AESEG COMMENTS ON THE CONCEPT PAPER ON THE DELEGATED ACT FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION.

AESEG'S COMMENTS ON THE CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION ON THE DELEGATED ACTS RELATED TO THE FALSIFIED MEDICINES DIRECTIVE AND ON A VERIFICATION SYSTEM OF PHARMACEUTICAL PRODUCTS IN EUROPE

27 APRIL 2012

AESEG - Asociación Española de Medicamentos Genéricos
Velázquez, 54 – 3ª - 28001 - Madrid – España - **T.** 91 572 12 62 - **F.** 91 571 34 20 - www.aeseg.es

Contents

1. Introduction

AESEG is the official representative body of the generic and biosimilar pharmaceutical industry in Spain, representing 96% of the Spanish generic market in value. Any pharmaceutical company manufacturing raw materials and pharmaceutical active substances as well as technological development companies that focus activities on generic medicines in Spain can be a member of AESEG. AESEG is the main association that represents the generic medicine sector before Public Administrations and professional groups (doctors and pharmacists) to guarantee the correct development of generic medicines within a consistent regulatory and legal framework. One of the foundational aims of AESEG is to establish a strategy to help its members comply with deontological and health regulations.

AESEG has a double aim: to support the recognition of the role of generic medicines as a saving mechanism for the budget of the Spanish Health System and, at the same time, to develop a friendly culture for the generic medicines in Spain.

AESEG supports the European Union and other international initiatives in their fight against counterfeit and falsified medicines. However the Directive 2011/62/EU aims only to prevent falsified medicines from entering the legal supply chain[1] whilst the real public health problem and threat to patients lies in falsified and counterfeit medicines being dispensed through illegal channels. Moreover there are no exact figures available on falsified medicines in the legal supply chain[2], and there is frequent confusion between the reporting of falsified medicines, counterfeit medicines, and unlicensed products.

The scope of falsification and counterfeiting in other sectors (such as clothing, electronics) is proven to be a problem that is driven by price and demand[3], especially targeting well-known brands. The same drivers have been identified in the health sector, for example a Pfizer-sponsored study[4] demonstrated that the counterfeit medicines market (which is almost exclusively via the internet) is dominated by so-called "lifestyle" medicines and most are counterfeit versions of well-known erectile dysfunction and weight loss products, followed by oncology and influenza[5].

In contrast to this, there are no reports of counterfeit generic medicines in the EU at all and especially not in the legal supply chain. Generic medicines

[1] recital 29 – Directive 2011/62/EU
[2] See Annex 1: Parliamentary questions (14 December 2011)
[3] OECD, "The Economic Impact of Counterfeiting and Piracy"
[4] Nunwood survey data November 2009. Online consumer survey, participants 14,000 in 14 countries
[5] WHO – fact sheet N° 275

should even be considered as preventing the falsification of medicines as they trigger competition, resulting in lower prices, and fragmenting the market into multisource volumes, which are unattractive for counterfeiters.

Consequently, AESEG supported the adoption of Directive 2011/62/EU as it pursued a risk-based approach to identify products that are at high-risk of being falsified which would require them to be subject to safety features and its verification process. Moreover the co-legislators recognised the low risk of generic medicines being falsified and expressed this in recital 11: *"The scope of these safety features should take due account of the particularities of certain medicinal products or categories of medicinal products, such as generic medicinal products. Medicinal products subject to prescription should as a general rule bear the safety features. However, in view of the risk of falsification and the risk arising from falsification of medicinal products or categories of medicinal products there should be the possibility to exclude certain medicinal products or categories of medicinal products subject to prescription from the requirement to bear the safety features by way of a delegated act, following a risk assessment."*[6]

Paragraph 9 of the Commission's concept paper states the obligation that all medicinal products should in principle be obliged to bear the safety features. To ensure complying with this principle in a cost-effective and cost-proportionate way, products at risk of being falsified should be defined using a robust weighted risk assessment[7] that can ensure a rapid evaluation[8] of the products that are judged by the national competent authorities[9] to be at risk or not at risk of falsification.

