SANOFI

To: European Commission
Att.: sanco-pharmaceuticals@ec.europa.eu
Ref.: Sanco.ddg1.d.3(2011)1342823

Chilly-Mazarin, April 12, 2012

Sanofi appreciate the opportunity to answer to the consultation items on the Concept paper on the **Delegated Act on the detailed rules for a unique identifier for medicinal products for human use, and its verification (Sanco.ddg1.d.3(2011)1342823)**, released for consultation in November 2011.

Enclosed you will find **Sanofi answers and comments** on this public consultation Concept paper document.

We wish to inform you that we have also participated and we fully support the comments submitted by the European Federation of Pharmaceutical Industries and Associations (EFPIA) on these consultation items.

Yours faithfully,

Susanna DEL SIGNORE, M.D.

Associate Vice President, Global Regulatory Policy

Global Regulatory Affairs

Sanofi-Aventis Recherche & Développement
1, avenue Pierre Brossolette - 91385 Chilly-Mazarin Cedex - France - Tél : +33 (0)1 60 49 77 77 - Fax : +33 (0)1 60 49 67 67 - www.sanofi.com
Siège social : 1, avenue Pierre Brossolette, 91380 Chilly-Mazarin – France – Société Anonyme au capital de 3 881 100 € - 713 002 269 R.C.S. Evry

DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION
CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION – SANOFI COMMENTS

Question	Policy option de référence	Sanofi Comments
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?	**1. Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer** 15. Under this policy option, the delegated act would create a broad framework, leaving it up to the manufacturer to choose the appropriate technical solution for the serialisation number and its carrier. 16. This policy option is very flexible and therefore may be cost-neutral for companies which already have a system of serialisation in place. 17. However, this policy option may lead to a high degree of fragmentation of product coding in the EU. This, in turn, may make it difficult to ensure prompt verification (see consultation topic n°2). **2. Policy option n°1/2: Harmonisation through regulation** 18. Under this policy option, the Commission would set out in the delegated act details concerning the serialisation number (see point 2.1) and the carrier (see point 2.2). 19. This may enable a smoother implementation than policy option n°1/1.	Serialization efficiency depends of the ability to read and check each serial number in the supply chain before it reach patient. Non-harmonized coding and identification of medicines will not allow the supply chain actors to verify medicines as needed and will limit serialization efficiency. Having different information carriers technologies on the pack will oblige supply chain stakeholders to have different readers and will generate higher cost and complexity A harmonized standard system for coding pack information across the European Union (according to ISO Standards) will facilitate exchange of information between member states which is essential for patient safety (considering the unique EU market and the flow of products between the different European countries). Harmonization through regulation will provide the following benefits :

<table>
<tr><th>Question</th><th>Policy option de référence</th><th>Sanofi Comments</th></tr>
<tr><td></td><td></td><td>-Interoperability between countries (and between manufacturers and re-packagers)
- Possibility to control medicines systematically at their point of dispensing in order to improve patient security

Open standards (according to ISO) are needed : serialized Data Matrix ECC 200 for the information carrier
and product coding following ISO standards (such as GS1 or IFA in Germany)</td></tr>
<tr><td>Consultation item n°2 :
Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.</td><td>2.1.1. Manufacturer product code and pack number

20. In order to allow identification of a pack of medicinal products, a serialisation number would have to contain, as a minimum, a manufacturer product code and the pack number.

21. For the purpose of this public consultation, based on existing international industry standards and global regulatory developments, the following composition of the unique identifier is proposed:

<table><tr><th>Manufacturer Product code (which includes
the prefix of the country)</th><th>Unique identification number of the pack</th></tr><tr><td>XXXXXXXXXXXXX</td><td>XXXXXXXXXXXXX</td></tr><tr><td></td><td></td></tr></table></td><td>Unique identifier of a pack should contain 2 elements which need to be standardized and harmonized according to ISO standards:

- Product code (unique worldwide) : preferably a GTIN or NTIN (GS1) or a PPN code (IFA)
- The choice between these different options (all ISO compatible) should not be set by law but be agreed in a consensus approach by relevant stakeholders.

