementation and involves also lack of predictability for generic VMP developers. The criteria to define the VMPs with potential risk to the environment should be defined (preferably here or in subsequent guidance). "Might", and "can" are still used in the paper which is not in line with the intention of this document which is to provide certainty on interpretation of Art 18(7). Other important issues remain – see section specific comments.	
3	Given that: the last version of the Veterinary Guideline CVMP/VICH/790/03-FINAL came into effect last October 2005, concerning the environmental risk assessment (ERA) for generic VMPs: please to evaluate the inclusion of a procedure for the pre-submission meeting required to the National Competent Authorities (NCA).	

Stakeholder no. *(See cover page)*	General comment (if any)	Outcome (if applicable)
4	FVE welcomes that the approach of the reflection paper concluding that competent authorities should only require the submission of ERA data from generic applicants in case no ERA has been performed for the same active substance and exposure level in the EU/EEA in accordance with VICH GL. As generic VMPs rely on the safety and efficacy data presented in the dossier of their reference product, ERA for generics should only be required if compelling reasons. Otherwise, the market entrance of recent generics could be significantly hampered.	
5	AnimalhealthEurope welcomes the opportunity to comment on this draft reflection paper and applauds the pragmatic approach laid out. The approach is also in line with our proposal for an alternative to monographs. The effort not to duplicate studies and encourage mutual trust is recognised. A key procedural issue for this Article is the need to have a firm decision given to the applicant on whether an ERA will be required, far enough in advance of the applicants proposed submission date to allow all the relevant studies to be completed without delaying that submission date.	

2. Specific comments on text

Line no.	Stakeholder no. *(See cover page)*	Comment and rationale; proposed changes	Outcome
36	5	**Comment:** …. "on the volume used" despite being laid down in Recital 35 of Regulation 2019/6, volume terminology is not the most appropriate, as VMPs are not assessed based on volumes as chemicals but on a risk benefit assessment. **Proposed change:** please add clarification.	Not accepted. It is acknowledged that the ERA does not take into account the sales volumes, but the single use of the VMP in line with SPC directions. Nevertheless, Recital 35 (lines 40–46 of the reflection paper) indirectly aligns with that concept in that it links the ERA to VICH guidance, which is already in line with that approach. In addition, the aim of the present reflection paper is not to interpret or clarify Recital 35 of Regulation (EU) 2019/6, but to provide the CVMP's views on how to apply Article 18(7) of said regulation. Therefore, no changes to the reflection paper are considered necessary.
45, 79, 100	5	**Comment:** Does it have to be in the same target species? An ERA is predominately based on the PEC calculation. If the target species of the generic product has the same type of husbandry and reveals a PEC below the PEC of a target species of the "similar VMP" for which the ERA package is found to be satisfactory, then the environmental risks of the generic will not exceed those of the "similar VMP". **Proposed change:** … in the same**/comparable** target species… to be discussed in the dossier.	Not accepted. The reviewer rightly points out that the ERA is based on the predicted environmental exposure (PEC). Its calculation depends on the total dose, fraction of the herd treated and also on parameters specific to the target animal (bodyweight, amount of nitrogen produced, etc.). Consequently, different species would result in different PECs and different risk characterisation. Therefore, no changes to the reflection paper are considered necessary.

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61–65	5	**Comment:** As the decision to request an ERA is not an obligation for a generic and as it is at the discretion of the NCA or the Agency to decide whether an ERA is needed for a generic, does it mean that the NCA/Agency should commit their positions during (very early) pre-submission meetings with the Applicant? An ERA generally requires long studies and assessment and could not be performed rapidly. On the other hand, the EPAR for the reference product will be accessible in the UPD, where the generic applicant can verify if an ERA is available for the reference product. This could greatly simplify the question about necessity of an ERA **Proposed change:** please include that the generic applicant can verify the existence of an ERA in the EPAR that is stored in the UPD.	Not accepted. The reviewer is right, but the paragraph he is referring to (lines 61–65) is still setting the scene. Later paragraphs (e.g. lines 77–88) give further definition along the lines suggested by the reviewer. Therefore, no changes to the reflection paper are considered necessary.
64	3	**Comment:** "Specific criteria" must be included in the article 18. **Proposed change:** line 64 - to substitute "discretion" with "written evaluation by a committee composed by 4 experts" of the national competent authorities (NCAs).	Not accepted. Although the reviewer's concerns are understood, the CVMP is of the opinion that the paragraph referred to contains a description of Article 18(7) with the intention, precisely, to define criteria on when regulatory authorities can request an ERA. Therefore, no changes to the reflection paper are considered necessary.