It should be stressed that any introduction of expensive safety features for low cost medicines while there are no incidents of falsified products reported in the EU legal supply chain is contrary to the principle of cost-effectiveness and proportionality. Moreover it would place an unjustifiable burden on the sustainability of an industry which is a corner stone of healthcare provision in Europe.

AESEG has calculated that the implementation costs for the EU generic industry could reach:

- € 1 billion

  In addition to this, the costs for running repository systems in the EU for the verification of authenticity of generic medicines would be an additional:

[6] Recital 11 - Directive 2011/62/EU
[7] Article 54a(2)(b) - Directive 2011/62/EU
[8] Article 54a(2)(c) - Directive 2011/62/EU
[9] Article 54a(4) - Directive 2011/62/EU

- € 200,000,000 / year.

  Taking into account the costs of these investments above and the fact that the life-span of the additional hardware on the production line is only 5 years, the overall costs would be € 500 million per year for the EU generics industry.

  As the generic medicines industry is highly cost-sensitive where API supply and manufacturing alone can account for over 50% of the total cost of a product, the introduction of regulations affecting production costs has a major impact on the overall sustainability of the industry. Such a significant increase in relative production costs for generic medicines especially puts at risk small and medium sized companies. The EGA also stresses that the application of anti-tampering features requires unprecedented and substantial changes in the production process of all pharmaceutical manufacturers, not only involving costs but significant time delays with risks of medicines shortage. All this reduces patient access to affordable treatment as portfolios of many companies may be reduced. Costs may even be passed on to consumers and payers, which is unethical in times of crisis where there is a high demand for affordable medicines.

  Furthermore, the generic medicines industry represents 50% of the medicines that are dispensed in the EU while only using 18% of the total pharmaceutical budget. If safety features applied to all prescription medicines in the EU, the Commission would fail to apply the principles of proportionality and cost-effectiveness. This is because it would result in the unjustifiable and contradictory situation of generic producers of low-cost, low-risk, affordable medicines subsidising 50% of the cost of the systems to the benefit of producers of higher priced patented products who benefit from over 80% of the value of the pharmaceutical budget and whose products are the target of counterfeiting.

  It has come to our attention that the implementation of the 2D-matrix barcode, and the information within it, is in the interest of a number of stakeholders. However, in the case of extending the scope of the Directive from *falsified medicines* to *improvement of supply chain, distribution and inventory management, facilitating recalls on a batch level, improving pharmacovigilance processes and controlling national reimbursement*, the EGA stresses that these additional objectives can be achieved by introducing specific coding on the outer package of the medicinal product but do not require the implementation of very costly anti-tampering features and repository systems. The necessary features for these two different objectives should not be confused.

Therefore we would propose that the delegated act applies

a) A robust weighted risk assessment to identify high risk products, taking into account the intentions of the co-legislators as indicated in Recital 11, especially regarding generic medicines.

b) A cost-effective and cost-proportional solution to prevent falsified items of these high risk products from entering the supply chain.

2. AESEG's Views on the Consultation Items

1. 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?

AESEG sees the need for a proper set-up of a system which is inter-operable, where the technical characteristics of the carrier are harmonised and are in line with Directive 2011/62/EU which is to act proportionally and cost-effectively according to the risk assessment (Article 54a(2)(a) - Directive 2011/62/EU). Cost-effectiveness means that the requirements of the amending Directive are met with a system that is the best value for money. Paragraph 4 of the concept paper explains that the Commission is required to carry out an impact assessment with regard to the characteristics of the unique identifier, the detailed procedures for verification, and the repositories system. In this context, the Commission has to assess the costs, benefits and cost-effectiveness.

2. Consultation item N°2

Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.? Please comment.