- Pack serial number: randomized number (up to 20 digits) with an alphanumeric structure defined by manufacturer. This alphanumeric structure should constitute a unique serial number for this particular product code. Length of the serial numbers should be defined by manufacturer according to the expected level of randomization (which defines the protection level) and according to the batch size (or annual volume produced).</td></tr>
</table>

Question	Policy option de référence	Sanofi Comments
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.	**2.1.2. Additional product information** 22. The serialisation number allows for inclusion of a range of other product related information. (a) Batch number 23. The serialisation number could include the batch number of the medicinal product. If the serialisation number is machine-readable (see point 2.2), this would facilitate identification of batches. This may be relevant in view of the obligation of the wholesale distributor to keep records of the batch number in accordance with the fourth indent of Article 80(e) of Directive 2001/83/EC. It may also facilitate recalls on a batch-level in the distribution chain. (b) Expiry date 24. The serialisation number could include the expiry date. This may facilitate storage management and verification of expiry dates of medicinal products at the level of wholesale distributors and pharmacists/retailers.	**Unique Medicine Identifier should be constituted by the product code and the pack serial number**. However, batch number and expiry date are important information and should be encoded in the datamatrix carrier in order to allow traceability by automatic reading of the datamatrix code (especially by wholesalers). Even if **batch number and expiry date are not part of the UMI (**sensu stricto), they should be considered as attributes of the UMI and incorporated systematically in the standardized datamatrix carrier in order to facilitate batch recall and avoid dispensing errors. Finally , it is important to differentiate : **UMI**= product code + pack serial number (= combination of two separate elements) **UMI attributes** = Batch number and expiry date **And Standardized carrier** = Datamatrix code (ECC200) Considering the EU global market and the corresponding flow of products within Europe, all machine readable information contained in the code (UMI + batch number + expiry date) should be standardized and harmonized according to international standards in order to allow readability and interoperability between countries at supply chain level

<table>
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<td>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.</td>
<td>
2.1.2. Additional product information

(c) National reimbursement number

25. Directive 2011/62/EU lays down exhaustive rules on labelling for medicinal products as regards authenticity and identification. Member States are not allowed to create additional requirements in this respect.

26. In addition, Directive 2011/62/EU provides that Member States may, inter alia for the purposes of reimbursement, extend the scope of application of the unique identifier to include any medicinal product that is subject to prescription or to reimbursement.

27. Most Member States have national product codes for reimbursement purposes in place ('national reimbursement number'). Therefore, two alternative options could be considered:

28. Option 1: the national reimbursement number is replaced by the abovementioned serialisation number.

29. Option 2: The abovementioned serialisation number includes the national reimbursement number. In this case, the serialisation number could be composed as follows:
<table>
<tr><td>Manufacturer Product code (which includes the prefix of the country)</td><td>Unique identification number of the pack</td><td>National reimbursement number (see point c)</td><td>Expiry date (see point b)</td><td>Batch number (see point a)</td></tr>
</table>
</td>
<td>
In addition, when required the coding system should allow management of other functionalities such as reimbursement processes by integrating national relevant product code in the product code structure (NTIN such as CIP code in France)

Option 1: Logistic code (such as GTIN) does not allow management of reimbursement processes because logistic codes vary versus time according to logistic rules. Using a logistic code for reimbursement processes would require a permanent correspondence table in all the organizations in charge of managing the reimbursement processes.

<u>Option 2 is the preferred option i.e.:</u>

- a national reimbursement number encapsulated in an ISO compatible structure such as GS1 NTIN (EAN 14) or IFA code (pharmacy Product Number concept which could allow integration of existing national product codes in Germany, Italy, Belgium and Portugal for example).

- Having only one product code (encapsulating the national product code when required) is preferred than having 2 product codes for the same product (i.e. logistic product code + administrative/ regulatory product code). This will reduce complexity and risk of confusion. In addition, it will avoid the technical additional complexity of integrating a 5th element in the Data Matrix
</td>
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	XXXXXX XXXXXX XXXXXX XXXXXX XXXXXX (instead of 4 elements) - In all cases, UMI should preferably contain only one product code and the pack serial number. All other product information - batch number, expiry date and potentially further national registration number (in case it cannot be encapsulated in the product code) - should be considered as specific UMI attributes	
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.	**2.2. Regulation of the technical characteristics of the carrier** 30. Various ways to carry the serialisation number on the outer packaging could be considered: 2.2.1. Linear barcode 31. This carrier is widely used for all industrial and consumer goods.  32. It is used currently in Belgium, Greece and Italy as a carrier for the serialisation number of medicinal products. Linear barcode readers are now present in almost every pharmacy in Europe. 33. There may be difficulties with regard to the amount of information that needs to be stored in this code (see point 2.1). This applies in particular in the case of small outer packagings.	Using linear barcode technology to carry all the required information (product code + pack serial number + batch number + expiry date) needed by wholesalers and pharmacists for traceability purposes (batch number and expiry date) will not be possible with a normal pack size (linear barcode would be too long). In addition, linear barcode is less robust than 2 D barcode (Data Matrix) which can be read in all positions and for which a Reed Solomon algorithm allow to retrieve all information when the code is partially damaged.

