BPI Bundesverband der Pharmazeutischen Industrie e.V.

Comments from German Pharmaceutical Industries Association on the 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

GENERAL COMMENTS

The German Pharmaceutical Industry Association wishes to express in general that it is important to restate the primary goal of the Directive: to combat falsification of medicinal products and to impede potential falsified medicines to reach patients via the licit or illicit supply chains.

In this light the legal supply chain and all of its parts have to be strengthened. We believe this important goal needs to be translated into measures which fulfil the primary objective of the legislation in a targeted and proportionate way.

Several points are, from our point of view, too premature to decide and are, unfortunately, not yet adequately addressed in the Concept Paper. These are, amongst others,:

- What are the consequences of the different prescription status in the different countries throughout the EU? Would it be enough to relief a drug from the burden of the Directive 2012/62/EC if its status is "OTC only" in one EU country? Or, would it fall under the Directive if it is "Rx" in only one of the EU member states?

- What happens if the turnover of one of the "Rx" drugs of a company is over/ below of the criteria mentioned in para 87, crit 1b), resulting in place in the white list? How often is this adjusted? Who will be responsible to receive this information? How will this information be supervised?

- How will any information of an alleged/ real falsification of a medicinal product be checked/ justified? And by whom? Does the EC plan to establish a Pan-European law enforcement agency for falsified drugs? How often will this panel meet and how/ by whom will its activities be monitored? Will the decisions of this panel/ board, as they will have a significant influence on the commercial fate of the medicinal product in question, be subject of administrative law? And if so, who will be in charge for this?

As these points will be crucial for the success of the Falsified Medicines Directive 2011/62/EU (FMD), we cannot see how the intention of the FMD will be accomplished without further clarification/ discussion of these points with the relevant stakeholders.

One of the major important issues is, from our point of view, the question in whose hands the responsibility for the safeguarding of the FMD and its measures lies – the MAH or the MAH? As this is a question of drug/ patient safety and the responsibility for this usually (and for good reasons) is in the hands of the Marketing Authorisation Holder (MAH) and is NOT the duty of the Manufacturing Authorisation Holder (MAH) we strongly ask that the Commission will thoroughly survey their approach in this respect. The proposal that a contract manufacturer without proprietary products/ marketing authorisations is obliged to finance parts of the repository system does not seem to be appropriate. But in item no. 60 of the concept paper it is stated that the costs of the repositories system shall be borne by the manufacturing authorisations holders of medicinal products bearing the safety features. The manufacturing authorisation holder, especially when he is only acting as contract manufacturer, will not be the addressee in the verification process. This is in any case the marketing authorisation holder, who is responsible for the product in the market. **Therefore only the marketing authorisation holder should be obliged to install a repositories system and should therefore bear the costs.**

To allow a better differentiation between the two abbreviations we suggest the introduction of the term "ManAH" (for Manufacturing Authorisation Holder) and leave "MAH" (for Marketing Authorisation Holder) as the latter is more widely used.

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GUIDELINE SECTION TITLE	
Line no. + paragraph no.	**Comment and Rationale**
Consultation item No 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? Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer/ Policy option n°1/2: Harmonisation through regulation?	The German Pharmaceutical Industry Association strongly recommends policy option n°1/ 2, harmonization through regulation. For a feasible and effective system throughout Europe it is necessary that the Commission defines the basic rules and procedures how this system should work. In this respect we suggest to use the variety of established and accepted technical standards (ISO and CEN) in this area. Speaking about harmonisation, it is necessary to review the different functional levels with their differing requirements. ▪ Harmonisation Level: Data for Verification: The verifiable data content, to be used in the databases, should be harmonised throughout Europe. ▪ Harmonisation Level: Syntax: The syntax to be used should be based on the international standard ISO / IEC 15 434 "Information technology - Automatic Identification and data capture techniques - Syntax for High-capacity ADC media". ▪ Harmonisation Level: Structure: Allow the use of standardised Application Identifier (AI) and Data Identifier (DI) with the associated system identifiers according to ISO / IEC 15418/ANSI MH10.8.2 "Information technology - Automatic identification and data capture techniques / Data Identifier and Application Identifier Standard" within the data carrier. ▪ Harmonisation Level: Data Carrier: The regulations should be based on the international ISO standards. ▪ Harmonisation in principle: Committing both Commission and stakeholders to the specification of just one commercial operator or user group leads to a distortion of competition. From our point of view, there is a certain difference between harmonisation (e.g. CEN- and ISO-standards) and organisations seeking a dominant position, potentially a monopoly. Critical are the use of: o Single proprietary specifications. o Specifications which promote the commercial interests of a service or a product. A major problem for a harmonised approach is, from our perspective, the prescription status of medicinal products in Europe that are regulated nationally but should be the basis for this European Delegated Act/ the Directive. This national prescription regulation would automatically lead to different requirements for the application of Unique Identifiers/ Tamper-evidence-devices in different countries and would thus result in a different level of protection for European citizens living in different European countries. Does the Commission plan to harmonise the prescription status of medicinal products throughout Europe in this context? And if so –what would be the legal basis for this action? Another crucial issue is the liaison of the two safety features: the Unique Identifier and the Tamper-Evidence-Device (more correctly the Tamper-Verification-Device as one cannot exactly proof the tampering of a pack). Both are only effective together. From this point of view we strongly suggest to stipulate their use only simultaneously. This is even more important as an actual Standardisation Procedure on CEN level on the subject of Tamper-Verification-Devices is currently pending. We do invite the Commission to join/ to follow the development in this Committee (CEN / TC 261/ SC05 / WG12 "Marking").