Whilst there is a need for a regulated harmonisation of the technical characteristics of the carrier to ensure inter-operability in the EU, the composition of the serial number should not be harmonised through regulation but should be adjustable to national requirements. Different standards of product coding are used at national level (e.g. PZN in Germany, CNK in Belgium, and GS1 in France). An open code will be required to make the system cost-effective and has no effect on the inter-operability of the system.

Adding a unique identification number to the pack will only be required in case a pack requires identification for authenticity i.e. a high risk product. In the case of extending the scope of the Directive for reimbursement and pharmacovigilance purposes, there is in fact no need for expensive anti-

tampering features and an expensive repository system. Including a unique identification number beside the manufacturer product code should suffice.

3. 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.

Including a batch number and expiry date in a barcode so it can be machine-readable are not required in order to make a pack uniquely identifiable and are therefore not needed to comply with the scope of the Directive.

Including a batch number in addition to the manufacturer product code could improve inventory, supply chain and distribution management and it can facilitate recalls on a batch-level. However there is no need for expensive anti-tampering features and expensive repository systems to achieve this objective and it is out of the scope of the Directive.

Including an expiry date beside the manufacturer product code would be of interest to improve inventory management and to prevent the pharmacist from dispensing expired products. Again, there is no need for expensive anti-tampering features and expensive repository systems to achieve this objective and it is out of the scope of the Directive.

All codes should remain physically readable on the outer package, in case of illegibility of the barcode, and for patients to be able to read this information (especially the expiry date) at home.

AESEG, together with the EGA calculated that printing the expiry date and batch number online (during the production process) would represent an additional cost for small and medium sized manufacturers. For small sized batch productions, it is more cost-effective to have barcodes (including only a product code with or without a unique identification number) pre-printed by the carton-box manufacturer. The EGA considers that cost-proportionality should also be taken into account as these additional costs will have a greater impact on smaller companies than on larger ones.

4. 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.

AESEG considers that a manufacturer product code and a unique serialisation code will provide a unique number; the requirement for a reimbursement code also foresees the need for a unique number. But as we consider that the carrier of the code information should be harmonised in the EU and not the content, a Member State can select which code can be used for reimbursement control if applicable. As mentioned above, in case of extending the scope of the Directive for reimbursement purposes, there is no need for expensive anti-tampering features and an expensive repository system.

5. 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.

AESEG considers it is sufficient to have a linear barcode to be in line with the scope of the Directive. The product code and serialisation number can be printed into a linear code. A linear code is also widely used, such as in the food industry. Current scanners used in pharmacies are able to read linear barcodes. If additional information is printed in the code, 2D-matrix barcoding will be required.

AESEG considers RFID is not an option because of the higher costs and the technical imperfections. RFID will also not increase patient safety.

AESEG, together with the EGA has performed cost calculations, based on information received from different hardware and software providers, to implement the new features and verified these with its members. Depending on the European Commissions' interpretation of the Directive 2011/83/EU these will have a different impact for the manufacturing authorisation holders. Small manufacturers will have proportionally higher costs than larger manufacturers. The following calculations are based on the generic medicines industry in the EU that provides 10 billion packs per year. It is assumed that the life-span of a manufacturing line is 5 years.

- Implementation costs for adapting packaging lines for harmonizing an EU carrier of codes to 2D-matrix barcodes + adapting software to upload codes to repository systems + adapting packaging lines to implement anti-tampering features:
  - € 1 billion
- Verification costs generic industry (if not cost-proportionate):
  - € 200 million / year

Taking into account the costs of these investments and the fact that the life-span of the additional hardware on the production line is only 5 years, the overall costs would be € 500 million per year for the EU generics industry.

6. 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?

