EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2015

Submission of comments on "Questions and answers on sodium in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00 Rev.1)" (EMA//CHMP/338679/2014)

Comments from:

Name of organisation or individual
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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	We agree with the statement provided in line 124 "Information on sodium should be ...in an **understandable format**...". We at PAINT-Consult are a provider of readability tests of package leaflets and a researcher of this important patient information, with several published studies involving more than 10000 participants. See http://www.paint-consult.com/en/publikationen/publikationen/. Our research and readability test experience informs us that texts used in package inserts must be short, precise and without difficult terms. The suggestions provided in "2. Specific comments on text" consider the findings of our extensive practical knowledge in package leaflets.	
	We agree with the statement provided in lines 130 and 131 that "Sodium may not be familiar to patients and parents as being part of sodium chloride and the main component of dietary salt (common table salt)." However, we disagree with the intention to provide the information that sodium is contained in table salt, in the excipients labelling. The package leaflet is intended to inform of the medicine and must remain focussed on this task. It is not a medium for providing general	

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	information or anything else, which is not directly related to the medicine. Extending the content of the package leaflet to include the latter would precipitate an extreme increase in the volume of text - with all of the attendant negative outcomes of same, such as overtaxing patients. Furthermore, most sodium-containing medicines do not contain sodium chloride. Including the proposed wording "(found in table salt)" will only mislead patients to believe that table salt is contained in the medicine.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	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 Agency)*
163 - Parenteral (Less than 1 mmol per dose)		Comment: "Medicinal product" should be replaced by the shorter term "medicine". This brings the Excipients labelling in line with the QRD template, which uses the proposed term. The term "1 mmol" must be deleted as the unit "mmol" is not comprehensible for laymen. In addition, both texts relating to thresholds of 1 mmol and over do not provide amounts in mmol, which renders this unnecessary in the lowest category. Furthermore, the abbreviation "e.g." is not necessary and the space character between "sodium-" and "free" should be deleted. The first proposed change is almost 30 % shorter than the proposal dated 21 May 2015 (83 characters, including space characters, versus 114 characters). The alternative proposed change does not need the second sentence ("It is essentially 'sodium-free'.) and could be more demonstrative for patients (90 characters, including space characters). Proposed change: This medicine contains less than 23 mg per <dose>. It is essentially 'sodium-free'. Alternative proposed change: This medicine contains less than 1.1 % of the recommended maximum daily intake per <dose>.	

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163 - Oral / Parenteral (1 mmol [23 mg] per dose)		Comment: See previous line and under "1. General comments" for an explanation in relation to deleting information pertaining to table salt. The wording relating to the "dose" to the first sentence should be similar to the previous category. It makes no sense to fix it to "one dose" as contained in the original proposal. Using the suggested wording allows more flexibility and where the usual daily dose is, for example, three tablets, the MAH can also insert the daily dose. Proposed change: This medicine contains <X mg> sodium per <dose>. This is equivalent to <Y %> of an adult's recommended maximum daily intake of sodium.	
163 - Oral / Parenteral (17 mmol [391 mg] in the maximum daily dose)		Comment: See first line under "2. Specific comments on text" and under "1. General comments" for an explanation in relation to deleting information pertaining to table salt. Similar to the previous line, we do not recommend fixing the wording to the maximum dose ("The maximum recommended daily dose of this medicine contains <X mg> sodium.") For most medicines, the maximum daily dose would not be used. It must be decided, dependent of the medicine, which dose should be provided; preferably the most commonly used dose, which could then be explained in the "comments" column of the Excipients guideline.	

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		The term "<or> <your child>" should be deleted as parents can comprehend that the word "you" refers to the patient. Where the patient has a caregiver (for example Alzheimer patients), the original version "...if <you> <or> <your child> need(s)..." would not apply. It is unrealistic for all package leaflets to cover all possible situations! The word 'doctor' should be included before 'pharmacist', similar to the QRD template. With 36 words, the last sentence of the original proposal is too long according to the readability guideline ("Talk to your pharmacist or doctor if <you> <or> <your child> need(s) [product name] on a daily basis for a prolonged period of time, especially if <you><they> have been advised to follow a low salt diet.") It should be substantially compressed. The provided suggestion illustrates that this is possible without losing important information. Proposed change: This medicine contains <X mg> sodium per <dose>. This is equivalent to <Y %> of an adult's recommended maximum daily intake of sodium. Talk to your doctor <or pharmacist> if you need [product name] for a long time and require a low salt diet.	