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	2.2.2. 2D-Barcode 34. This carrier is being used increasingly for industrial and consumer goods.  35. This carrier is able to carry a large number of data on a small label. However, many pharmacies in Europe are not currently equipped with a suitable reader to read a 2D barcode. 2.2.3. Radio-frequency identification (RFID) 36. RFID uses radio waves to exchange data between a reader and an electronic tag attached to an object. 37. RFID has been discussed in the context of the identification of pharmaceuticals. However, at present, it is relatively expensive in comparison with other carriers. Moreover, little is known about how the RFID technology may interfere with the quality of certain medicines.	2D Barcode (Data Matrix ECC200) is the preferred option as it can contain all the serialization and traceability information required in a 7 mm x 7 mm square code (product code, batch number, expiry date and serial number). It is the smallest code for a given quantity of information. In addition, Data Matrix is robustand can be printed with technologies already used within the pharma industry. It has been successfully implemented in different countries for traceability and/or serialization purposes: France, Korea, Turkey, and Sweden (for an EFPIA pilot in 2009/2010). Data Matrix has also been used successfully by IFAH to code all animal heath products. Data Matrix is cost competitive (1 to 2 euro cents per pack including associated infrastructure) RFID cannot be considered up to now as a universal track & trace technology (at pack level) in the pharmaceutical industry , both for technical and economic reasons: - Interference from metal and liquids which impact the read rate (< 100% in most of the cases) - compatibility with Biologicals (vaccines and biotech products) is not yet proven - Lack of harmonized standards in the world (Europe, US, Asia) - High cost: RFID passive tags cost = 20 to 40 euro cents (tag only without needed infrastructure). In addition, use of RFID can lead to privacy concerns due

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		to the possibility to read pack codes without requiring any line of sight (for example within a patient's bag). Finally, RFID tags can be easily destroyed (in microwave for example). So, usage of RFID would probably not prevent the need for an additional 2D barcode anyway.
B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY FEATURES		
C 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? 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	**1. Policy option n°2/1: Systematic check-out of the serialisation number at thedispensing point** 46. In this option the pack is checked out following the reading (scanning) of the serialisation number at the end of the supply chain i.e. by a retailer or a pharmacy, including a hospital pharmacy. In this policy option, the wholesale distributor is not required to check out or verify the serialisation number. 47. This policy option ensures that any medicinal product with security/safety issues is detected before it is dispensed to the patient. 48. Under this policy option the authenticity of the medicinal product is verified at a late stage in the distribution chain. If the serialisation number is copied several times, and subsequently channelled into the	In addition to community and hospital pharmacies, 2 additional dispensing points could be considered for a systematic verification of medicines: - Registered dispensing doctors, and - Registered on-line pharmacies (in countries where they are authorized). In addition to systematic verification of medicines at their point of dispensing, there should be a possibility to control medicines on an exceptional voluntary basis(in case of product return or suspicion of falsification for example) by authorized wholesalers or public Health authorities. Control of the original pack should also be mandatory for

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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.	distribution chain, packs with falsified medicines may circulate for months in the Union before they are detected. 49. In terms of costs, the following actors may have to be equipped with suitable reading systems: • Pharmacies, including hospital pharmacies; and • Retailers who dispense medicinal products which have to include the safety feature. **2. Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors** 50. In this policy option, in addition to the systematic check out at the point of dispensation, wholesale distributors perform random verifications of the serialisation number. 51. In this case the serialisation number can not be checked out by the wholesale distributor from the repositories system. 52. A verification of the serialisation number without check out provides only limited additional protection as it can not always detect duplicates of the serialization number. 53. On the other hand, it can be argued that, even if duplication of serialisation numbers cannot be always detected, this policy option is likely to be preventive and dissuasive, and therefore helps to protect against falsification of medicines in the distribution chain. 54. This policy option requires additional investments for wholesale distributors. It may delay the preparation of delivery orders.	re-packagers before conducting any repackaging activity on a pack. **Option n°2/2 is the preferred option .** In addition to systematic control at point of dispensing (by community and hospital pharmacies, …) it should be useful for authorized wholesalers to verify medicines which are returned to them , as well as products which they consider as suspicious. Wholesalers should therefore have a “Read Access” to the verification system for specific control purpose.