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77–81	2	**Comment:** According to this document it is assumed that products authorised after 1 October 2005 have an acceptable ERA in accordance with the VICH GL38 as this guideline came into effect at this date. However, we would like to point out that the additional supporting Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMA/CVMP/ERA/418282/2005-Rev.1- Corr.1) came into effect on 1 March 2009. This guideline is vital for the correct application of VICH GL 38. Additionally, according to Notice to Applicants the ERA for generics was fully implemented only in 2009. Hence, we are of the opinion that it cannot be safely assumed that all products authorised after 1 October 2005 and before 1 March 2009, have an acceptable ERA. **Proposed change:** We consider the cut-off date 1 March 2009 more appropriate and protective for the environment than 1 October 2005.	Not accepted. Although the CVMP acknowledges the reviewer's rationale, it considers that Article 18(7) clearly sets the cut-off date to 1 October 2005 for the marketing authorisation of the reference veterinary medicinal product (RVMP). Therefore, no changes to the reflection paper are considered necessary.
81–84	1	**Comment:** Aside from the previously mentioned "broad" provisions and the presence of the word "discretion" in line 64, the reference to "assumed" on line 82 adds extra uncertainties or "grey areas". In addition, it has to be mentioned that aside from VICH GL38, there are other guidelines issued later on by the CVMP/EMA "**in support to GL38**" and even further revised (e.g. EMA/CVMP/ERA/418282/2005,	Accepted.

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		EMEA/CVMP/ERA/172074/2008) to provide more detailed technical guidance on ERA that VICH GL38 may lack of. As such, our association is concerned that some Competent Authorities may not assume an ERA submitted according to VICH GL38 after 1 October 2005 being sufficient to waive the need to submit a Phase II ERA, if the so mentioned ERA has not been performed in line with subsequent "supporting" (or current) guidelines. As such, we would kindly request EMA to put an obligation into the reflection paper for the competent authorities to consider the provision set by the Regulation 2019/6. A slight modification to the text is proposed as follows: **Proposed change:** "If such products are authorised in the EU/EEA, then it will be **considered** ~~assumed~~ that an ERA according to VICH GL38**, and/or any other relevant guidelines in effect at that time,** has been performed by a competent authority and that the ERA data package has been found to be satisfactory, …."	
81	5	**Comment:** …"The outcome of this check should be provided and discussed in the dossier."	Accepted. The reflection paper has been amended accordingly.

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		Proposed change: please indicate clearly in which part, DACS for Safety and Residues for example?	
82–88	2	**Comment:** We consider that solely the assumption that products comparable to the candidate generic product are listed in the UPD does not necessarily mean that an acceptable ERA for these products exists. MS might have assessed the ERA differently with different conclusions. How will such a problem be identified and tackled if the new approach is based solely on mutual trust?	Not accepted. The concerns of the reviewer are understood. Nevertheless, the authorisation of VMPs in the EU is not solely based on a centralised process, i.e. there are several Competent Authorities with authority to grant a marketing authorisation across the Union. Therefore, different assessment outcomes can be expected and may occur, not only regarding ERA, but also with respect to any other part of the dossier.
		Additionally, as we understand from this document an ERA for the generic is considered not necessary if comparable products are on the market, despite the RVMP lacks an ERA. How is it justified that conclusions on products other than the respective RVMP and from different MAH can be applied to a new generic product but not the respective risk mitigation measures?	It is agreed that the issue raised by the reviewer appears paradoxical, but the legislation only allows for generic products to use conclusions (e.g. risk mitigation measures [RMMs]) drawn during the assessment of the RVMP they refer to. The RMMs included in the product information of other generic VMPs cannot be used in a newly authorised generic product, even if it is known that the use of this VMP would pose a risk for the environment. In those cases, the reflection paper recommends the triggering of a referral procedure to align the product information (i.e. the RMMs) of the RVMP and its generics.

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		Proposal: Option 1: In principle, no other references than the RVMP should be acceptable for generic products. If ERA is missing in the RVMP, the applicant should be asked to provide ERA data from an acceptable source (e. g. data sharing with ERA owners or after implementation of active substance based monographs).	Option 1 proposed by the reviewer would be against the underlying principle of the reflection paper, i.e. "that an ERA should only be requested from generic applicants in case no ERA has been performed […] in the EU/EEA in accordance with VICH GL38".
		Option 2: However, if the conclusion is that an ERA exists for generics on the market should be applied to new generics, the respective RMM, if any, of these generics should be applied to new generics, too.	Option 2 is not in line with legislation, which does not allow to use of RMMs from generics in the frame of authorisation procedures of other generics citing the same RVMP.
89–95	5	**Comment:** (see also comment lines 61–65) For reference products (RPs) marketed before 2005, the NCA/Agency have to check, at the request of the Applicant, if an ERA has been provided in post-authorisation procedures. If an ERA is available, no ERA should be requested for the generic. However, it is not clear how the confirmation of an available ERA will be addressed to the applicant. Clarification on how the information is made available to the applicant would be necessary. **Proposed change:** If it is confirmed that an ERA is available for the reference product, **and based on the principle of mutual trust,** the competent	Accepted. The reflection paper has been amended accordingly.

