A. Consultation Topic N°1: Characteristics and Technical Specifications of the Unique Identifier

1. Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer
2. Policy option n°1/2: Harmonisation through regulation

FCIO:
FCIO prefers, that the commission will set out details concerning the serialisation number and the carrier in the Delegated Act.

Individual systems for each manufacturer may lead to a high degree of fragmentation of product coding in the EU. Prompt verification would be difficult.

2.1. Regulation of the composition of the serialisation number

2.1.1. Manufacturer product code and pack number

Manufacturer Product code (which includes the prefix of the country)	Unique identification number of the pack
XXXXXXXXXXXXX	XXXXXXXXX

FCIO:
The whole unique identifier should consist of the country code or the prefix of the country, the manufacturer product code and the serialisation number of the pack.
The manufacturer product code should include the country code or the prefix of the country. It should be possible to include the Austrian "Pharmazentralnummer" within the manufacturer product code.
The second part of the unique identifier should be a randomised serialisation number which has to contain the pack number.

2.1.2. Additional product information

(a) Batch number
(b) Expiry date

FCIO:
The inclusion of batch number and expiry date into the serialisation number should be possible. This would facilitate the identification of batches.

(c) National reimbursement number

Option 1: the national reimbursement number is replaced by the abovementioned serialisation number.
Option 2: The abovementioned serialisation number includes the national reimbursement number. In this case, the serialisation number could be composed as follows:

Manufacturer Product code (which includes the prefix of the country)	Unique identification number of the pack	National reimburse-ment number (see point c)	Expiry date (see point b)	Batch number (see point a)
XXXXXXXXXXXXX	XXXXXXXXX	XXXXXXXX	XXXXXX	XXXXX

FCIO:
FCIO prefers option 2.
In Austria there is the "Pharmazentralnummer" alternatively to the national reimbursement number. The Pharmazentralnummer with 7 digits is placed on each medicinal product which is distributed by pharmacies.

The Pharmazentralnummer should be used directly within the Manufacturer Product Code (as said before).
Therefore the composition of the unique identifier should be:

U N I Q U E I D E N T I F I E R			
Country Code and Manufacturer Product code, which consists the Austrian 'Pharmazentralnummer')	*(Batch number)*	*(Expiry date)*	*serialisation number of the pack*
14 digits	*12 digits*	*6 digits*	*12 digits*

The batch number and the expiry date should be placed - if they are included - before the serialisation number, because the code should bear all specific information about the product.

The serialisation number, which is randomized by the manufacturer, can be used again in combination with different manufacturer products codes, batch numbers or expiry dates.

2.2. Regulation of the technical characteristics of the carrier

2.2.1. Linear barcode
2.2.2. 2D-Barcode
2.2.3. Radio-frequency identification (RFID)

FCIO:

The 2D-Barcode (12x12mm maximum size) is preferred because it is able to store all the suggested data. It could also be placed on small packages.
A linear bar code would need too much space on small packages.
RFID is seen as too costly.

B. Consultation Topic N°2: Modalities for verifying the Safety Features

1. Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point – other points of dispensation?

FCIO:
Additionally to the systematic check-out at the point of dispense other points of dispensation have to be considered, for example:

Samples for doctors
damaged products
recalls
reference samples
medicinal product which is given directly to hospital pharmacies or reblistering companies

Because of the high number of dispensing doctors in Austria, the check-out has to be possible at that point of dispensation as well.
It has to be possible to cancel an accidental check-out.

---

2. Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors

FCIO:
Beside the systematic check-out of the serialisation number at the dispensing point the wholesale distributers have to be able to check with an additional random verification.

---

3. Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors

FCIO:
The serialisation number has to be checked out at the dispensing point. In addition wholesale distributers perform random verifications of the serialisation number.

C. Consultation Topic N°3: Provisions on the Establishment, Management and Accessibility of the Repositories System

1. Policy option n°3/1 – 'stakeholder governance'
2. Policy option n°3/2 – EU governance
3. Policy option n°3/3 – national governance

FCIO:
We prefer stakeholder governance, because this policy option would define the obligations to the relevant actors to set up the appropriate and cost effective infrastructure for the repositories system. It is necessary to adapt the system to national conditions. The delegated act should define only the key responsibilities. We support a centralised check-in together with a local check-out of the data. The verification system must be able to cooperate between several member states, the flow of products has to be guaranteed.

---

4. Other issues related to the repositories system
4.1. Information of a commercially sensitive nature

FCIO:
All data which are generated in the serialisation process has to be secure.
The manufacturer shall have access to his own data.
Authorities may use the data only in accordance with the manufacturer.

4.2. Protection of personal data
4.3. Re-packaging of medicinal products

FCIO:
regarding 4.3.: All safety features have to be equal for manufacturers and re-packers.

D. Consultation Topic N°4: Lists containing the Medicinal Products or Product Categories which, in case of Prescription Medicines shall not bear the Safety Features, and in case of Non-prescription Medicines shall bear the Safety Features

1. Identification criteria

FCIO:

Point 83: ***Classification criteria for the "black list" and the "white list"***

- ***The price of the medicinal product:*** *It is assumed that medicinal products at a very low price are, for economic reasons, less at risk of being falsified. Therefore, a manufacturer's gross price of more than 2 EUR could be considered as a high prize.*
  We suggest a manufacturer's gross prize of at least 10 EUR as a limit for a high prize medicinal product. Medicinal products with a prize below this limit should be listed in a "white list". If other risks are low for a product, it has to be possible for such a product with a higher prize than this limit also to be listed in the white list.

- ***Sales volume of the medicinal product:*** *It is assumed that medicinal products placed on the market in very low volumes are less at risk of being falsified. "Sales volume" is a relative term, which has to be defined.*

- ***Specific characteristics of the product:*** *One example might be products that are delivered direct from the manufacturer to hospital pharmacies. This is only one example, so that we need a list of "specific characteristics".*

Point 85: ***EU-scope of Unique Identifier non-optional:***

A medicinal product which falls within the scope must bear the unique identifier. A medicinal product will falls outside the scope must not have to bear the unique identifier. This means, there is no optional scope for manufacturers. Additionally the manufacturer shall have the right to opt a product into the "black list" or out from the "white list".

Point 86: ***Regarding approach to identification criteria:***

We support a flexible approach on a case-by-case basis. This would leave room for some flexibility.

Point 87: ***Applying the classification criteria:***

*Generally we support a quantified approach to apply a classification criteria. But the example listed in the concept paper is not flexible enough (1 point **or** 5 points for each criterion). We would prefer a graduated system with a range of **1 to 5** points for each criterion. The manufacturers shall have the possibility to take part in the creation of the white and the black list.*

E. Consultation Topic N°5: Other Issues

1. Procedures for the notification of medicinal products from the national competent authorities to the Commission
2. Date of application of the delegated act

FCIO:
Point 90: Date of application of the delegated act
The date of application of the delegated act is 3 years after the date of publication of the Delegated Act.
The date of publication of the delegated act shall refer to the production date of the pharmaceutical products which have to bear safety features.