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	3. Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors 55. In this policy option, in addition to the systematic check out at the point of dispensation, each actor in the supply chain (i.e. all wholesale distributors) has to verify the individual pack. 56. As in policy option n°2/2, the serialisation number would not be checked out by the wholesale distributor from the repositories system. Therefore, the weakness of the checks in the distribution chain as set out above (point 2) remains. 57. However, this policy option does ensure the traceability of each individual pack. To date, traceability is usually ensured by referring only to the name of the medicinal product and the batch.26 This policy option would thus facilitate the recall of medicines, including individual packs, at any stage of the distribution chain. This policy option may also make it easier to trace back the trade flow of falsified medicines. 58. However, this policy option involves major additional operational costs, in particular for wholesalers. The systematic scanning of each pack will delay the preparation of the orders and this increases the human resources needed for these operators.	Systematic control of Serial Numbers at all levels of the supply chain requires that the manufacturer provides the "Parent-Child" relationship between all the logistic units to the wholesalers (who cannot open the pallets and cases to read each individual pack). Building a full aggregation between all logistic units of a batch is highly complex and costly. This aggregation process requires an investment 2.5 to 3 times greater than conducting a unique serialization of the packs alone. It can also significantly reduce the rate of production and it impacts all the distribution sites which need to update the hierarchy each time they modify a logistic unit (pallet or case). Considering the high level of complexity and investments as well as the running costs required from Stakeholders to run a full Track & Trace system, and comparing to the limited added value of the aggregation process in terms of patient security, the full Track & Trace option does not bring enough benefits compared to the high costs generated (very limited "Benefit/Cost" ratio).

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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).	**1. Policy option n°3/1 – 'stakeholder governance'** 61. Under this policy option the delegated act would define the objective to be achieved and the obligations on the relevant actors (manufacturers, wholesale distributors, pharmacists/retailers) and also set out the legal framework and limits (for example, the obligations to protect personal and commercial data). On the basis of these obligations, this policy option would leave it to the relevant actors to set up the appropriate infrastructure for the repositories system ('stakeholder governance'). 62. Thus, the delegated act would define only the key responsibilities, such as: • The manufacturer would be responsible for ensuring *inter alia*: - that the serialisation number is available for authenticity checks, while being secured against illegal infiltration (hacking); - that the response from the repositories system is delivered without delay; - that the serialisation number is checked out. • The person dispensing the medicinal product/wholesale distributor (see consultation topic n°3) would be responsible for ensuring *inter alia:* - that the serialisation number is verified (details depend on the choice made under consultation topic n°3); - that data enabling the medicinal product to be traced to the final dispensing point are not made available to the	**Stakeholder Governance Model is the preferred option.** This type of governance model is justified by the complexity of the supply chain operations and the proprietary and commercially sensitive nature of the serialization information and its respective controls (at point of dispense). All this information needs to be strictly under the stakeholders' control. This stakeholder governance model was tested successfully through a pilot project carried out in Sweden from September 2009 to February 2010. In order to manage reimbursement processes with the same technology as for traceability/serialization (serialized datamatrix), EAEPC, EFPIA, GIRP and PGEU are proposing a "stakeholders governance" model where manufacturers (including re-packagers) would upload serialization information of their products in a European Hub interconnected with interoperable national databases (also managed according to a "stakeholders governance" model). This would allow management of reimbursement processes, control/handling of repackaging as well as adaptation to supply chain countries specificities.