As discussed in the concept paper, paragraph 38, the concept of a unique identifier to verify the authenticity of medicinal products only works if there is a reliable verification system in place. According to the Directive, safety features must enable wholesale distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product, and identify individual packs (Directive 2011/62/EU - Article 54o). When harmonising the technical characteristics of the carrier (e.g. a 2D-matrix code), traders, wholesaler, re-packagers and pharmacists will be able to scan all medicinal products and collect the information that the code contains. Also the products that will be assessed as being high risk products can be verified for authenticity with the repository and falsified products can be detected.

Directive 2011/62/EU already includes an obligation for re-packagers (such as parallel traders) to verify the safety feature (Article 47a(1)(a) - Directive 2001/83/EC). For other actors in the supply chain, the detailed procedures for verification are to be established in the delegated act (Article 54a(2)(d) - Directive 2001/83/EC) following an impact assessment (Article 4(b) - Directive 2011/62/EU). The Commission is placed under an obligation, when establishing those modalities, to take into account the particular characteristics of the supply chain in Member States and the need to ensure that the impact of the verification measures on particular actors in the supply chain is proportionate. The obligation of a systematic check-out of the serialisation number of a product that is assessed as being a high risk product, at the dispensing point, is not described in the Directive 2011/62/EU since the regulations concerning the scanning of products are addressed in national regulations. If products are not checked-out at the point of dispensing, the EGA would like to point out to the Commission that this is an important failure of the effectiveness of the system. Policy option n°2/1 is thus not in line with the amending Directive which does not provide the obligation for the pharmacist to check every pack dispensed if it carries a safety feature.

Besides pharmacists, the EU has other dispensing points of medicines that are not taken into account. Doctors will also require the possibility to dispense products as they have an inventory of lifesaving products as well as company samples. In some EU countries, the dispensing of non-prescription drugs is also allowed by internet pharmacies, home-care services, drug stores, para-pharmacies, normal retail stores and even petrol stations. These will also be points of dispensing and the authenticity of products that are at high risk of being falsified will also need to verified.

7. 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 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.

If a high risk product could only be verified for authenticity at a late stage in the distribution chain, the serialisation number can be copied several times, and subsequently channeled into the distribution chain. As a result packs with falsified medicines may circulate for months in the Union before they are detected.

As described in the Directive 2011/62/EU, the implementation of the delegated act should be in accordance with the principle of proportionality set out in Article 5 of the Treaty on European Union: the Directive does not go beyond what is necessary in order to achieve its objective (Recital 33 – Directive 2011/62/EU). The objective of the directive is specifically to prevent falsified medicinal products from entering the legal supply chain (Recital 29 – Directive 2011/62/EU).

To ensure that this can be done proportionately, without involving major costs for the stakeholders, the EGA stresses again that a robust weighted risk assessment should be in place to identify products that are at high risk of being falsified. The additional cost for the wholesale distributors depends on the number of medicines that are at risk of falsification according to the risk assessment.

In response to the questions from the European Commission, AESEG estimates that there are 6,000 wholesale distribution licenses and 140,000 retail pharmacies in the EU that ensure the trading and dispensing of 18 billion prescription medicines per year. In order to prevent falsified medicines from entering the legal supply chain, taking into account proportionality and cost-effectiveness, the focus of the Delegated Act should be on the products that are at high risk of being falsified. If only the high-risk products require verification of authenticity with the repository systems, the duration of scanning for wholesalers and pharmacists will decrease significantly, reducing the risk for system down-times and burdens for the distribution of medicines to patients. The expected response times are less than a second.

Paragraph 57 of the concept paper describes the option of traceability for each individual pack in order to facilitate recalls. The obligation for 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 suffices to facilitate recalls at batch level and provides the possibility to trace back the trade flow. For recalls on batch level, no systematic verification of high-risk products is required to ensure traceability. As mentioned before, there is no need for expensive anti-tampering features and an expensive repository system to achieve this objective and it is out of the scope of the Directive.

8. 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).

AESEG has no preference for a specific model for running repository systems as this will be highly dependent on the number of products that will be assessed as being high risk.

