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Public consultation on the

DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE AND ITS VERIFICATION

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Comments of the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)

The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE, www.eucope.org) was founded to promote companies and associations active in research, development, production and distribution of pharmaceutical products and enhance their scientific, technical, economic and legal objectives. Via the member associations (the German Pharmaceutical Industry Association (BPI), the Ethical Medicines Industry Group (EMIG) of the UK, the German Biotech association BioDeutschland as well as the Swedish associations of mid-sized innovative companies IML and SwedenBIO) EUCOPE represents more than 900 mid-sized innovative member companies, many of them SMEs. In addition, many innovative companies from Sweden, UK, France, Bulgaria, Italy, Greece, Germany, the Netherlands and Austria are represented on the board of the association.

I. General findings

EUCOPE supports the European Union and other international initiatives in their fight against counterfeit and falsified medicines. Thus, EUCOPE members are investing in the German pilot project securPharm to test an end-to-end verification of medicine packages at the dispensing point in the pharmacy.[1] For the implementation of the EU Directive the main German stakeholders agreed to develop and implement a concept in Germany aiming at the verification of the packaging of medicinal products using a Data-Matrix Code. The verification system prevents falsified medicines from entering the supply chain and safeguards patients from receiving falsified medicines.

[1] See www.securPharm.de.

EUCOPE welcomes measures to increase patient safety – but underlines that the threat to patients does not come from non-prescription (OTC), generic or other low risk medicinal products where no incidents of falsification have been found in the EU legal supply chain. We would like to stress that the scope of counterfeiting in medicines is like in any other sector (such as clothing or electronics) driven by price and demand. The European Commission in its own impact assessment pointed out that no cases of falsified OTC or generic medicines were found. Directive 2011/62/EU on falsified medicines therefore rightfully focuses on other than those medicines.

Producers of OTC, generic and other low priced medicines are raising concerns about the huge cost implications of new anti-counterfeiting technologies that will be required as a result of the delegated acts foreseen in this Directive. EUCOPE stresses that an obligatory introduction of safety features and the need to run repository systems for low risk medicines is contrary to the principle of cost-effectiveness and proportionality, as there are no incidents of falsified versions of these products reported in the EU legal supply chain.

Directive 2011/62/EU explicitly provides for a risk based assessment regarding which products should be subject to mandatory safety features and indicates that special attention should be given to low risk products. OTCs are even generally excluded from the scope of the measure. EUCOPE stresses that the delegated acts must clearly reflect this aspect of the legislation.

We would like to quote the Commission's Impact Assessment stating that "SME are going to profit from the possibility of pursuing a risk-adopted approach. Therefore, it can be expected that both OTC manufacturers and generic manufacturers, who form the larger share of SME-manufacturers in the pharmaceutical sector, are less affected by compliance cost." We appreciate the concept paper of the European Commission but we see the need for an adapted approach to reflect market realities and the scope of the Directive. This includes a viable risk-based assessment.

Financial resources of manufacturers of products which are not at risk of falsification / counterfeit could be far better used elsewhere either in developing new formulations or indications of existing products or for increasing the EU competitiveness.

In the EU, approx. **30% of manufacturers of prescription medicines fall within the definition of SME** (Commission Impact Assessment, SEC(2008)2674, p. 70). It is therefore crucial that the needs of SMEs are adequately taken into account in the delegated acts.

We would like to highlight some aspects of particular relevance and comment on the particular consultation items in more detail below.

1. **Need for a viable risk-based approach for prescription medicines (Rx)**

This concerns above all a **viable risk-based approach** which provides a **realistic chance** for prescription medicinal products with a low price and a low risk to be excluded from the obligation to bear the safety features under the conditions foreseen in Art. 54a (2) of Directive 2011/62/EU. The Commission consultation paper sets out that for 5 of the 6 categories foreseen in the Directive (1. Price, 2. Volume, 3. Incidents in the EU or third country, 4 Characteristic of the product and 5. Severity of the conditions intended to be treated) the medicinal product automatically receives at

least 1 point - even if no previous cases of falsification exist. This means that each product automatically gets 5 points while only products with 6 points or less are eligible for the exemption via the white list. Therefore, it would be **de facto almost impossible for prescription medicinal products to be exempted via the white list**.