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Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1. Please comment.	As a general remark, the German Pharmaceutical Industry Association would like to draw the attention of the European Commission to a lack of clarity in the terminology “serialisation number” and “unique identifier". In several cases, the term “serialisation number” is used in the Draft Document when referring to the complete data content of the code, in other cases, serialisation number” is used where actually the term “unique identifier”, in the sense of a combination of „Product code“ and „Individual pack number“ is meant. In this context we suggest to distinguish it from other product groups like medical devices where the term “Unique device identifier (UDI)”is being used and introduce the term “unique medicinal product identifier (UMI)” when Medicinal products are concerned. We propose that this clarification should be incorporated in the Delegated Act. Furthermore, the corresponding terminology of the standards ISO/IEC 19762 Part 1 + 2 should be applied. The German Pharmaceutical Industry Association is very much in favor of the use of harmonized and internationally recognized standards for the identification of products and comments on the approach as set out in point 2.1.1. as follows: A country prefix is not necessary for verification. The reference is also potentially ambiguous and its definition inexplicit. What is meant - the country of manufacture or the country of sales? The international uniqueness of the product code is of paramount importance. The "Manufacturer product code" proposed is unnecessarily restrictive. Until now a "Manufacturer code” has not been established in Germany (or other countries like Austria, Belgium, France, Italy, Portugal and Spain). Such a code is therefore not easily applicable. The introduction of a new "Manufacturer product code" would add a high burden on Europe's healthcare system. Instead, there should be an internationally unique product code ideally generated by a national registry. Please note that the guidance document referred to in footnote 16 quotes the optional use of the GTIN as the product code from GS1. Commitment to the use of a fee-based use of a single (potentially monopoly) organization is for competitive reasons critical. The German Pharmaceutical Industry Association suggests a combination of a 12-digit national product number (that might also serve as a national reimbursement number in different European Countries for the unharmonised social systems in Europe) and a randomised 9-digit serial number that will give the companies enough real randomised serial numbers for a vast number of products. On the other hand, this will result in a rather small Data Matrix Code (if the Delegated Act will be in favor of this solution) that will be feasible even for companies distributing rather small packs, e.g. producers of eye-care products and others who will otherwise have great difficulties to bring this additional information on the folding box/ secondary packaging.
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.	As a principal remark, the German Pharmaceutical Industry Association would like to point out that machine-readable batch-number and expiry date have nothing to do at all with the target of the directive and the intention of the European Legislator, the fight against falsified medicines. According to all experts the serialization number in combination with a product number is enough to give every product a bijective marking. It might well be that the inclusion of batch number and expiry date will have logistical benefits and would make life easier for the partners in the legal supply chain but this is neither the object nor the intention of the Directive 2011/62/EU. Furthermore, as only a part of the products in the market will carry this information in a machine-readable manner and a vast number of products (many OTC- and some Rx- products) will not it is, therefore, not a standard for the supply chain in any case. On the other hand, the implementation of variable data would add another burden on the pharmaceutical industry as this leads inevitably to the need of "inline-printing", e.g. the printing of variable data during the process of packaging. With this requirement all packaging lines (our estimate is 1,500 lines in Europe) have to be equipped with printers and camera modules. As a result investments up to 120,000 € per line have to be made by pharmaceutical companies. Furthermore, indirect cost for pharmaceutical companies are caused by the resulting decrease of speed in the lines as even high-speed printing systems cannot print as fast as packaging lines nowadays work. Serious estimation assumes a decrease of speed up to 25% that will definitely create a significant cost increase. This should motivate the Commission to look for alternatives that allow industry to achieve the same amount of safety for patients at lower cost.

