ROADMAP			
TITLE OF THE INITIATIVE	**Delegated act(s) on the detailed rules for a unique identifier for medicinal products for human use, and its verification**		
LEAD DG – RESPONSIBLE UNIT	DG SANTE – Unit D6 "Medicinal products: Quality, Safety and Efficacy"	**DATE OF ROADMAP**	05/2015
This indicative roadmap is provided for information purposes only and is subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.			

A. Context and problem definition

(1) What is the political context of the initiative?

(2) How does it relate to past and possible future initiatives, and to other EU policies?

(3) What ex-post analysis of existing policy has been carried out? What results are relevant for this initiative?

(1) The falsification of medicinal products is a growing concern in the European Union. This initiative aims at increasing the protection of public health by preventing the entry of falsified medicines into the legal supply chain.

(2) On 1 July 2011, Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products was published.[1] Directive 2011/62/EU introduced obligatory 'safety features' (a unique identifier and an anti-tampering device) for the purposes of identification and authentication of medicinal products. It puts the Commission under an obligation to adopt delegated act(s)[2] setting out the detailed rules for the safety features[3], after having performed an impact assessment as regards the technical characteristics of the unique identifier, the modalities of verification of the safety features and the repositories system where the unique identifiers are to be stored.[4]

(3) This is a new area of action where no ex-post evaluation has therefore been conducted.

What are the main problems which this initiative will address?

Directive 2011/62/EU establishes the basic legal framework for the placing and the verification of the safety features but leaves it to the Commission to establish, by way of delegated acts, the details of the verification system.

The aim of the delegated act is to define the detailed rules for the verification system intending to ensure a correct identification and authentication of individual packs of medicines and the timely detection of the falsified medicines which enter the legal supply chain.

Who will be affected by it?

Amongst economic operators, this delegated act is going to affect manufacturers, re-packagers (e.g. parallel traders), distributors and pharmacies/retailers of medicinal products: Manufacturers and re-packagers of medicinal products will have to adapt the packaging lines to place the safety features on the outer packaging of medicines. Additionally, pharmacies/retailers and wholesale distributors will have to verify the authenticity of individual packs of medicines by scanning the unique identifier.

It will also affect national authorities as they are responsible for supervising the system.

Is EU action justified on grounds of subsidiarity? Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? Can the EU achieve the objectives better?

The initiative is an obligation for the Commission established by the Union legislator in Article 54a of Directive 2001/83/EC.

Due to the cross border dimension in the manufacture of medicinal products in the EU and the circulation of medicines in the internal market, an EU response is necessary to avoid diverging approaches in implementing the unique identifier. Diverging approaches through national regulation would increase the costs for manufacturers, for example for the adaptation of the packaging lines in the different national territories of the internal market.

B. Objectives of the initiative

What are the main policy objectives?

Directive 2011/62/EU builds on the concept of a unique identifier on the outer packaging of each medicinal product. The unique identifier is a unique number unambiguously identifying an individual pack. A 'carrier' affixed on the outer packaging (e.g. a bar code) 'holds' the unique number. The unique identifier is read with a reading device (e.g. a scanner) and its authenticity is checked against a repositories system, i.e. a (system of) database(s) holding the authentic identifiers.

On the basis of this concept, Article 54a(2) of Directive 2001/83/EC puts the Commission under an obligation to set out the following 5 key elements:

1. *The characteristics and technical specifications of the unique identifier;*

2. *The modalities for the verification of the safety features by the manufacturers, wholesalers, pharmacists and persons authorised or entitled to supply medicinal products to the public and by the competent authorities;*

3. *The provisions on the establishment, management and accessibility of the repositories system in which information on the safety features shall be contained;*

4. *The lists containing the medicinal products or product categories which, in the case of prescription medicines should not bear the safety features, and in the case of non-prescription medicines should bear the safety features;*

5. *The procedures for the notification to the Commission of medicinal products at risk of falsification.*

Do the objectives imply developing EU policy in new areas?

No.

C. Options

(1) What are the policy options (including exemptions/adapted regimes e.g. for SMEs) being considered?

(2) What legislative or 'soft law' instruments could be considered?

(3) How do the options respect the proportionality principle?