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	manufacturer (see point 4.1 in this consultation topic). 63. This policy option may be the most cost-efficient as it may create a market that provides best value for money. 64. This policy option may make it more difficult for Member States to use the information contained in the repositories system for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology. **2. Policy option n°3/2 – EU governance** 65. Policy option n°3/2 is a pan-European repositories system to which all actors are connected, and which is governed by an EU-body (Commission or EMA) ('EU governance'). 66. This system would provide a single point to check serialisation numbers in and out. To that extent, it can simplify processes. 67. However, the complexity of the system may be considerable: It would require a central repositories system storing all data from all actors in the supply chain, the simultaneous connection of thousands of actors at the same time, and the instantaneous authentication of individual packs. **3. Policy option n°3/3 – national governance** 68. This policy option is the establishment of a system 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	Member states should have access to the information, as needed. A European central and unique database would have the following disadvantages : - Longer response time due to the extremely high number of data coming from all European pharmacists (and distributors) -Impossibility to manage from one unique European database (and one technology) the reimbursement processes which are by essence nationally based. - A unique central system cannot take into account the specificities of all country-based national supply chains National governance (without European consolidation) would need to have interoperability between national databases for handling repackaging. This would make the

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	national bodies, established by each Member State ('national governance'). 69. The national databases would have to be interconnected in order to allow intra-Union trade. 70. The advantages of this policy options are that: • the number of actors linked to a national repositories system is limited. This might reduce the complexity of the system; • Member States can select the appropriate characteristics of the national repositories system in view of the national characteristics of the distribution chain. 71. However, the interconnection of systems run by national official bodies might present a challenge. Moreover, a manufacturer supplying medicines to various Member States would have to be connected to a multitude of national repositories.	system more complex and costly for manufacturers as they would have to interact with all national databases for uploading and decommissioning serial numbers (as compared to a unique interface with a European hub proposed in the EAEPC/EFPIA/GIRP/PGEU model). In addition, the proprietary and commercially sensitive nature of the data (points of sales, volumes, …) as well as the fact that repositories costs have to be borne by the relevant stakeholders justify the management of the verification system through a stakeholders governance model.
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?	**4.1. Information of a commercially sensitive nature** 73. The Commission is to take due account of the legitimate interests to protect information of a commercially confidential nature.31 In the context of a repositories system, the following information could be commercially sensitive: • Information that allows the number of packs manufactured to be established; • Information that allows the point of dispensation of a pack to be established;	Number of packs (volumes) sold at a specific point of dispensing is also a commercially sensitive information However, the repackaging operations and especially the link between serial numbers of original and repacked medicines should not be considered as confidential information and it should be made available to the original manufacturer for public health and patient safety reasons. It is highly important that the original MAH will

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	• Information that allows the point of re-packaging of a pack to be established.	be able to answer professional requests about the presence and validity of a product serial number in a specific country. This would not be possible if the original MAH is not aware of the repackaging operation.
Consultation item n°10 : Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?	**4.2. Protection of personal data** 75. The issue of protection of personal data is explicitly addressed in Directive 2011/62/EU.32 In any event, the repositories system would *not* contain personal data related to patients, as this is not necessary in order to fulfil the purpose of the unique identifier. **4.3. Re-packaging of medicinal products** 76. Article 47a of Directive 2001/83/EC addresses manufacturing activities where the safety features are removed or covered. It obliges *inter alia* the re-packager to replace the safety features with equivalent features. An equivalent safety feature is another unique identifier, which is checked into the repositories system and replaces the original unique identifier.	The European Medicines Verification System (EMVS) as proposed by EAEPC/EFPIA/GIRP and PGEU does not contain any personal data (no patient data, etc.). This is in full compliance with the requirements of the European Directive. EMVS would be a highly secured system and would permit to access system data under strict and defined conditions (i.e. serial numbers duplicate for alerts, correspondence between original and repacked products' serial numbers, existence of serial numbers in the database). The management principle is that all stakeholders having access to the system will own the product verification data they generate in interacting with the system. Re-packagers should be subject to the same obligations as original manufacturers (tamper evident packs and serialization). Link between Serial Numbers of repackaged products and Serial Numbers of original manufacturer packs is essential in order to guarantee patient