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 and small and medium sized companies will need to be taken into account if a pan-European system is presented as being the best solution. A pan-European hub

would increase the costs for these companies, as they might only operate in few countries. If however a robust weighted risk assessment identifies the products that are at risk of being falsified, one single European database will be sufficient for verifying products for authenticity.

Whatever system is adopted, AESEG strongly believes that the division of costs should be proportionate and relative according to the price of the products. Lower priced products should contribute in a relative way compared to high priced products.

As almost all data processed during the verification process is confidential or considered trade secret each stakeholder, it is in the interest of every individual stakeholder to make the system as secure as possible against hacking and misuse of data. Thus the requirement of the Directive for data protection and confidentiality of data is best met (Article 54a(3)(b), Article 54a(3)(c) – Directive 2011/62/EU).

9. 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?

AESEG agrees with the Commissions' interpretation that the scope of the Directive 2011/62/EU should remain focused on the prevention of falsified items of high-risk products from entering the legal supply chain and that the setting up of repository systems could provide information of a sensitive nature. For purposes outside the scope of the Falsified Medicines Directive such as reimbursement purposes, pharmacovigilance and pharmacoepidemiology data which are of interest for Member States, there is no need for expensive anti-tampering features and expensive repository systems and these objectives can be reached without putting a burden on the generic medicines industry.

10. Consultation item n°10

Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

AESEG agrees with Article 54a(3)(a) of the Directive 2011/62/EU concerning the protection of personal data.

11. 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?

In the legal supply chain, there are in fact very few problems of medicines being falsified, the exception being highly priced and branded patented products. Patented products are being counterfeited as a response to their brand popularity and are therefore at risk, while generic names (INN's) are usually not known at all. For example, for one of the most falsified products for erectile dysfunction only very few people would know the generic name of the product. In addition, as generic medicines trigger competition, resulting in lower prices, and fragment the market into multisource volumes they are unattractive for counterfeiters. Generic medicines could even be considered as helping to prevent the falsification of medicines in the legal supply chain, but there have not been a sufficient number of analyses that have been carried out prior to publishing the amending Directive and concept paper.

The Directive requires the Commission to put a rapid system in place in order to evaluate and decide upon notifications from national competent authorities on products at risk. When a rapid system is in place it can easily react to changing risk evaluations for certain products and for newly requested marketing authorisations (Article 54a(2)(c) - Directive 2011/62/EU).

AESEG would like to propose a risk assessment approach which incorporates a weighting in order to identify all high-risk products that should bear safety features; a weighting is a value given to a risk factor according to how high it is perceived to be, or how significantly it contributes to the overall risk rating: the higher the risk-factor, the greater the weighting. Previous incidents of falsification and price should be taken into account as the most important and highest weighted risk factors. The only objective for counterfeiters is high profit; high priced products should therefore be considered in the Delegated Act as those priced at €100 or more (ex-manufacturers' gross price, excluding V.A.T.) as proposed by the Ministry of Health of a Member State. This approach will focus efforts on the fight against counterfeiting where there are in fact risks i.e. with lifestyle drugs and expensive branded patented medicines (Article 54a(2)(b) - Directive 2011/62/EU).

AESEG stresses that the risk assessment as described in the concept paper is not in line with the amending Directive 2011/62/EU. In paragraph 84, the concept paper states that "The possibility of exemptions from the general principle laid

down by the legislation should be interpreted narrowly. It should not be used as an opportunity to dilute the general principle that all prescription medicines shall bear the safety feature while non-prescription medicines shall not bear the safety features". The Directive should be applied in line with its wording and follow the processes set out. This clearly does not allow scope being "narrow" which prejudges these issues prior to implementation and the following of relevant processes. This is an unreasonable and unsustainable interpretation of the provisions of the amending Directive 2011/62/EU. Article 54a makes clear that the safety features shall be required to be applied only on the basis of an assessment of "the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products", as the Commission has acknowledged in paragraph 82.

