Allergy Therapeutics Ltd.

Comments on:

Delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification

Concept paper submitted for public consultation

27 April 2012

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1. Introduction

Allergy Therapeutics Ltd. who is a medium sized Europe based pharmaceutical company with focus on diagnosis and treatment of various allergic conditions, would like to present comments on this concept paper.

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Page 17 **Point 86** **Consultation item no. 11** 86. Directive 2011/62/EU leaves open the criteria for identifying medicinal products to be listed in the "black list" and the "white list" (hereafter "identification criteria"). Four different approaches are put forward for discussion. <u>Identification by Anatomical Therapeutical Chemical Code (ATC):</u> This criterion is easy to establish. However, taken on its own it may be insufficient, in view of the classification criteria set above. <u>Identification by brand name</u>: Apart from being a very narrow identification criterion, the main difficulty concerns the differing brand names of identical medicinal products in the EU. In addition, brand names may change. Lastly , there may be a variety of commercial reasons that militate against highlighting individual brands in a delegated act on falsified medicines. <u>Identification by the name of the active pharmaceutical ingredient</u>: The difficulty as set our above for the ATC also applies here. <u>A flexible approach on a case-by-case basis</u>: This leaves room for some flexibility. This flexibility would facilitate the application of the classification criteria set out above.	The most plausible approach from Allergy Therapeutic Ltd's perspective is the flexible approach on a case-by-case basis.

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Page 17 **Point 87** **Consultation item no. 12** 87. In order to apply the classification criteria in Article 54a (2) of Directive 2001/83/EC consistently, a rough guide might be the to adopt a quantified approach. The following should serve as an example of how such a quantified approach could be applied. <u>Criteria 1</u> Price – Volume – High price: 5 points Low price: 1 point High volume: 5 points Low volume: 1 point <u>Criteria 2</u> Incidents in the EU or Third country Several incidents: 5 points No incident: 1 point <u>Criteria 3</u> Characteristic of the product Characteristics indicate risk of falsification: 5 points Characteristics indicate no risk of falsification: 1 point <u>Criteria 4</u> Severity of the conditions intended to be treated Conditions severe: 5 points Conditions not severe: 1 points <u>Criteria 5</u> Other potential risk to public health Max 5 points	Allergy Therapeutics Ltd. believe that the proposed quantification approach set out in point 87 is unworkable for Allergy products as the outcome from the one or two assessments we performed using this classification criteria were inconsistent. Thus leading to difficulties in assigning our products to white / black list as some products would pass the criteria and some would not. **<u>Proposal:</u>** Allergy products which include Named Patient Products, diagnostics and allergen specific immunotherapy medicinal products should be exempt from the black / white lists.

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On the basis of this scheme, it would be considered that: A prescription medicine which has 6 points or less is listed in the “white list”. A non-prescription medicine which has more than 10 points Is listed in the “black list”	
Page 18 **Point 88** **Consultation item no. 12** 88. An approach along these lines would remain within the logic of the legislation (see the introduction to this consultation topic), i.e. as a general rule, it would include prescription medicines in the scope, while excluding non-prescription medicines.	Allergy Therapeutics Ltd do not believe that the scope of the general rule provides enough clarity for Allergy products because, for Named Patient Products a) These are made individually for each patient therefore the risk of them being counterfeited is very little. b) Each Named Patient Product is labelled individually and delivered directly to the patient. NPP therefore will not enter the conventional pharmacies supply chain route. c) Named Patient Product packs are labelled individually therefore each one is easily verified and identified. for Allergy diagnostics (i.e. skin prick tests) a) These products do not treat allergy diseases but are used to diagnose them. Falsification of such products does not have serious consequences for the patients. b) We believe risk associated with these products being falsified is low. c) Skin prick tests are not packed in individual cartons. In order to

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	introduce anti-counterfeit measures (2D matrix) for diagnostics it would be very costly for essentially small companies which would need to pack each individual diagnostic in individual carton. for allergy therapy treatments a) We agree that these should fall into the prescription medicines category for 2D matrixing. However if the legislative text is to remain straightforward we would propose the category of the product (immunotherapy products) be exempt. **Proposal:** 88. An approach along these lines would remain within the logic of the legislation (see the introduction to this consultation topic), i.e. as a general rule, it would include prescription medicines in the scope, while excluding non-prescription medicines **and allergen specific immunotherapy medicinal products.**