We see an urgent need to significantly raise the number of points in order to allow for an exception which is foreseen in Directive 2011/62/EU.

2. Mandatory safety features for OTCs must remain an exception

Furthermore, the point system must be adapted in a way to ensure that the underlying principle of Directive 2011/62/EU whereafter non-prescription medicinal products are generally excluded is respected. For this reason the number of points which leads to an inclusion in the so-called "black list" must be raised significantly. The delegated acts must clearly reflect the principle that only by way of exception OTCs have to bear the safety features.

In this context it has to be borne in mind that even the Commission stated in its own Impact Assessment that no cases of falsified OTC medicinal products were found in the EU legal supply chain.

However, there is no reason that manufacturers of non-prescription medicinal products should be prevented from applying safety features as a precautionary measure. This contradicts the very purpose of patient protection.

3. Who bears the costs of the safety features and the repository system?

In item no. 60 of the concept paper it is stated that the costs of the repositories system shall be borne by the manufacturing authorization holders of medicinal products bearing the safety features. But the manufacturing authorization holder, especially when he only is acting as contract manufacturer, will not be the addressee in the verification process. It is in any case the marketing authorization holder, who is responsible for placing the product on the market. Therefore only the marketing authorization holder will be obliged to install a repositories system and should therefore bear the costs. The proposal that a contract manufacturer without proprietary products/ marketing authorizations is obliged to finance parts of the repository system does not seem to be appropriate. Even though the English version of the Directive also points to the manufacturing authorization holder in Art. 54 (2) (e) we consider this as an unintended confusion of terms since this does not reflect the responsibilities foreseen in Directive 2001/83/EC for the labeling and for the release of the product on the market.

II. CONSULTATION TOPIC N°1 - Characteristics and technical specifications of the unique identifier

Consultation item n° 1 – Harmonization and flexibility

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?

Given the complexity of serialization systems and to ensure interoperability between national systems it is important to operate with **clear and reliable standards**. Therefore, EUCOPE believes that **harmonization** in regard to the characteristics and technical specifications of the unique identifier is **absolutely necessary** to avoid a 'patchwork' across Europe as the Commission also pointed out in the consultation paper (para. 17). EUCOPE 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 principle rules and procedures on how this system should work. In this respect we suggest to use the variety of established technical standards (ISO and CEN) in this area.

As regards harmonization, it is necessary to review the different functional levels with their differing requirements.

- Harmonization Level: Data for Verification

The verifiable data content, to be used in the databases, should be harmonized throughout Europe.

- Harmonization 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".

- Harmonization Level: Structure

Allow the use of standardized 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.

- Harmonization Level: Data Carrier

The regulations should be based on the international ISO standards.

- Harmonization overall

Committing to the specification of just one commercial operator or user group leads to a distortion of competition. Critical are the use of:

- Single proprietary specifications.
- Specifications which promote the commercial interests of a service or a product.

Consultation item n° 2 – Manufacturer product code and pack number

Consultation item n° 2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.

EUCOPE is very much in favor of the use of harmonized and internationally recognized standards for the identification of products but 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.

It is also important to 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 (monopoly) organization is for competitive reasons critical.

EUCOPE further suggests a combination of a 12-digit national product number (that might also serve as a national reimbursement number in Member States for the unharmonized social systems in Europe) and a randomized 9-digit serial number that will give companies enough real randomized serial numbers for a vast number of products. In addition, this will result in a rather small Data Matrix Code 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 – Additional product information

Consultation item n° 3: Where do you see the advantages and disadvantages of the approach set out in point 2.1.2.? Please comment.

In our view the inclusion of **additional product information** such as batch number or expiry date **should not be mandatory**.