AESEG stresses the fact that generic medicines should be seen as a product category and they should be taken into account as being low-risk products for falsification when developing a "white list" (recital 11 – Directive 2011/62/EU). Generic medicines should even be considered as preventing the falsification of medicines as they trigger competition, resulting in lower prices, and fragmenting the market into multisource volumes making it unattractive for counterfeiters.

Paragraph 85 states that "A manufacturer cannot decide to apply the unique identifier to medicinal products which do not fall within the scope of the safety feature". The Commission makes no justification for this, and there is apparently no such prohibition in the amending Directive 2011/62/EU or Directive 2001/83/EC, which appears to set minimum standards in accordance with its major Treaty Base of Article 95 (now Article 114 of the TFEU). It is open, therefore, for manufacturers to apply the safety features even if not required to do so.

In paragraph 86, the Concept paper debates whether the "medicinal products or product categories" to be placed on the white or black lists should be defined by ATC, brand name, name of the active pharmaceutical ingredient, or by taking a flexible approach on a case-by-case basis. We note that "medicinal product" is defined in Directive 2001/83/EC as a "substance" which is given a name as part of its marketing authorisation. "Product category" is not defined, but it is clear from Recital 11 that generic medicines are a category envisaged by the amending Directive 2011/62/EU. Defining the black or white lists by ATC does not meet the terms of the amending Directive. Following this reasoning, medicines should be identified by invented name or marketing authorisation.

12. Consultation item n°12

Please comment on the quantified approach set out above.

With regard to the Commissions' proposed risk assessment in the concept paper AESEG stresses that the application of the proposed risk-assessment will identify every medicinal product being considered a high-risk product; The identification of products of € 2 being "high-price" products bears no reflection on current or future market realities and the allocation of the proposed point system appears to be designed in order to include all medicinal products and it therefore fails to identify products that are at low or at high risk and it is therefore not a risk assessment.

AESEG considers that the approach for quantification of the classification criteria should be weighted in the following order of importance (see Figure 1: Weighted Risk Assessment):

1. Frequency or previous incidents of medicinal products found falsified in the legal supply chain: If a product has been found counterfeited, this is the highest weighted risk factor.
    a) High risk: counterfeits reported in the EU legal supply chain
    b) Medium risk: counterfeits reported in other highly regulated countries in the legal supply chain
    c) Low risk: counterfeits reported in third countries in the legal supply chain
    d) No risk: no counterfeits reported