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		security/safety. This correspondence should be done "pool to pool" at batch fraction level when a "one to one " link (pack to pack) is not technically possible due to differences in countries packaging formats.
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?	**1. Identification criteria** 86. Directive 2011/62/EU leaves open the criteria for identifying medicinal products to be listed in the 'black list' and the 'white list' (hereafter 'identification criteria'). Four different approaches are put forward for discussion: • Identification by Anatomical Therapeutical Chemical Code (ATC): This criterion is easy to establish. However, taken on its own it may be insufficient, in view of the classification criteria set out above. • Identification by brand name: Apart from being a very narrow identification criterion, the main difficulty concerns the differing brand names of identical medicinal products in the EU. In addition, brand names may change. Lastly, there may be a variety of commercial reasons that militate against highlighting individual brands in a delegated act on falsified medicines. • Identification by the name of the active pharmaceutical ingredient:	In principle, all prescription medicines should be subject to the same level of security. Introducing safety features only on some medicines will simply move the threat to those non-protected, shifting rather than eliminating the problem. **In order to phase in the pack protection and the safety features deployment process, Sanofi favours a flexible case-by-case approach and would support a progressive extension to all prescription medicines over a 5-7 years period.** During this implementation phase, and in alignment with the EFPIA position, Sanofi favours an identification process based on Anatomical Therapeutic Chemical Code (ATC 4) in order to keep the exception list as small as possible and not to generally exclude huge amounts of prescription drugs from bearing safety

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<tr><td></td><td>The difficulty as set out above for the ATC also applies here.
• A flexible approach on a case-by-case basis: This leaves room for some flexibility. This flexibility would facilitate the application of the classification criteria set out above.</td><td>features.

The main criteria to consider for progressive deployment (priorities) , as proposed by the Commission, would be :
- Product volume and prices
- Previous incidents in the EU and third countries
- Characteristics of the products: risk of “off-label use “, innovative character of the medicine, short therapeutic window,…
- Severity of the conditions intended to be treated
- Other potential risks to public health</td></tr>
<tr><td>Consultation item n°12 :
Please comment on the quantified approach set out above.</td><td>2. Applying the classification criteria

87. In order to apply the classification criteria in Article 54a(2) of Directive 2001/83/EC consistently, a rough guide might be to adopt a quantified approach. The following should serve as an example of how such a quantified approach could be applied:

<table>
<tr><td>Criteria 1:</td><td>Price</td><td>High price: 5 points;
Low price: 1 point</td></tr>
<tr><td></td><td>Volume</td><td>Volume High volume: 5 points;
Low volume: 1 point</td></tr>
<tr><td>Criteria 2:</td><td>Incidents in the EU or third country</td><td>Several incidents: 5 points;
No incident: 1 point</td></tr>
<tr><td>Criteria 3:</td><td>Characteristic of the product</td><td>Characteristics indicate risk of falsification: 5 points;
Characteristics indicate no risk of falsification: 1 point</td></tr>
</table>
</td><td>Exceptions (prescriptions drugs on the white list) should be very limited (exceptional), which means that getting less than 6 points to be on the white list (for prescription medicines) should be very difficult. Sanofi agree with the goal of having all prescription medicines serialized.</td></tr>
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<tr><td>Criteria 4:</td><td>Severity of the conditions intended to be treated</td><td>Conditions severe: 5 points;
Conditions not severe: 1 point</td></tr>
<tr><td>Criteria 5:</td><td>Other potential risk to public health</td><td>Max. 5 points.</td></tr>
</table>

On the basis of this scheme, it would be considered that:

• A prescription medicine which has 6 points or less is listed in the 'white list';
• A non-prescription medicine which has more than 10 points is listed in the 'black list'.

88. An approach along these lines would remain within the logic of the legislation (see the introduction to this consultation topic), i.e. as a general rule, it would include prescription medicines in the scope, while excluding non-prescription medicines.</td><td></td></tr>
<tr><td colspan="3">E. CONSULTATION TOPIC N°5 - OTHER ISSUES</td></tr>
<tr><td>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.</td><td>1. Procedures for the notification of medicinal products from the national competent authorities to the Commission

89. The delegated act shall contain procedures for the notification to the Commission of those medicinal products which they judge to be at risk of falsification and those which they deem not to be at such risk, and a rapid system for evaluating and deciding on such notification.38</td><td>A minimum of 18 months would be needed for implementation of the safety features by manufacturers (after definition by the Commission of the “high risk” products to be protected).

Manufacturers should be able to decide to serialize a product when a rationale exists for it.</td></tr>
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Question	Policy option de référence	Sanofi Comments
:	**2. Date of application of the delegated act** 90. According to Article 2(2)(b) of Directive 2011/62/EU, the date of application of the delegated act is three years after the date of publication of the delegated act.39	OK – This timing is compatible with the implementation of the required technical measures (equipment of the packaging lines and construction of the information systems repositories).