Firstly, the Directive 2001/83/EC does not require additional information. It is clearly pointed out in recital no. 11 of the Directive 2011/62/EU that the "safety features should allow verification of the

authenticity and identification of individual packs". The inclusion of the batch number and the expiry date is not foreseen in the Directive and would not increase patient safety.

Secondly, the inclusion of batch number and expiry date could prevent that pharmaceutical companies have the possibility to outsource the production of packages to carton manufacturers. This reduces the flexibility for pharmaceutical companies, especially if they only have a small portfolio of prescription medicines. Many mid-sized companies are mainly active in OTC markets and are thus generally not concerned by the safety features. They would have to make significant changes in the production line and bear high costs while only a minor part of their product portfolio is concerned by the safety features.

Considering the fact that Art. 54a (2) (a) (2) of Directive 2011/62/EU[2] states that "when establishing the safety features due consideration shall be given to their cost-effectiveness", in our view a mandatory inclusion of the expiry date and the batch number would neither be in line with the principle of cost-effectiveness nor serve as a benefit for patient safety. As a result of this consideration EUCOPE strongly suggests that printing variable data on the outer packaging in a machine-readable way should only be carried out on a voluntary basis.

A further disadvantage of the expiry date and the batch number is that, since packs would still need to retain human-readable batch number and expiry date for the end-user, inclusion of the same data in the serialization number would also require an additional reconciliation step in the filling/packaging line, to ensure integrity of the information. In addition, it would not be possible to include batch number/expiry date information in the aggregate serialization numbers applied to mixed pallet loads due to the variety of products on the load with different batch numbers/expiry dates. In the USA the recommendation is not to include batch number/expiry date in the serialization number, since 1) this information is already included in the label under FDA regulations, 2) the serialization number can be linked to databases containing this information and 3) inclusion of this information unnecessarily increases the length of and introduces complexity into the Data Matrix Code.

Consultation item n° 4 – National reimbursement number

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 the advantages and disadvantages? Please comment.

Firstly, we would like to point to the fact that not all countries use reimbursement numbers and not all products that are deemed to require the unique identifier (ref. Consultation Topic No. 40) may be reimbursed – or they may be reimbursed in some countries but not in others.

EUCOPE supports the use of harmonized 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.

[2] See also Art. 54 a (3) (d) of Directive 2011/62/EU.

There do indeed exist several ways in which national product numbers can be made globally unique and can be used across Europe. IFA that serves as an ISO-certified issuing agency for Germany has already transformed the PZN (Pharmazentralnummer) into the globally unique PPN (Pharmacy Product Number). The PPN in combination with a unique identification number of the pack meets the verification requirements set out by the Commission.

Therefore, EUCOPE recommends a third option including the following:

- 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 of 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

Consultation item n° 5 – 2D-Barcode

Consultation item n° 5: Please comment on the three concepts described under point 2.2. Where do you see benefits and disadvantages of each of the three concepts? What are the costs of each concept? Please quantify your reply, wherever possible, by listing examples:
-costs for reading devices for different carriers;
-costs for adapting packaging lines of medicine packaged for the EU market.

The **2D-Barcode** seems to be **the most realistic and cost-effective option** because 2D-Barcodes are already widely used in the pharmaceutical industry (e.g. France) and allow to carry a large number of data on a small label which gives a great amount of flexibility for future developments. They are / were used in the pilot projects in Sweden and the German securPharm (www.securPharm.de) project. When setting the specifications (e.g. size) the need of small packages should be taken into account.

The 2D-Barcode offers the following advantages:

- 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;
- The concept allows for future developments.

EUCOPE considers RFID not an option because of the higher costs, data security issues and the technical imperfections. RFID would be expensive because a micro-chip would have to be embedded in the pack. RFID may be useful for higher levels of aggregation (e.g. pallets), but not at the carton level.

III. CONSULTATION TOPIC N° 2 - Modalities for verifying the safety features

Consultation item n° 6 – Other points of dispensing

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 the policy options?