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		authority **receiving the application for a new generic VMP should recognise the outcome of this assessment and** should not request the generic applicant to provide an ERA under Article 18(7) of Regulation (EU) 2019/6.	
93–95	2	**Comment:** As stated in the previous comment, it is not possible to safely assume that ERA provided after the cut-off date 1 October 2005 and before 1 March 2009 are acceptable. This also applies to the ERA of RVMP. **Proposed change:** We consider the cut-off date 1 March 2009 more appropriate for the protection of the environment than 1 October 2005.	Not accepted. Although the CVMP acknowledges the reviewer's rationale, it considers that Article 18(7) clearly sets the cut-off date to 1 October 2005. Therefore, no changes to the reflection paper are considered necessary.
102–106	5	**Comment:** Regarding data requirements this should be according to VICH GL 38 and further regional guidance. We presume that here the reference to "discussion" of data requirements refers to whether an ERA is required and, if so, if all data is required or partial data exists and additional data is needed to meet requirements not in place at the time the reference product was authorised. **Proposed change:** please clarify.	Accepted. A clarification has been included in the reflection paper.
115–117	2	**Comment:** Inclusion of information on inherent environmental properties in the PI is desirable indeed. However, we would like to note that solely information on environmental properties does by no	Not accepted. The CVMP acknowledges the reviewer's rationale. However, this is not in line with the legislation, as it does not allow to

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		means represent any environmental protection as long as appropriate risk mitigation measures are not included, too. **Proposed change:** It would be desirable to apply existing RMM for generics on the market also to new generics (see option 2 above).	use RMMs from already authorised generics in authorisation procedures of other generic VMPs. This is an issue to be solved by means of a referral procedure involving all authorised products on the market, as discussed later in the reflection paper.
115–117	5	**Comment:** Product Information (PI): "(...) Nevertheless, when there is public information available related to inherent environmental properties of the active substance (*e.g.*, persistence or leaching potential), a NCA or the Agency might request the applicant to complete the PI with such information for the sake of environmental safety." The definition of "public information" should be clarified as well as the criteria to establish the relevance of such information for the environmental risk assessment. **Proposed change:** Please clarify what constitutes "public information" within this requirement and the criteria for the relevance.	Accepted. The text has been amended as follows: "Nevertheless, when there is public information available **(European public assessment reports [EPARs], public assessment reports [PuARs], referrals or the PI of already authorised VMPs)** related to inherent environmental properties of the active substance […]".

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115–130	5	**Comment:** This would be an action based on a perceived hazard. VICH GL 38 is a risk-based approach, while this sentence states that mitigation may be added without any risk assessment based on information for which no quality or reliability criteria are proposed. This while the ERA is normally based on GLP-compliant studies performed according to well-recognised testing protocols from organisations such as the OECD. Yet the availability of any data whatsoever would be sufficient to trigger a referral procedure without any further justification?	Not accepted. The mentioned paragraph only relates to environmental information contained in the section "Environmental properties" in the product information. This paragraph is not related to risk mitigation measures, which, as rightly pointed out by the reviewer, would require a risk characterisation that will not take place.
		Additionally, the definition of public information should be clarified	Accepted. The text has been amended as follows: "Nevertheless, when there is public information available **(European public assessment reports [EPARs], public assessment reports [PuARs], referrals or the PI of already authorised VMPs)** related to inherent environmental properties of the active substance […]".
		Proposed change: Please clarify what constitutes public information within this requirement and provide quality criteria for information that might be used to trigger a referral and/or a request for further information from the RP.	Accepted. Text has been added to provide more clarity on the acceptable sources of public information. However, the public information referred to originates from the competent authority. Therefore, a referral could be triggered as for any other part of the dossier. Considering

