Concept paper of the European Commission for public consultation about the delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification

Comments from the European Coalition on Homoeopathic and Anthroposophic Medicinal Products

1 Introduction

The European Coalition on Homoeopathic and Anthroposophic Medicinal Products (ECHAMP) is a European Economic Interest Grouping, representing the interests of more than 50 enterprises producing and/or distributing homoeopathic and anthroposophic medicinal products in the European Union.

This document contains general comments on the Commission paper as well as specific comments to the concept paper. We focus on specific points that have particular significance for homoeopathic and anthroposophic medicinal products.

2 General comments

Homoeopathic and anthroposophic medicinal products are well defined and accordingly labelled *categories* of medicinal products (see article 1, n° 5 of Directive 2001/83 as well as recital 22) of Directive 2001/83. These products have a comparatively low share on the pharmaceutical market in the EU; they hold 0,7 % of it (Facts and Figures ECHAMP 2011) as they are mostly low price medicines. *Only a very small proportion of all homoeopathic and anthroposophic medicinal products are prescription medicines (see further in table). Mostly they are low price over the counter products.* OTC products have a turnover of 12,1 % sales volume ex factory in the EU (www.aesgp.be). We feel that the market segment of the categories of homoeopathic and anthroposophic medicinal products with a turnover of 0,7 % is not a focus area for counterfeit. **Therefore, homeopathic and anthroposophic medicinal products should be exempted as whole categories from the duty to bear any safety features.** This will be substantiated further in the document.

We would like to point out to another aspect: it is foreseen that “The costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features” (Article 54a, 2. (e)). We clearly state here, that the costs may not be shared by the industries based on the number of marketing authorisations or registrations. Homoeopathic manufacturers have a huge quantity of authorisations, of which only a small part generate profit. Example: An ECHAMP member may have over 600 authorisations/registrations in one EU country. Of these only ½ may cover costs and of this ½ only 1/3 will generate profit. This profit is partly needed for cross subsidization. It is therefore of paramount importance, that the costs are not allocated by the number of marketing authorisations, but e.g. by the respective sales volume.

3 Specific comments to the concept paper

Notwithstanding our position that homeopathic and anthroposophic medicinal products should be exempted as whole categories from the duty to bear any safety features, we give our comments on technical issues from a purely technical point of view.

A. Consultation Topic N°1

Consultation item n° 2

The coding capacity might be increased. In France, the complexity and number of references of the homeopathic medicines were at first not taken sufficiently well into account. This was one of the reasons to extend the initial 7-character into a 13-character identification code. We might need much more than 14 characters for the product identification to cover the homeopathic medicinal products in Europe (to include each stock, their specific level of dilution and the different pharmaceutical form).

Consultation item n° 3

Only the serial number should be mandatory to be part of the unique identifier. It should be optional to put batch number and expiry date: An obligation would raise additional and unnecessary costs as the integration of these data into the unique identifier doesn't contribute to a reduction of the risk for falsification. However, if a manufacturer would like to add these data, it should be possible.

Consultation item n° 5

The ECHAMP industries opt for the endorsement of option 2.2.2., i.e. 2D-Barcode.

B. Consultation Topic N°2

Consultation item n° 6

The ECHAMP industries opt for the endorsement of option n° 2/1., i.e. the systematic check-out of the serialisation number at the dispensing point, as at last the patient needs to have the necessary guarantee on the authenticity of the medicine.

C. Consultation Topic N°3

Consultation item n° 8

The ECHAMP industries opt for the endorsement of option n° 3/1. The stakeholders generating the falsification guarantees stay primarily responsible for the data management in order to maintain best flexibility for any further evolution.

D. Consultation Topic N°4

Consultation item n° 11

ECHAMP opts for a case-by-case basis, because this will best consider particularities of homoeopathic and anthroposophic medicinal products.
These show, e.g. partly traditional homoeopathic names or brand names; they are marketed in a lot of strengths (degrees of dilution).

Consultation item n° 12

General observations

The Commission points out that the possibility for exemptions of the duty to bear safety features will be interpreted narrowly: the general principles of the Law shall not be diluted. For ECHAMP "narrow" means careful adjustment between the Law and the economic reality of falsification. This will count for prescription as well as for non prescription medicines. For the latter the legislator did not intend to implement counterfeit measures in the first place. Therefore legal legitimacy for counterfeit measures for non prescription products is given to a minor extent. Out of that ECHAMP requests two basically different assessment rules for prescription versus non prescription products.

