Stakeholder's workshop

on the delegated act on safety features for medicinal products for human use

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IMPACT ASSESSMENT

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Impact Assessment - Inclusions

Directive 2011/62/EC requires the Commission to perform a study assessing benefits, costs and cost-effectiveness of:

- the technical characteristics of the unique identifier;
- the options for the verification of the authenticity of the medicinal product bearing the safety features and the practical arrangements for such verification;
- the technical options for establishing and managing the repository system.

This study was conducted in the form of an impact assessment and finalised at the end of 2013.

Impact Assessment - Exclusions

This study did not discuss options for:

- ***the anti-tampering device*** *(the Commission will leave the choice of the most appropriate device to the manufacturer).*
- *the criteria for establishing* ***the lists of exceptions*** *from bearing/not bearing the safety features (these criteria are already set out by the Directive itself).*

1. Characteristics and technical specifications of the unique identifier

- Policy option 1/1: Harmonisation of the composition of the number and the data carrier to fight against falsified, recalled and expired medicines

- Policy option 1/2: Partial harmonisation of the composition of the number and the data carrier to fight against falsified medicines

Impact Assessment – Outcome (I)

Objective 1: to ensure efficient and effective characteristics and technical specifications of the unique identifier

Selected option: Harmonisation of the composition of the number and the data carrier to fight against falsified, recalled and expired medicines

In practice:

- The UI shall contain the following information:
  - **Manufacturer product code**
  - **Serial number**
  - **A national reimbursement number, if present**
  - **Batch number**
  - **Expiry date.**

- The UI will be carried by a 2D barcode (data matrix).

2. Verification of the safety features in order to combat falsified medicines

- Policy option 2/1: Systematic verification of the safety features at the dispensing point — end-to-end verification
- Policy option 2/2: Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors

Impact Assessment – Outcome (II)

Objective 2: to introduce proportionate verification of the safety features in order to combat falsified medicines

Selected option: Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors

In practice:

- *Medicines will be systematically checked-out at the dispensing point*
- *Wholesale distributors will verify the safety features when:*
  - ***The product is not obtained from the holder of the manufacturing authorisation or the holder of the marketing authorisation;***
  - ***The product is returned by another wholesale distributor or a pharmacy.***

3. Set up and management of the repository system

- Policy option 3/1: Establishment and management by stakeholders with supervision by the relevant competent authorities
- Policy option 3/2: Establishment and management by a public authority at EU level
- Policy option 3/3: Establishment and management by public authorities at national level

Impact Assessment – Outcome (III)

Objective 3: to ensure interoperability of the repository system, free movement of medicines and supervision by the competent authorities

Selected option: Establishment and management by stakeholders with supervision by the relevant competent authorities

Impact Assessment – Outcome (III) – Cont'd

In practice:

The manufacturers and parallel importers will have to ensure that:

- The unique identifier is placed on the pack for authentication;
- The serial number can be checked out at the dispensing point;
- The repository system is suitable to ensure authentication of medicinal products at the dispensing point;
- The response from the repository system is virtually instantaneous;
- The repository system guarantees the protection of commercial, confidential and personal data;
- The concerned competent authorities have full access to the repository system and can supervise its functioning.

Conclusions

- In summary, the Commission will propose:
  - Harmonisation of the composition of the number and the data carrier
  - Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors
  - Establishment and management by stakeholders with supervision by the relevant competent authorities

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Thank you

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