	One alternative would be the serialisation of packaging material at the premises of folding box manufacturers. As a result, all printing processes would stay where they belong and the printing quality would be much better and robust as the folding box manufacturer would print on the folding box before coating. Using these boxes the pharmaceutical companies will activate and validate the codes by reading them in-line on their machines. In the end, all verification problems within the supply chain caused by poor printing quality and/ or environmental conditions will be avoided. After all, wholesale distributors and pharmacists who wish to read the batch number and expiry date will be able to do so by using the link between serial numbers and batch number/ expiry date in the database. Recall procedures will also be possible using this link. As a result of this consideration German Pharmaceutical Industry Association strongly suggests that printing variable data on the outer packaging in a machine-readable way should only be carried out on a voluntary basis.
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 Germany, the product number for pharmaceuticals is the Central Pharma Number (PZN) which is allocated based on central registration by IFA (Informationsstelle für Arzneispezialitäten). The PZN serves for all logistic practices and is embedded into all IT systems and business processes. The allocation rules follow the specific characteristics of pharmaceuticals. In addition, the German reimbursement system requires the use of the PZN as anchored in legal statutes. Therefore, replacing the PZN as pointed out in option no. 1 would not be possible. The German Pharmaceutical Industry Association would also like to draw the attention of the Commission to the fact that die PZN is the only unique product number for pharmaceuticals in Germany due to the fact that it is centrally issued and registered by IFA. On the other hand, a parallel existence of two product identifications as pointed out in option no. 2 would increase both the complexity and risks associated with the ambiguous declaration of pharmaceuticals. The existence of two parallel product identities (new manufacturer product code and existing national product and reimbursement numbers) in the market would mean: ▪ Potential source of error through use of the wrong primary key. ▪ Two product identifier that follow different allocation rules. ▪ Additional costs of maintaining two product identifiers. ▪ Additional costs due to double license fees for the product codes. ▪ Potentially additional costs due to higher volume of data (increased code size). ▪ Potential error through inaccurate timing of synchronisation during the update of the product code. Regarding the consultation paper, both, options 1 and 2 have advantages and disadvantages, therefore both are not fully accommodating present needs. The German Pharmaceutical Industry Association supports the use of harmonised and internationally recognized ISO Standards for the identification of products. But instead of being replaced by a new manufacturer product number, existing national product numbers should be made globally unique and become applicable across Europe There do indeed exist several ways how national product numbers can be made globally unique/ bijective and can be used across Europe. IFA that serves as an ISO-certified issuing agency as well has already transformed the PZN into the globally unique PPN (Pharmacy Product Number). The PPN in combination with a unique identification number of the pack will be perfectly able to meet the verification requirements set out by the Commission.

<table>
<tr><th colspan="2">SPECIFIC COMMENTS ON TEXT, page 5 of 11</th></tr>
<tr><td></td><td>Therefore, German Pharmaceutical Industry Association recommends a third option where harmonisation would mean:

• Use of ISO Standards for the symbology of the pack code.

• Use of ISO Standards for syntax and structure of the content of the pack code

• The Pack Code consists out the following items:

1. Globally unique Manufacturer Product code, that includes national product and reimbursement numbers

2. Unique identification number with the pack (serial number)

<u>On a voluntary basis:</u>

3. Expiry date

4. Batch number</td></tr>
<tr><td>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</td><td>The German Pharmaceutical Industry Association supports a 2D-Bar Code holding the information related to each single pack (product code, a unique randomized serial number and, where necessary, the national product number as well as expiry date and batch number on a voluntary basis) as:

▪ It has the ability to store the information multiple times in the same code which allows a reading even if 25% of the code is damaged;

▪ It is applicable to small packs;

▪ It is widely used and thus tried-and-tested (the 2D Data Matrix has been an ISO standard for 12 years and is widely used globally);

▪ Manufacturers have wide experience of its use due to requirements in France, South Korea, Turkey and other countries;

▪ It is future proof.

