April 2019

Submission of comments on

Draft CMDh Guideline

Recommendations on Common Regulatory Approaches for Allergen Products

(CMDh/399/2019/Rev.0, April 2019)

Comments from:

Name of organisation or individual
EFA – European Federation of Allergy and Airways Diseases Patients' Associations Submitted by EFA Policy Officer Panagiotis Chaslaridis (Panagiotis.chaslaridis@efanet.org) in coordination with EFA members. www.efanet.org

Please note that major comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the CMDh Secretariat (H-CMDhSecretariat@ema.europa.eu) in Word format (not PDF).

1. General comments

Stakeholder number *(To be completed by the CMDh)*	General comment (if any)	Outcome (if applicable) *(To be completed by the CMDh)*
	EFA welcomes the initiative of the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) of the Heads of Medicines Agencies (HMA), to put forward recommendations on common regulatory approaches for allergen products. It is important to see that HMA takes into consideration the diverse state of play of Market Authorisation (MA) for allergen products across the European Union, especially in light of the increasing prevalence of allergies– including rare allergies. Most importantly, the document summarises well the various MA regimes currently in place, as well as the involved shortcomings, thus making the case for greater harmonisation among the different regulatory approaches. Considering the different MA regimes, EFA is happy to note that HMA understands harmonisation as a gradual move towards individual MA application dossiers for each medicinal product put on the EU market, as a central principle arising from relevant EU guidelines. Creating a harmonised framework that ensures full transparency and oversight of MA procedures can help improve decentralisation but also transferability (mutual recognition) of authorisations. Essentially, EFA perceives the harmonization of MAs among member states as bearing multiple benefits. These include: - The convergence of rules for MAs across the EU, which can contribute in reducing major discrepancies in the quality, efficacy and effectiveness of marketed medicines, and indeed in improving access, coordination and information in case of shortages. By implication, putting in place more stable and predictable MA framework constitutes an important step towards	

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	addressing medicine shortages. Both issues i.e. the quality and the availability of medicines are extremely important for patients with chronic conditions such as food or pollen allergies, typically associated with long-term treatment requirements. - Enabling the process of developing allergen products for common allergies, and for rare (non-prevalent) allergies in particular. It is encouraging that HMA acknowledges the need to provide guidance on when a medicine needs to be dealt with as a named patient product (NPP), or under the MA for allergen products regime. Furthermore, EFA would like to highlight the benefits of greater patient involvement in the MA process both at the central and the decentralized level. As the end users of medicinal products, and with unmet needs and specific real life perspectives, and therefore directly impacted by their quality, efficacy, and safety features, patients should be part of the discussions that affect their health.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the CMDh)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the CMDh)*
60-64		Comment: When reflecting on the current requirements, it would also be interesting to mention that **some current diagnostic tests are unreliable,** further restricting the available options for patients. Proposed change (if any): *'Meanwhile, clinical practice has shown that some current diagnostic tests **may even fail** to detect certain types of allergies that are not IgE-mediated.'*	
65-73		Comment: In addition to a guidance for non-prevalent allergies, which is highly needed, HMA should also look into the existing MA regulations for **new or recently emerged allergies**. Against a background where availability of new products is low, and existing authorisations have been lost in some Members States, patients with such allergies run the risk of limited access to appropriate medicines. Proposed change (if any):	
88-95		Comment: For the sake of clarity, EFA recommends HMA to explicitly cite **the different sub-types of allergy associated with the allergen product classes under the scope of these recommendations** (possibly in an Annex). In this respect, it would be particularly important to highlight the differences, if any, among Member States as to what constitutes rare allergies.	

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		Proposed change (if any):	
162-172		Comment: While agreeing in principle with a framework that gradually transfers umbrella MAs to individual MAs, EFA suggests that such initiatives should advance with quality, safety, efficacy and unmet needs (which can be integrated involving patients) as highest priorities when it comes to assessing a medicine. As the EU regulator, we believe that the **EMA is the best-placed authority to set the relevant criteria, requirements, and due process** in an efficient and transparent way and due to its' track record in involving patients and their organisations, hearing their specific perspective in controversial dossiers (benefit-risk). Proposed change (if any):	
185-199		Comment: EFA is glad that HMA recognizes the specificities of less prevalent allergies, in terms of the content of the dossiers in mixed MA applications. Therefore, a simplification of the process is highly welcome. However, it should be clearly stated (in line with Annex I, Part II, Section 7 of the Directive 2001/83/EC), that **such MA applications are to be accepted by the competent authority on a case by case basis.** Proposed change (if any): *'In line with Annex I, Part II, Section 7 of the Directive 2001/83/EC, it can be acceptable in such cases that Modules 4 and/or 5 consisting of a combination of reports of*	

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		limited non-clinical and/or clinical studies carried out by the applicant and of bibliographical references, are provided. ***The competent authority shall accept the proposed format presented by the applicant on a case by case basis.****'*	
200-219		Comment: Patients should be **systematically consulted in the context of the well-established use application process,** especially in the discussions on medicines intended for the treatment of rare or severe allergies. Input from patients can offer a valuable empirical perspective into the efficacy and safety aspects of a medicine, with information on potential side effects and related adverse events. Proposed change (if any):	
232-265		Comment: EFA agrees that the **Mutual Recognition Procedures (MRP) and the Decentralised Procedures (DCP) should be strengthened and better coordinated**. By harmonising the MA requirements among Member States, the two procedures will be streamlined, thus improving the availability of allergen products across the EU and clarity for the European patient community. Proposed change (if any):	
269-273		Comment: In the discussion about allergic rhinitis/ rhinoconjunctivitis, EFA suggests adding an element on the **quality of life** of patients, in the case where the disease is left	

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		untreated, is only treated by symptomatic medication, or treated ineffectively. Proposed change (if any): Rephrase to *'When allergic rhinitis/ rhinoconjunctivitis is (i) left untreated, or (ii) is only treated by symptomatic medication based on pharmacotherapy, or (iii) is treated by immunotherapy products lacking efficacy, there is a risk to escalate to more serious conditions, e.g. asthma, which can be a chronic and life-threatening disease.* ***This will lead to unnecessary impact on daily, educational and working life, considerable decreasing quality of life'***	
368-392		Comment: EFA appreciates the recommendations on the acceptability for named patient products (NPPs), and on the demonstrated willingness to put them under a MA framework. With regards to the former, it would be welcome if HMA could elaborate on the **links between the marketing of NPPs and the well-established use application process**, which is commonplace in cases of allergen products for which available clinical data are insufficient. Such a reference would further clarify the criteria for the acceptability of NPPs. Proposed change (if any):	

Please add more rows if needed.