Systematic check-out of the serialization number at the point of dispense is the safest way to protect patients from receiving falsified medicines. Therefore EUCOPE strongly favors policy option 2/1 and 2/2. Pharmacy level verification at the point of dispensing with an interface for wholesalers is a robust way to improve patient protection.

Once introduced into the System, products must subsequently be "checked out" (meaning that their serial numbers are to be decommissioned) by the relevant stakeholders.

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 serialized product codes applied and checked into the system. The old and new serialized 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 Authorization 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 serialization numbers/packs;
- By wholesalers in the event of their export outside of the EEA/other participating countries.

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.

Through the amendments set out in Directive 2011/62/EU no obligation for pharmacists to scan and verify medicinal products is foreseen. This should be clarified in the delegated act.

Consultation item n° 7 – Verification by pharmacies/retailers only

Consultation item n° 7: Please comment on the three policy options set out in points 1 and 3. Where do you see benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible.
This applies particular to the:

- number of wholesale distribution plants;

- costs of adapting such plants;

- duration of scanning of the serialisation number;

- number of pharmacies, including hospital pharmacies;

- number of medical products dispensed by pharmacies and hospital pharmacy.

EUCOPE is in favor of a verification system that foresees checks at the dispensing point (i.e. pharmacies/retailers). The end-to-end verification, as described in Policy option 2/1 seems to be the most suitable way to achieve an effective and cost-efficient verification system and is sufficient to achieve the goal of Directive 2011/62/EU which focuses on patient safety. Even if a serialization number is copied several times and thus the falsified packs might "circulate for months in the Union" as the Commission suspects, the packs will not reach the patient and thus cause harm if a robust system at the dispensing point is in place.

Even though additional (randomized or systematic) verification on wholesaler level does not present much added value as mentioned in the Commission concept paper, policy option 2/2 can be supported since falsified medicines can be detected at an earlier stage in the supply chain.

Option 2/3 is not favored by EUCOPE as it would increase costs significantly and would slow down supply of medicines.

IV. CONSULTATION TOPIC N°3 – Provisions on the establishment, management and accessibility of the repositories system

Consultation items n° 8 – Stakeholder governance

Consultation items n° 8: Please comment on the three policy options set out in points 1 and 3. Where do you see 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 repositories system. Where possible, please provide information of past experiences with a repositories system at individual company level and national level (taking into account the experiences of Member States and companies.

EUCOPE strongly advocates a system with **stakeholder governance** under the condition that all stakeholders which were represented in the Commission stakeholder meetings are equally represented as full members in the stakeholder governance board.

The stakeholders have the only experience when it comes to the supply chain which is highly complex and technical. Industry – by contrast to other systems – has gained practical experiences through existing systems and pilot projects whereas this would be a whole new process for most authorities. It is also unclear who would bear the responsibility for the functioning of the system and the supply of medicines to patients if authorities would run the system.

Furthermore, according to Art. 54a (2) (e) of Directive 2001/83/EC the costs of the repositories system shall be borne by the stakeholders. This clearly indicates a legislative intent to shift the responsibility to the stakeholders. Another advantage – as the Commission already outlined in the concept paper – would be the favorable cost-effectiveness of a "stakeholder"-system (see also Art. 54a (3) (d) of Directive 2001/83/EC).

If a stakeholder model is adopted, the Delegated Act should allow a plurality of providers of stakeholder models to ensure competition and decrease the price of the repositories. Companies should also be able to run their own system. Whatever system is adopted, EUCOPE suggests that the division of costs should be proportionate.

Consultation item n° 9 and 10 – Data protection and Re-packaging

Consultation item n° 9: Please comment on point 4.1. Are there other items of information which should be taken in consideration when addressing the issue of commercially sensitive information in the delegated act?
Consultation item n° 10: Please comment on point 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

From the perspective of data protection it has to be underlined again that **it is essential that the system ensures data security**.