Based on this analysis, the German Pharmaceutical Industry Association recommends a 2D barcode (Data Matrix Code) as the data carrier as the only reasonable technical solution. The Data Matrix Code has technical and economic advantages in comparison to the two other concepts and in our view should be used for serialisation of pharmaceutical products in Europe.

For the time being, the RFID chip might cause, amongst other things, several problems in the field of data protection, especially in a sensitive area like the health care system.</td></tr>
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for the different carriers; - costs for adapting packaging lines of medicines packaged for the EU market.	
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?	From the German Pharmaceutical Industry Association point of view there are several other points of dispensation to be considered, apart from pharmacies and licensed, legal internet pharmacies, Those might be: • Several points of dispense in the area of hospitals, even though we find it almost impossible to define each and every one of them separately. • GPs that are dispensing pharmaceutical products (like in Austria). • GPs that are applying Practitioner's samples to the patients. • Other places where commercial drugs are being sold (gas stations etc., where usually only OTC-drugs could be distributed – but what if an OTC-product will be on the black list – will they automatically banned from sales via non-pharmaceutical dispensing points?
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	1. Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point Systematic check-out of the serialisation number at the point of dispense is the only safe and secure way to protect patients from receiving falsified, expired or recalled medicines. It also fulfils the terms of the Directive to protect patients from receiving falsified medicines. Therefore, the German Pharmaceutical Industry Association endorse policy option n° 2/1, Point-of-Dispe nsing Verification by the pharmacist. Pharmacy level verification at the point of dispensing with an interface for wholesalers is a robust and cost-effective way to improve patient protection. Systems should be configured so that pharmacists can undertake checks at any point after receipt of goods, as well as performing the check-out operation at point of dispensing. The process of verification in the pharmacy should be virtually instantaneous in order to ensure efficient pharmacy workflow and avoid delays. In order to ensure that products are verified in one scanning action, verification software should be integrated with existing pharmacy software. <u>Other points of dispensation to consider - Check Out Rights</u> Once introduced into the System, products must subsequently be “checked out” (meaning that their serial numbers are to be decommissioned) by the relevant stakeholders.

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.	Check out rights should be provided for the following actors and scenarios: • By the pharmacists at the point of dispense, including legitimate internet pharmacies, hospital pharmacies; • By the parallel distributor engaged in repackaging. The pack should be checked out prior to repackaging and new serialised product codes applied and checked into the system. The old and new serialised numbers must be linked at the batch level in the database to enable the product to be tracked in case of recalls or other safety issues; • By the MAH (Marketing Authorisation Holder, see General Points of this Table of Comments) in the event of product returns, recalls, accidents, damaged products, the correction of uploading errors in the initial check in phase, unforeseen logistics adjustments, theft of serialisation numbers/packs; • By wholesalers in the event of (1) disposal due to damage or expiry, whether caused at the wholesaler's premises or returned as damaged by pharmacists, or (2) their export outside of the EEA/other participating countries. Unless every individual serialised pack is correctly "checked out" at one of the points listed above, patients will not benefit fully from the safety features. The unique serial number can only provide protection against falsified medicines if it is systematically checked out and the status changed on the database to "dispensed" when the product is handed to the patient or processed in repackaging. 2. Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors While we believe that policy option n°2/1 already s ufficiently protects patients from receiving falsified medicines, wholesalers should have unlimited "read" access to the repository for verification purposes. German Pharmaceutical Industry Association believes that a systematic check-out of the serialisation number at the dispensing point could be accompanied by an additional risk-based verification at the level of wholesale distributors. German Pharmaceutical Industry Association sees the risk-based verification of medicines as follows: For medicinal products carrying safety features obtained from (i) the ManAH[1] or a person who is authorised by the ManAH to supply these products, or (ii) the marketing authorisation holder or a person who is authorised by the marketing authorisation holder to supply those products, the wholesale distributor is deemed to have satisfied Article 80(a)(ca) of the Directive. Medicinal products carrying safety features on the outer packaging obtained from other authorised sources must be checked by the receiving wholesale distributor. Similarly, if medicinal products are returned from persons authorised or entitled to supply to the public, the wholesale distributor must verify that they are not falsified or tampered with by checking the safety features on the outer packaging. 3. Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors

[1]ManAH – Manufacturing Authorisation Holder(s) which term, for the purposes of this paper, includes both manufacturers and parallel distributors engaged in repackaging to the exclusion of contractors and subcontractors involved in the manufacturing process but not responsible for putting pharmaceutical products on the market. For the avoidance of doubt, a manufacturer engaging contractors or subcontractors to produce on its behalf shall be considered the ManAH.