(1) The impact assessment analysed the policy options[5] for the following key issues[6]:

1- The characteristics of the unique identifier:

The policy options are: a full harmonisation (policy option n°1/1) or a partial harmonisation (policy option n°1/2) of the unique identifier and its carrier (bar code etc.) at EU-level.

2. The modalities of verification of the safety features: the options will address who will verify the safety features (unique identifier and anti-tampering device) and in which circumstances.

Policy option n°2/1 is the systematic verification of the safety features at the point of dispense.

Policy option n°2/2 is equal to option n°2/1 with additional verifications at the level of wholesale distributors.

3. The establishment, management and accessibility of the repositories system:

Policy option n°3/1: the repositories system is set up by the relevant actors (manufacturers, distributors, pharmacists/retailers) ('stakeholder governance'), subject to certain conditions set by the delegated act (for example, the obligations with regard to the protection of personal and commercial data and the supervision by national competent authorities).

Policy option n°3/2 proposes a pan-European repository to which all actors are connected, and which is governed by a EU-body (Commission or EMA) ('EU governance')

Policy option n°3/3 proposes the establishment of national repositories to which all actors in the Member State, and actors supplying medicines to the territory of that Member State, are connected. The national repositories would be governed by official national bodies, established by each Member State ('national governance').

(2) Directive 2001/83/EC provides for a legally-binding delegated act (Directive or Regulation).

(3) The options respect the proportionality principle insofar as they explore the most cost-efficient approach for the unique identifier in the EU: The Union legislator has put the Commission under an obligation to give 'due consideration to cost-effectiveness'[7] and 'proportionate impacts', as concerns in particular the characteristics and technical specifications of the unique identifier[8] and the verification measures.[9]

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

Directive 2011/62/EU stipulates that the Commission shall perform an impact assessment of the possible options for the following elements of the delegated acts: *the characteristics of the unique identifier, the modalities of verification of the safety features and the repositories system*. Initial assessment of benefits and costs are therefore presented below:

1. Characteristics of the unique identifier of the safety features

Benefits: A harmonised unique identifier and carrier (policy option n°1/1) means avoiding different packaging standards and processes for each country of destination and facilitating reimbursement and surveillance activities, including the supervision of recalled products. Policy option n°1/2 is convenient for manufacturers who have already a serialisation system in place.

Costs: Policy option n°1/1 and policy option n°1/2 (to a lesser extent) create costs in the short term for manufacturers, who have to adapt their packaging lines and ensure a connection/interface with the repositories system. Policy option n°1/2 might also create costs for wholesale distributors and pharmacies by requiring multiple reading devices/software to read the different formats of unique identifiers and carriers.

2. The modalities of verification of the safety features

Benefits: Policy option n°2/1 ensures that 100% of packs are checked before dispense to the patients. Policy option n°2/2 not only ensures that all packs are checked before being dispensed to the patients but also allows for detecting falsified medicines earlier in the supply chain.

Costs: the costs increase with the number of checks in the supply chain. Policy options n°2/2 has a financial impact on wholesale distributors: it may require the purchase of additional equipment and may increase the delay for the preparation of orders, with consequential costs.

3. The repositories system

Benefits: Policy option n°3/1 would allow for flexibility and use of market-forces to ensure a sufficiently robust, while reliable and flexible system. Policy options n°3/2 and n°3/3 build on the involvement of (European or national) public authorities, which would re-coup their costs through fees.[10] Option n°3/2 creates a single point of contact for all operators. However, setting up a functioning infrastructure on the basis of option n°3/2 is extremely challenging and may not work reliably. Option n°3/3 may allow better to take national characteristics into account, for example for aspects of reimbursement of medicines.[11] However, option n°3/3 may cause important difficulties in terms of interoperability within the repositories system.

Costs: Policy option n°3/1 allows for economic operators to better control the costs of the system. The costs of policy option n°3/2 will depend on the design of a central system storing all data from all actors in the supply chain, the simultaneous connection of hundreds of thousands of actors, the instantaneous authentication of billions of packs and the access in all languages. Policy option n°3/3 may entail higher costs in the long run, in terms of needs for interfaces within the repositories system.

Generally speaking, the system will create costs and burden for manufacturers, wholesalers and/or pharmacists/retailers in the building-up of the implementation. Once the system (packaging lines, repositories system, readers) is in place, the costs will be limited and stable.