The Legislator has foreseen to include *products* or *product categories* into the exemption list (see Article 54a, 2. "(b) the lists containing the medicinal products or product categories"). The main likelihood for falsification comes from the price together with sales volume. Past incidence is the empirical factor that proves likelihood.

In order to allow an accurate assessment concerning homoeopathic and anthroposophic medicinal products and relevance of counterfeit, in 2011 the ECHAMP industries have gathered data on price, sales volume, past incidence of falsification of homoeopathic and anthroposophic medicinal products on prescription marketed from its member companies. Please find the results in the table below.

Homeopathic and anthroposophic medicinal products <u>on prescription:</u>

			Price range in €		**Unit sales range**		
Company (anonymised by numbers)	**Country**	**N° prod. Rx**	**Min**	**Max**	**Min**	**Max**	**Known case of falsification**
1	Austria	155	5,63	133,18 (*)	5	5075	No
2	Czech Republic	1		5,00		800	No
3	Hungary	1		10,00		9700	No
4	Latvia	7	5,25	17,02	720	4200	No
5	Poland	7	1,88	3,57	861	168054	No
6	Slovakia	1		17,85		320	No
7	Poland	13		2,50		1000	No
8	Germany	14	3,27	25,97	33	2754	No
9	Austria	6	3,87	5,61	1000	10000	No
10	Germany	68	4,00	36,60	30	50000	No

(*) refers to multiple packages

The table shows, that the amount of relevant products, the manufacturers' gross prices as well as the sales volumes are quite low. Please consider that homoeopathic and anthroposophic medicinal products only hold 0,7 % of the whole of the pharmaceutical market in the European Union. The minor figures given in the table reflect this small market proportion.
Furthermore, there is no past incidence of falsification of homeopathic and anthroposophic medicinal products.

Therefore, homeopathic and anthroposophic medicinal products should be exempted as whole categories from the duty to bear any safety features.

The necessary investments for safety features are disproportionate.

***Alternatively* to a category exemption for homoeopathic and anthroposophic medicinal products a *maximum sales limit per medicinal product* for exemption can be defined.**

As for the criteria themselves, please find some **specific observations**:

*** Price, sales volume**
In order to establish fair, reasonable as well as proportionate rules for the lists, *price and sales volume must be seen jointly.* Please find the following example of comparison:

Case 1: A medicine with a manufacturer's gross price of 1,90 Euro with a sales volume of 10 million pieces; we assume a 3 cent overall net margin for the falsifier and a falsification ratio of 10 %: One million x 3 cent = 30 000 Euro net margin.

Case 2: A medicine with a manufacturer's gross price of 15 Euro (value chosen between max and min out of ECHAMP data) and 150 000 units sales volume; we assume a one Euro overall net margin for the falsifier at a ratio of falsification of 10 %: 15000 x 1 Euro= 15 000 Euro net margin.

These examples show that price and sales volume must be seen jointly.

The scope of the regulation is to reduce falsification risk and not to overregulate the industries out of a merely theoretical fear. The concept paper of the European Commission artificially separates price from sales volume, what no falsifier actually would do. We therefore underline, that a well balanced rule uniting price and sales volume needs to be found.

*** Past incidence**
The data gathered by ECHAMP show no past incidence of falsification of homoeopathic and anthroposophic prescription medicines. Even if there were very sporadic falsification in the future, this should not force industries to implement expensive technology in these cases. Furthermore please consider, that it is not excluded, that competing pharmaceutical entrepreneurs may spark off a falsification in order to harm their competitor, if past incidence will have a major impact independently from price and sales volume.

*** Characteristics of the product**
Homoeopathic and anthroposophic medicinal products constitute 0,7% of the pharmaceutical market in the EU. They are mostly low price products. The vast majority is produced in *small batches* for individual therapy. This counts in particular for the prescription products. Low prices as well as low sales volume make the likelihood for falsification for the categories homoeopathic and anthroposophic medicinal products significantly low.

*** Severity of the conditions to be treated**
Homeopathic and anthroposophic medicines are rarely used for more severe condtions, as indicated in the related marketing authorizations. They are mostly used as adjuvants with other medication indicated for these more severe conditions. For this reason this criterion should not apply to homoeopathic and anthroposophic medicinal products.

*** Other potential risk to public health**
This criterion opens the door for any theoretical risk consideration. Total security will never be achievable in such an open profit driven social model/market. From our point of view the efforts on “any other potential risk to public health” should be focussed on *internet commerce*, as the latter is the major source of relevant risks. *Internet commerce needs to be addressed with appropriate rules with a high priority.*