AIM
ASSOCIATION INTERNATIONALE DE LA MUTUALITE

Secretariat

Public consultation on Concept paper

Delegated Act on the detailed rules for a unique identifier for mediinal products for Human use, and its verification

AIM contribution
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About AIM

The International Association of Mutual benefit societies (AIM), created in 1950, brings together 42 national federations of autonomous health insurance and social protection bodies in 25 countries mainly in Europe, all operating according to the principles of solidarity and not-for-profit orientation. The members of AIM mainly provide coverage against sickness to more than 160 million in Europe, either by participating directly in the management of compulsory health insurance, or by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; finally, non profit orientation as a guiding principle for health insurance based upon the needs of citizens.

The Association Internationale de la Mutualité is registered as professional organisation in the Union's Register for Interest Representatives:
ID number: 42108495378-73

A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Consultation item n°1: Please comment on points 1 and 2 (policy options n°1/1 and n°1/2). Where do you see the benefits and disadvantages of each policy option?

The characteristics and technical specifications of the unique identifier should be harmonised through European regulation. This would offer every citizen the same level of security within the EU. Leaving the choice of the technical specification to the individual manufacturers would not ensure the same high degree of protection.

AIM thus prefers policy option n°1/2: harmonisation through regulation

Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.

The advantage of using a serialisation number including the manufacturer product code and pack number would avoid confusions as it is easily understandable and would avoid language problems.

Consultation item n°3: Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2? Please comment.

The inclusion of batch number and expiry date in the serialisation number would be a great improvement for safety measures (pharmacovigilance). If the serialisation number may be understandable throughout the EU, recalls of products would be facilitated. Through network alerts, pharmacists would be easily informed and may check if he received or delivered implied products.

Consultation item n°4: Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.

AIM would prefer option 2 where the serialisation number includes the national reimbursement number.

Consultation item n°5: Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts. What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example:
- costs for reading devices for the different carriers;
- costs for adapting packaging lines of medicines packaged for the EU market.

AIM prefers the 2D-barcode.

It may be more easily printed on outer packaging since it is not too big. A Data Matrix symbol can store up to 2,335 alphanumeric characters. Data Matrix codes are part of a new traceability drive in many industries in the United States, particularly aerospace where quality control is tight and a black market exists for counterfeit or non-serviceable parts. In the future, this system would be the most convenient to be used by patients. Smartphones are nowadays equipped to read such codes. If patients want to check the medicine they bought is not falsified, this system would be a good solution**.**

B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY FEATURES

Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered? How can these be addressed in this policy option?

Regarding the legal supply chain, in principle no other point of dispensation should be included in the list. However, in case national legislation would foresee other official dispensing points (e.g. official dispensing doctors), they should be submitted to the same obligations (systematic check-out).

Consultation item n°7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible.
This applies in particular to the:
- number of wholesale distribution plants;
- costs for adapting such plants;
- duration of scanning of the serialisation number;
- number of pharmacies, including hospital pharmacies;
- number of medicinal products dispensed by pharmacies and a hospital pharmacy.

Considering public health reasons, AIM prefers policy option n°2/3: systematic check-out at the dispensing point + additional systematic verification by the wholesale distributors.

C. CONSULTATION TOPIC N°3 - PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

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Consultation item n°8: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible. This applies in particular to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).

AIM considers option n°3/3 as most suitable: national governance. This would enable the national medicines agencies to organise the system and to exchange data with other EU countries. These data have to be public and accessible, so that national authorities may conduct post-marketing studies and exploit the results for pharmaco-epidemiology or pharmacovigilance.

Consultation item n°10: Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

It would be necessary to define what personal data is. Any collection of private patient information has to be forbidden. The unique identifier deserves public health interest and no commercial interest. Concerning repackaging, re-packagers should be obliged to use the same unique identifier as the original one.

D. CONSULTATION TOPIC N°4 - LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

Consultation item n°11: Which approach seems the most plausible from your view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?

The best approach would be to use INN name. This international language is the easiest to use to identify problematic substances.

In 2007 the French agency for sanitarian security of health products already informed the public of the dangers not to know the INN name of their treatment products. A French citizen was delivered e.g. the wrong treatment in Spain, because he asked for the commercial name of the molecule, which was not the same in Spain[1].

Consultation item n°12: Please comment on the quantified approach set out above.

For AIM, all medicines should be included in the scope of the unique identifier.

Consultation item n°13: any other issue

Article 54a(2) (e) of Directive 2001/83/EC foresees that the costs of the repositories system shall be born the manufacturing authorisation holders of medicinal products bearing the safety features.

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[1] AFSSAPS, press release 15/06/2007. http://www.afssaps.fr/Infos-de-securite/Communiques-Points-presse/Depart-a-l-etranger-3-bons-reflexes-avec-vos-medicaments/%28language%29/fre-FR