Data security has the highest priority for the technical and organizational realization of the verification of medicinal products and has to be ensured by the stakeholders in their fields of responsibility.

The serial number itself is highly sensitive especially in the context of re-packaging. It should be the **re-packagers' responsibility to check out a pack's serial number and to check in a new serial number with equivalent features**. This responsibility of the re-packager should be clarified in the delegated acts. The old and new serialized 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

In this context the **Commission** also **needs to clarify their "definition" of an equivalent safety feature**. The definition given in the concept paper (para. 76) focuses merely on the "procedural" steps of replacing the safety features.

IV. 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, an in the case of non-prescription medicines shall bear the safety features

Consultation items n° 11 and 12 – Procedural aspects, "optional scope" regarding the "black list", adequate name for the lists etc.

Consultation item n° 11: Which approach seems the most possible from your view? Can you think of arguments other than those set out above? Can you think about other identification criteria to be considered?
Consultation item n° 12: Please comment on the quantified approach set out above.

Directive 2011/62/EU explicitly provides for a risk based assessment regarding which products should be subject to mandatory safety features and indicates that special attention should be given to low risk products. OTCs are even generally excluded from the scope of the measure. EUCOPE stresses that the delegated acts must clearly reflect this aspect of the legislation.

In this regard the Commission's Impact Assessment should also be borne in mind stating that "SME are going to profit from the possibility of pursuing a risk-adopted approach. Therefore, it can be expected that both OTC manufacturers and generic manufacturers, who form the larger share of SME-manufacturers in the pharmaceutical sector, are less affected by compliance cost."[3]

In the light of legal certainty pharmaceutical companies need to foresee early whether their product will have to bear the safety feature or not. Any unclarity cannot be justified because companies are required to undertake major (costly) technical changes in their production lines in order to equip the packages with the safety features.

EUCOPE underlines that it is necessary to **establish an efficient, transparent and timely procedure** for drafting and amending the lists.

Such a procedure has to meet constitutional principles, which are based on the Treaties of the European Union. Therefore, **procedural rights should be granted** to the concerned pharmaceutical company such as consultation rights, the right to access files, the obligation to state reasons and the right for legal protection. Moreover, timelines for the decision should be considered. In this respect we would like to refer also to Art. 15 – 19 of Regulation (EC) No 1924/2006 on nutrition and health claims. These articles lay down a complex procedure for applications for certain claims.

[3] Commission Impact Assessment, p. 70.

Art. 54a (2) (b) of Directive 2001/83/EC provides for the possibility to list product categories which could be placed on the "white" or "black" lists. To assess different kinds of product categories would be a way – which is already foreseen in the Directive 2011/62/EU – that would reduce the number of decisions significantly. This would be a practical working modus since decision-making on the individual level of products could generate similar problems to those which can be observed in the field of assessing the scientific evidence submitted for substantiation of health claims under Regulation (EC) No 1924/2006 on nutrition and health claims on foods by EFSA.

Since the national competent authorities notify the Commission of products which they judge to be at risk / not at risk of falsification (Art. 54a (4) of Directive 2011/62/EU) and the Commission has to react to this notification, **EUCOPE assesses that this procedure might in numerous cases take a lot of time due to the workload.** It should be secured that this decision involves the person who is informed best about a certain product at stake, the pharmaceutical company. Therefore, it needs to be ensured that **a right for a pharmaceutical company to apply for a "listing / delisting"** on the "white" and the "black" list exists. The decision on these applications needs to be taken quickly since the practical implementation of a listing is time consuming and costly at the level of production. Thus, **strict timelines need to be established**.

Furthermore, we would like to point out that the lists themselves are an essential part of Directive 2011/62/EU. In this context, Art. 290 TFEU sets clear boundaries to the powers of the Commission with regards to delegated acts:

"A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act. (…)" The "quantified approach" that is described in the concept paper would lead to the consequence that it is **de facto impossible to be included in the "white list"**. In other words: An approach which practically renders the white-list-exemption useless constitutes a significant change of the legal provisions which is – in EUCOPE's view – not in line with Art. 290 TFEU.