Article 2, second paragraph, point (b) of Directive 2011/62/EU provides that the delegated act becomes applicable 3 years after its publication. This shall allow operators to adapt more easily to the system and to take into account life cycles of existing systems. For example, some costs may be absorbed by the usual adjustments of the manufacturing lines with time.

In addition, any costs have to be evaluated against the risk to public health and the potential costs of a loss of confidence in the legal supply chain.

Finally, there is a trend world-wide towards obligatory security-technology in the area of medicines. A robust legal framework might support companies to gain/maintain a lead position in terms of technology.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?

(i): The measure would harmonise the provisions in the EU on labelling to ascertain authentication and identification of medicinal products. This harmonisation simplifies the rules applicable to the labelling of medicinal products placed on the EU market.

(ii): See above, as regards 'costs'

(iii): The provisions in the delegated act as regards the unique identifier apply to medicinal products for human use placed on the EU market, i.e. including imported medicinal products. The measure will be notified to the WTO under the Agreement on Technical Barriers to Trade (TBT).

(iv): No. The three Member States which already have an identification and authentication system in place have additional 6 years to align their system to the content of the delegated act.

(v): Although infringement procedures were initiated against 20 Member States in 2013 for the late transposition of Directive 2011/62/EU, all procedures are now closed or nearly so, so transposition difficulties are not expected.

(1) Will an IA be carried out for this initiative and/or possible follow-up initiatives?

(2) When will the IA work start?

(3) When will you set up the IA Steering Group and how often will it meet?

(4) What DGs will be invited?

(1) An impact assessment was finalised in 2013.

(2) Work on the impact assessment started in 2011, following the adoption of Directive 2011/62/EU.

(3) The IA Steering Group was set up and has started meeting in autumn 2011. It met three times.

(4) Apart from the SG and the LS, the following DGs will be invited: BUDG, INFSO, ENTR, HOME, MARKT, TRADE, TAXUD.

(1) Is any option likely to have impacts on the EU budget above € 5m?

(2) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial Regulation? If not, provide information about the timing of the ex-ante evaluation.

(1) Option n°3/2 would have an important impact on the EU budget (staff costs and operational costs for IT). Such option would oblige the Commission to allocate a part of its EMA budget for this purpose. In terms of human resources, at least 30 staff would be required to set up and to maintain the system.

(2) Yes.

E. Evidence base, planning of further work and consultation

(1) What information and data are already available? Will existing IA and evaluation work be used?

(2) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when?

(3) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?

(4) Is any particular communication or information activity foreseen? If so, what, and by when?

(1) An impact assessment was conducted in 2008 for the preparation of Directive 2011/62/EU. Costs of the safety features were already estimated in that impact assessment exercise. The public consultation (see below) was used for updating the data used in the 2008 impact assessment.

(2) Further information on the costs of each option was gathered through consultation with Member State experts and stakeholders. A public consultation was launched on 18 November 2011 and closed on 27 April 2012. A competitiveness proofing study was conducted by by an external contractor.

(3) The competitiveness proofing study was supported by an existing framework contract in 2012, the results of the study were made available to the Commission in February 2013.

(4) No.

Which stakeholders & experts have been or will be consulted, how, and at what stage?

The public consultation (see above) involved all Member States and the relevant stakeholders.

Experts from national authorities from all Member States were be consulted in accordance with the Commission Communication COM(2009) 673 - Implementation of Article 290 of the Treaty on the Functioning of the European Union.[12]

[1] OJ L 174, 1.7.2011, p. 74.

[2] The measures may be contained in one delegated act or several delegated acts. For the purpose of this roadmap, reference is made to 'delegated act'.

[3] Article 54a(2) of Directive 2001/83/EC.

[4] Article 4 of Directive 2011/62/EU.

[5] As legislative action is mandatory, there is no policy-option 'no EU action'.

[6] Article 4 of Directive 2011/62/EU.

[7] Article 54a(3)(d) of Directive 2001/83/EC.

[8] Article 54a(2)(a) of Directive 2001/83/EC.

[9] Article 54a(2)(d) of Directive 2001/83/EC.

[10] Article 54a(2)(e) of Directive 2001/83/EC provides that the costs for the repositories system shall be borne by the manufacturing authorisation holders.

[11] Cf. the first and second paragraph of Article 54a(5) of Directive 2001/83/EC.

[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0673:FIN:EN:PDF