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Summary table outlining preferred option for each consultation item

Consultation Item	
1	Policy option n° 1/2: *"harmonization through regulation"*
2	Harmonized and internationally recognized standards for the identification of all products in Europe is a good opportunity and an instrument against counterfeiting
3	Add batch number and expiry date to the pack code
4	Option 2.2.2 - 2D-Barcode
5	2D Barcode is presently the best solution
6	GDO and parapharmacies (In Italy all products have the serial number)
7	Policy option 2/3 is the best solution because in this way the supply chain is tracked.
8	Policy option 3/3 : *"national governance"*
9	High degree of data security needed - In accordance with existing legal principles, all stakeholders having access to the system will own the product verification data that they generate through their interaction with the system
10	No personal data related to patients. Equivalent level of safety features for parallel distributors
11	Identification by brand name linked to active pharmaceutical ingredient is the best solution
12	Agree with quantified approach set forth in the Concept Paper
13	

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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?

Farmindustria recommends policy option **n°1/2,** that guarantees a smoother implementation**.**

Policy option **n°1/1** might bring high fragmentation of Coding in UE.

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

Serialization number which contain the manufactured product code and pack number is the best solution for tracking and the best instrument against counterfeiting.

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.

We consider very important that the serialization number can include also information like batch number and expiry date to facilitate the recall of the products and to improve internal activities of wholesalers and pharmacists.

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

In our view option 2 is preferable in fact we consider the national reimbursement number important.

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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.

- ***Linear Barcode***: is an old solution and can hold only few information.

- ***2D-Barcode***: at the moment this is the best solution because can hold a lot of information, it's applicable to small packs and this not too expensive.

- ***RFID***: expensive solution and possibility that this technology interfere with some materials like aluminum and glass so the reading of serial number in some cases is not possible.

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?

Yes in Italy also GDO and parapharmacies must be considered because actually all products (included OTC and non RX medicines) have the serial number.

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.

We support **policy option 2/3**: systematic check-out of the pack code at the dispensing point with additional systematic verifications at the level of wholesale distributors. Also policy **option 2/2** can be accepted if the random verification includes an important number of controls.

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

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).

We support Policy Option **3/3 "***National Governance"*

The other two options put forth in the Concept Paper present significant problems for the following reasons:

EU governance:

- A system runs solely by one body, outside the pharmaceutical supply chain, will not be able to fully integrate and rely on the necessary expertise from the key actors of the supply chain;
- The high number of information that each day the Data Base must control could cause a block of the System

Stakeholder governance:

- This option is too large and could cause the failure of the System due to hard dispute between stakeholders.

Consultation item n°9: Please comment on point 4.1. Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act?

We agree that there is a need for a very high degree of data security.

In accordance with existing legal principles, all stakeholders having access to the system will own the product verification data that they generate through their interaction with the system.

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

No personal data related to patients.

As regards the obligations on the parallel distributor to replace mandatory safety features, the original pack's serial number must be checked out in the database by the parallel distributor and a new number checked in. The new serial numbers must be linked to the original product number at batch level in the database to enable the product to be tracked in case of recalls or other safety issues.

Other safety features, including mandatory tamper-evident packaging should be replaced with similar features guaranteeing an equivalent level of protection (by effect).

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?

Identification by brand name linked with active pharmaceutical ingredient is the best solution.

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

We agree with quantified approach set forth in the Concept Paper.

E. CONSULTATION TOPIC N°5 - OTHER ISSUES

Consultation item n°13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

No additional comments.