The proposal set out in the concept paper contradicts the system foreseen in Directive 2011/62/EU. **The points which are decisive for the list position (6 for Rx / 10 for OTC) in combination with the automatic allocation of 5 points (1 point per 5 of the 6 categories) would mean in practice that the "white list" would remain empty and the "black list" could contain nearly all non-prescription products.** Art. 54 a (2) stipulates that the white list has to be established according to the risk of the products and not merely on the basis of the prescription status and that for OTC products the obligation to bear safety features remains an "exception". In order to comply with the system foreseen in Directive 2011/62/EU the number of points has to be significantly raised. EUCOPE suggests that prescription medicinal products with less than 15 points should be included in the white list and that the inclusion in the "black list" should be reserved for OTCs with 20 or more points.

In the context of the criteria for establishing the lists we would also urge the Commission to **reconsider the idea that a manufacturer's gross price of more than 2 EUR could be considered as a "high price"**. In EUCOPE's view a price of 2 EUR does not allow for a proper differentiation between different medicinal products. In this case, more than 90 percent of the

medicinal products would have to be considered expensive which is not reflecting market realities. EUCOPE suggests a price of 50 EUR.

With regard to the "black list" we would like to highlight that neither Directive 2011/62/EU nor Directive 2001/83/EC forbid applying **safety features on a voluntary basis in case of OTCs**. Much rather, the provisions set minimum standards for the application of the safety features. Neither does the concept paper contain a justification. However, an **"optional scope"** for manufacturers, in the form that the manufacturers of OTCs (which are not listed) may decide to apply the unique identifier to their medicinal products, **would promote to aim of patient safety**.

Last but not least, we think that the lists should also be named adequately. The **name "black list" could be misleading for patients** and would not reflect the fact that those medicines are even safer for them. This might lead to **compliance problems**. EUCOPE proposes a name like "'list of non-prescription products with safety features' (OTC-list)".

V. CONSULTATION TOPIC N° 5 – Other Issues

Consultation item n° 13: Please raise any other issues or comment you would wish to make which has not been addressed in the consultation items above.

Responsibility regarding the costs of the repositories system (manufacturer vs. marketing authorization holder)

In item no. 60 of the concept paper it is stated that the costs of the repositories system shall be borne by the manufacturing authorizations holders of medicinal products bearing the safety features. But the manufacturing authorization holder, especially when he only is acting as contract manufacturer, will not be the addressee in the verification process. This is in any case the marketing authorization holder, who is responsible for placing the product on the market. Therefore only the marketing authorization holder will be obliged to install a repositories system and should therefore bear the costs. The proposal that a contract manufacturer without proprietary products/ marketing authorizations is obliged to finance parts of the repository system does not seem to be appropriate. Even though the English version of the Directive also points to the manufacturing authorization holder in Art. 54 (2) (e) we consider this as an unintended confusion of terms since this does not reflect the responsibilities foreseen in Directive 2001/83/EC for the labeling and for the release of the product on the market.

EUCOPE proposes a change in the wording of Art. 54a (2) (e) (2) of Directive 2001/83/EC. It should be clarified that the marketing authorization holder should bear the costs.

In our view this change can be made via the delegated act. In this respect we would like to refer to the Communication from the Commission to the European Parliament and the Council regarding the Implementation of Article 290 of the Treaty on the Functioning of the European Union (COM(2009) 673 final). There (p. 4) the Commission states clearly “that by using the verb ‘amend’ the authors of the new Treaty wanted to cover hypothetical cases in which the Commission is empowered formally to amend a basic instrument. Such a formal amendment might relate to the text of one or more articles in the enacting terms or to the text of an annex that legally forms part of the legislative instrument.” Since this would not change an essential part of the Directive the Commission is empowered to carry out this change in the framework of Art. 290 TFEU.

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