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			this, no further changes to the reflection paper are considered necessary.
		Should a variation request for the RP not be requested by the CA, in advance of initiating a referral procedure? In that way, the originator has the opportunity to submit any new published data/scientific studies and propose mitigation measures, if appropriate.	Not accepted. The proposal from the reviewer is already included in the reflection paper (lines 127–130; Article 130(3)(a))
121–124	2	**Comment:** How should a possible concern regarding the environmental safety of a generic be identified when the ERA and possible RMM are not available to the NCA? In this case it seems that indications of possible environmental concerns are discovered only by chance and not systematically. Transparency regarding environmental data is lacking and the possible risk to the environment posed by "legacy" substances remain unknown in many cases. We consider that in particular with the NVR and the new provisions for generic applications, transparency of environmental data is needed more than ever and an active substance based review system like a monograph system could be the way forward.	Not accepted. The CVMP fully acknowledges the reviewer's concerns. However, it should be taken into account that potential environmental concerns that could lead to the triggering of a referral would be known to the competent authority which previously authorised the generic VMP in question. That information not being available would mean that the active substance has not yet been assessed in the EU and, consequently, a full ERA package should be provided by the applicant in the course of the authorisation procedure. Regarding legacy products, the CVMP acknowledges the reviewer's point. However, the monograph system mentioned is out of the scope of the present reflection paper.
115–130	1	**Comment:** The reflection paper states that when there is public information available related to	Not accepted.

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		inherent environmental properties of the active substance (e.g. persistence or leaching potential), an NCA or the Agency might request the applicant to complete the PI with such information for the sake of environmental protection. We cannot agree that the inclusion of this environmental protection information will not imply a deviation from the binding legislative provision that generics' summaries of product characteristics (SPC) should be "essentially similar" to the RP's SPC. It is also not clear why this request would apply to generic applicant only. We consider that for the sake of environmental protection, such information needs to be first thoroughly evaluated by the competent authorities and **potential serious risk** issues relating to safety to the environment identified. Afterwards, all existing MAHs and applicants should complete the PI with such information. Such course of actions will make obligation from Article 18(6) of the VMP-Reg feasible. **Proposed change:** Lines 115-130 need to be adjusted accordingly or text deleted as proposed below: "Nevertheless, when there is public information available related to inherent environmental properties of the active substance (e.g. persistence or leaching	It should be noted that Regulation (EU) 2019/6 does not provide a definition of "essentially similar". In addition, the reflection paper does contain a recommendation to include the same information in the PI of the RVMP in a future variation (lines 117–119). However, as the RVMP might be authorised by a different competent authority, it might not be possible for the competent authority assessing the generic application to ensure that the PI of the RVMP is updated in a timely manner. This should not preclude including relevant environmental information in the PI of the generic. The source of the environmental information in question would be other authorised products, i.e. it would not be completely new information (e.g. from a published literature search). The reflection paper already suggests that, should the information be related to known intrinsic properties of the active substance (i.e. what could be considered as "current scientific knowledge"), it could be included in the generic and also in the RVMP PI without a further evaluation. However should the review of the PIs of authorised products indicate that there could be a risk to the environment, then a Union interest referral procedure should be initiated, where all relevant products should be included. Therefore, no changes to the reflection paper are considered necessary.

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		potential), ~~an NCA or the Agency might request the applicant to complete the PI with such information for the sake of environmental protection. Any such information included in the PI of the generic product can be included in the RP in future variations that require an amendment of the SPC. The inclusion of this environmental protection information will imply neither a risk characterisation nor a deviation from the principle that generics' summaries of product characteristics (SPC) should be "essentially similar" to the RP's SPC. Should a concern regarding the environmental safety of a generic VMP be identified, indicating the need for inclusion of risk mitigation measures and/or environmental information in the PI, these would in principle also apply to the RP and would therefore be beyond the scope of the generic application. T~~**t**his concern should ~~hence~~ be addressed in a Union interest referral procedure under Article 82 of the VMP-Reg. This would allow for an assessment of all available data and for reaching harmonised conclusions for all relevant products, which would ensure better protection of the environment. As an alternative to a referral, CAs might consider applying Article 130(3)(a) of the VMP-Reg in order to request the marketing authorisation holder**(s)** ~~of the RP~~ to submit a variation to update the PI with the appropriate risk mitigation measures and/or relevant environmental information".	

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124–127	2	**Comment:** Same here as in our previous comment: How can a possible environmental concern be identified? The reflection paper proposes in the first place to initiate a Union interest referral under Art. 82 in case such an environmental concern has been identified and RMM should be included in the PI of the RVMP and associated products. We acknowledge that a Union interest referral would allow changing the PI of a RVMP and possibly a considerable amount of products in one procedure. However, it has to be kept in mind that such referral procedures are very time consuming and resource intensive processes and are in general initiated after careful consideration only. Therefore, it can be expected that in this way the implementation of RMM necessary for the effective protection of the environment may be delayed for a number of years and new generics on the market would lack RMM even when included in the PI of comparable products. In our view this would not ensure environmental safety and does not follow the precautionary principle. We are afraid we do not understand why solely the existence of comparable products on the market (without knowing the ERA or any RMM) allows waiving the ERA for a respective generic application (if the RVMP does not have an ERA) but RMM in the PI of	Not accepted. The CVMP acknowledges the reviewer's comments in that referral procedures can be time-consuming. That being said, it is the only legal provision outlined in Regulation (EU) 2019/6 that fits the purpose discussed in the reflection paper. Although a pragmatic approach to referrals could provide the necessary flexibility, this is out of the scope of the present reflection paper.