	Systematic check-out of the serialisation numbers at the dispensing point with systematic verification by the wholesale distributors is not feasible for wholesale distributors in terms of costs and time effort associated with this policy option. We therefore strongly oppose systematic verification by wholesale distributors as suggested in policy option n° 2/3, as this is costly, disproportionate to the objectives of the Directive, and would provide no greater level of safety to patients than point of dispensing verification. In this respect, we welcome the fact that track-and-trace is at no point mentioned as a policy option in the Concept Paper. On the whole, the arising burdensome costs would stand against the principle of proportionality as mentioned in Article 54a n°2d that expressly refers to the fact that the European Commission must take account of the particular characteristics of the supply chains in Member States when determining the verification process. In principle, the German Pharmaceutical Industry Association underlines its opposition towards any sort of internet-based sale of commercial drugs. The free trade with these products in Europe is not as important as the protection of its citizens from falsified drugs. Jeopardizing the health of European citizens for the benefit of some internet companies or the comparably small saving an internet user might get by ordering pharmaceuticals through the internet is inappropriate from the German Pharmaceutical Industry Association's perspective. We have severe doubts that the safety measures introduced by the Commission Directive 2011/62 will change this situation sustainably as these measures will be subject and an easy victim to falsifications themselves.
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.	1. Policy Option 3/1 ‘stakeholder governance’. The German Pharmaceutical Industry Association supports policy option 3/1 ‘stakeholder governance’. *securPharm as a model for stakeholder governance* The German Pharmaceutical Industry Association, ABDA, BAH, PHAGRO and the vfa are jointly developing a model for a cost-effective and scalable product verification system in Germany named securPharm to be run by a stakeholder organisation on a non-profit basis. securPharm could serve as a model for implementing the Falsified Medicines Directive on national level. The system is developed in coordination with the European umbrella organisations of the German stakeholders, ensuring that both the national and the European approach are not in conflict and follow the same rules. It should be interoperable with a European Hub currently developed as the European Stakeholder Model (ESM) by EAEPC, EFPIA, GIRP and PGEU. Given that stakeholders will use and pay for the needed verification system, a stakeholder-governed system is the optimal approach to ensure patient safety in a cost-effective manner. It drives for cost-effectiveness which is necessary in the current economic climate, it ensures that it is the people who know the system best that deal with it and it is a consensus driven model as it includes all relevant partners in the pharmaceutical sector. One also has to bear in mind that a system like the planned one has to be functional and reliable 24 hours a day/ 7 days a week. The German Pharmaceutical Industry Association wonders if the Commission really wishes to take over this responsibility. *Design of securPharm* The aim of the project is to establish a system to optimize the protection of patients against falsified medicines by means of the identification of a randomized serial number with regard to the individual packaging of medicinal products and its verification against original data held available by the pharmaceutical entrepreneur. The serial number shall be coded in a Data-Matrix-Code together with the product number, as well as expiry date and batch number on a voluntary basis on the level of the individual package.

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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).	The verification should in principle follow the "end to end" approach, meaning that the pharmaceutical entrepreneur labels the packs accordingly while the verification and the registration of the dispensing to the patient takes place online in the pharmacy. Independently, wholesalers can verify products as well. securPharm is based on the principle of separate databases owned and run by the respective stakeholder. The contents and rules for the exchange of data between market partners as well as data storage and procedures for making public cases of falsifications, attempts of falsifications or other abnormalities are set by an "umbrella organization" which is jointly borne by all stakeholders. Importantly, and in line with the Falsified Medicine Directive, the development of securPharm will be linked with the government, public agencies and the European Commission. As a fundamental principle, a stakeholder governance model will always run in partnership with public authorities as well as all other relevant actors along the supply chain such as parallel traders. *Use of data by third parties* If the Commission would decide for a repository system developed and operated by one or more authorities the strict confidentiality of all data should be guaranteed and every access of third parties to the data must be recorded and communicated to the Marketing Authorisation Holder. The access to data by other parties than the stakeholders should be made liable to costs as third parties will benefit from this repository system at least as much as the stakeholders in the supply chain do.
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?	Protection and security of the data have the highest priority for the technical and organizational realization of the verification of medicinal products and are to be ensured by the stakeholders in their fields of responsibility. Data have to be protected against attacks by counterfeiters and hackers according to the state of technology. Regarding information of a commercially sensitive nature, the concept of separate databases guarantees that the stakeholders keep the access and sovereignty over their own data. They process and operate their respective areas themselves and keep all rights and duties of their own data pools. Manufacturers will receive no pharmacy-specific information on the inquiring pharmacy. The anonymity will be accordingly agreed by contract and guaranteed through technical measures. But also the turnover of a product in a certain market (as a characteristic for the qualification for the Black/ White List) shall be made available only to certain bodies and not to the public.
Consultation item n°10: Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?	The repacker/ re-importer should be made fully responsible for the safety and quality of all products introduced into the market under his name/ license.