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		comparable products are not allowed to be applied to the new generic. This seems to be application of different standards. **Proposed change:** It is suggested to follow a parallel approach. As long as an Union interest referral had not been initiated to align the PI of RVMP and associated products, successively the RMM/warning sentences of comparable products on the market could be applied to each new generic. This allows at least the timely protection of the environment for some new products.	
128–130	2	**Comment:** The possibility to change the PI of a RVMP by "applying Article 130(3)(a) of the VMP-Reg in order to request the marketing authorisation holder of the RVMP to submit a variation to update the PI with the appropriate risk mitigation measures and/or relevant environmental information" is supported. However, once the necessity of an update of PI of an RVMP has been identified, this should be a mandatory step. This would be less time and resource consuming than initiating a referral. Future generics of the RVMP, the NCA and the environmental safety would benefit from this step and possibly Union interest referrals could be avoided. **Proposed change:** Change wording in:	Not accepted. The causality can be diverse and, depending on the specific situation, a competent authority might prefer to trigger a referral or to ask for an update of the ERA of the RVMP.

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		As an alternative to a referral, a variation to change the PI of the reference product, if necessary, should be mandatory.	
133	5	**Comment:** If a discussion is needed to ensure if an ERA is requested or not, the pre-submission meeting can be seen as too late if a phase II assessment is needed as studies will need to be conducted requiring, depending on the indication, extensive time. In fact, these data would need to be generated during the development phase of the product; if not, this will add 1.5 to 2 years at a point where a MAA is in fact close to submission. **Proposed change:** We suggest indicating "before submission" than "pre-submission meeting"	Accepted. The text has been changed accordingly.
134	3	**Comment:** the official list of the national competent authorities could be included. **Proposed change:** Line 134. After "… Dossier." Please to add the list of the competent national authorities.	Not accepted. The advantages of including such list are not followed. In addition, the competent authority is determined by each Member State and might be subject to change.
142–147	1	Same comment applies as for lines 115–130. **Proposed change:** Lines 142–147 need to be adjusted accordingly or text deleted as proposed below: "Whenever an ERA is not required for a generic application, its PI will be essentially similar to the one	Not accepted. It should be noted that Regulation (EU) 2019/6 does not provide a definition of "essentially similar".

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		of the RP~~, which does not exclude the possibility of including publicly available environmental information related to inherent properties of the active substance (for instance, persistence, leaching potential or toxicity to non-target organisms)~~. The alignment of the PI of concerned products in terms of environmental information and/or risk mitigation measures can be carried out by the CAs by means of a Union interest referral or applying Article 130(3)(a)".	In addition, the reflection paper does contain a recommendation to include the same information in the PI of the RVMP in a future variation (lines 117–119). However, as the RVMP might be authorised by a different competent authority, it might not be possible for the competent authority assessing the generic application to ensure that the PI of the RVMP is updated in a timely manner. This should not preclude including relevant environmental information in the PI of the generic. The source of the environmental information in question would be other authorised products, i.e. it would not be completely new information (e.g. from a published literature search). The reflection paper already suggests that, should the information be related to known intrinsic properties of the active substance (i.e. what could be considered as "current scientific knowledge"), it could be included in the generic and also in RVMP PI without a further evaluation. However should the review of the PIs of authorised products indicate that there could be a risk to the environment, then a Union interest referral procedure should be initiated where all relevant products should be included. Therefore, no changes to the reflection paper are considered necessary.
Figure 1	1	**Comment:** the last step of the decision tree states that *"The new generic should provide an ERA in the dossier".* This is not in line with previous paragraphs	Not accepted. The wording of the decision tree is correct, i.e. if there is no ERA information available withing the EU/EEA, the new

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		of the reflection paper which indicate that decision "may" trigger an ERA request, at the discretion of the NCAs, therefore not an obligation.	generic has to provide an ERA in accordance with the relevant guidance. Lines 96–103 detail the situations where an ERA could be requested by a competent authority. If those conditions are met, providing an ERA in accordance with current guidance should not be a possibility, but a requisite.