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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?	The identification criteria introduced by the Commission seem to be appropriate but need further clarification and scrutiny. Further to our General Remarks the German Pharmaceutical Industry Association would like to raise the following issues: The risk of falsified medicinal products is in most of the cases directly proportionate to the price of the product. Therefore, we welcome the fact that the product price (preferably the ex-factory price as different taxation systems in Europe cause different end-prices for medicinal products) is one of the major criteria in the assessment of the risk of counterfeit. However, the price of 2 €uro seems too low to avoid the situation where large number of OTC-products with a comparably low price (but still above 2 €uro) and a high turnover will find themselves on the "Black List" causing a direct confrontation to the expressed will of the legislator not to soften the strict distinction between OTC-products that shall not bear the safety features and Rx-products that have to. The German Pharmaceutical Industry Association, therefore, suggests after a survey amongst our members to lift up the financial borderline to 50 €. Considering the turnover of a product as another "qualifying criterion" we kindly ask the Commission which turnover is meant here. There are three scenarios possible: i) The turnover in one country is the basis, e.g. every country decides separately whether or not a product in question would be a candidate for the Black/ White List. This seems to be appropriate since the prescription status is also regulated nationally (see above) and prices also differ from one country to another. But this would lead to nightmare of bureaucracy throughout Europe and does not exactly comply with the European Idea. ii) The turnover in those European countries where the product is being distributed is the basis for the Black/ White-List-considerations. iii) The world-wide turnover of a product is the basis for any decision concerning the Black/ White-List-considerations. This seems to be fair as any counterfeiting incident in Third Countries (e.g. wold-wide) is used for the assessment of the risk of counterfeit. But this approach collides significantly with the scope of a European Directive. The criteria "specific characteristic of the product" and "other potential risks to public health" are, for the time being, too imprecise to be discussed. The German Pharmaceutical Industry Association refers to the definition "Serious risk for public health" that is interpreted in different European countries (and Courts!) differently. As a major point, the German Pharmaceutical Industry Association advocates that all manufacturers who see the risk/ danger of falsification for their OTC-products should have the legal right to apply the safety features on the products in question. If the Commission Directive 2011/62/EU is successful, the focus of counterfeiters will (more or less automatically) move on to attractive OTC-products. Many of those may be covered by the Black List, but the individual experience of the manufacturers with their products as a basis for their risk assessment cannot and must not be ignored. Therefore, the use of the suggested catalogue of criteria and the risk assessment by the MAH should both be the basis whether or not a product should bear the safety features and use the/ pay for the repository system. The precautionary protection of patients from potentially falsified medicines by their manufacturers is a benefit for all participants in the market and should be welcomed by everyone. On the other hand, if the Commission would bar the MAH from using of the safety features and a falsification of the product in question would emerge the Commission would be held fully responsible for any damage at the patient's side. As for the Identification criteria cited in para 86 the German Pharmaceutical Industry Association is very much in favor of solution (4), the flexible approach on a case-by-case basis, because too many of the criteria in question are differently pronounced in the different member states.

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Consultation item n°12: Please comment on the quantified approach set out above.	As this quantified approach is, according to the Concept Paper, only a "rough guide" we kindly ask the Commission for further elaboration and consultation. For the time being, we have severe doubts that this marking grid will cover all situations/ circumstances. Amongst other things the question arises why products with a very low turnover earn any point at all. Furthermore, a more detailed ranking scale might be advisable (1 to 5 instead of 1 or 5).

As of 27th April 2012