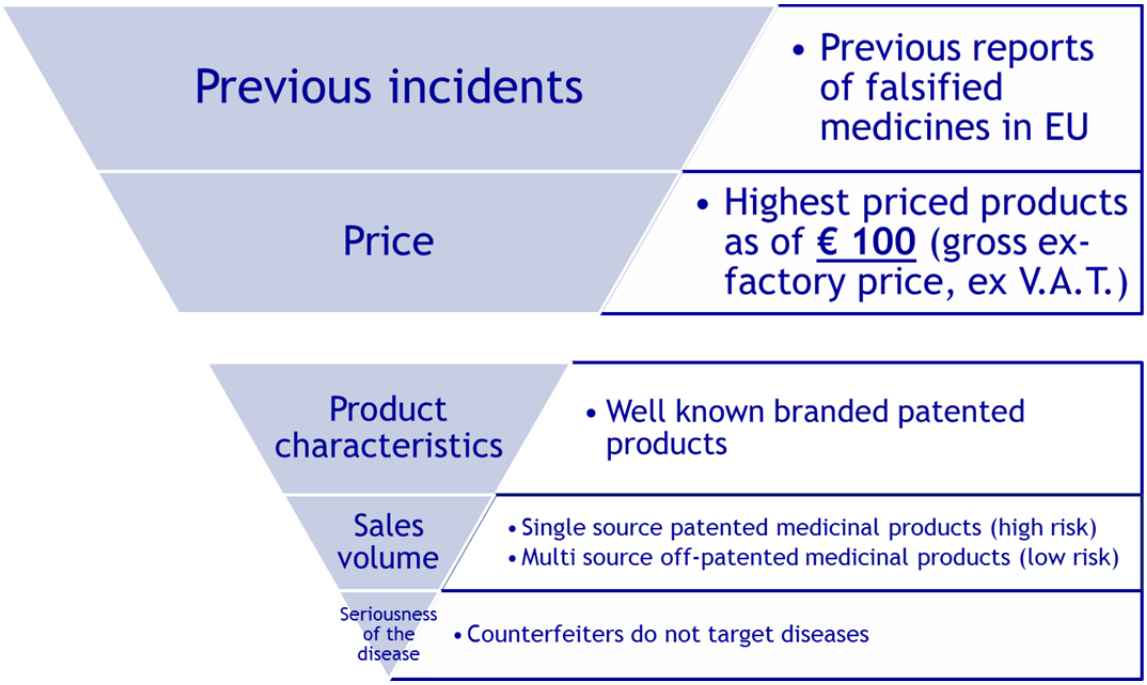

Figure 1: Weighted Risk Assessment

2. Price: Counterfeiting is mostly driven by price. See below (Figure 2: Products & Prices) a table of products that have been found counterfeited. The EGA therefore considers products below € 2 as low priced and € 100 as highest priced products.

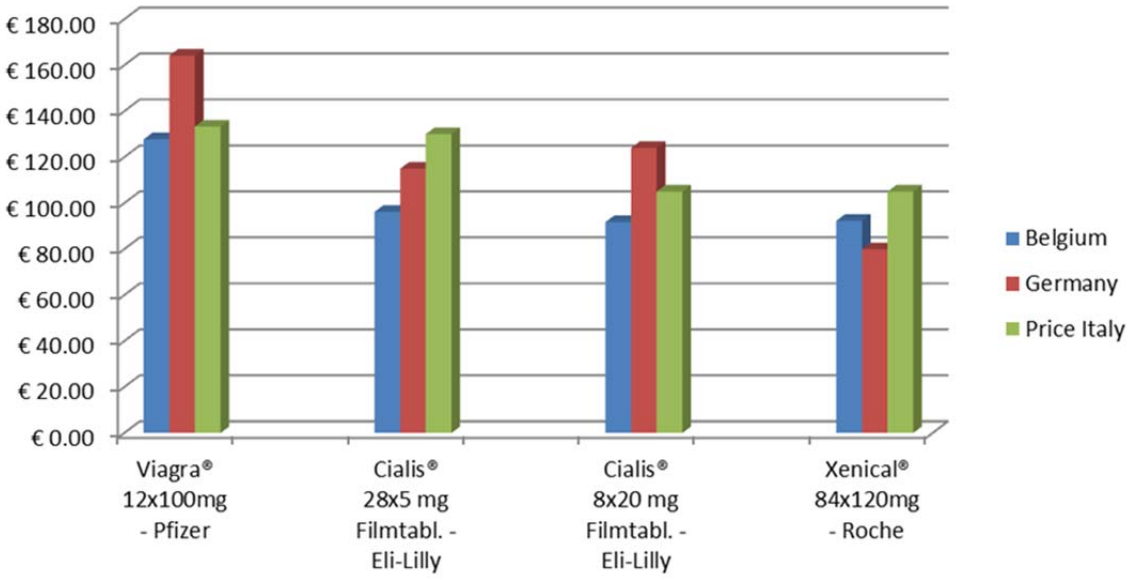

Figure 2: Products & Prices

3. Product characteristics: Well-known branded patented products are at a higher risk of being counterfeited. At the time of writing, evidence again shows that counterfeiters are targeting high-priced branded patented products. For example in the USA, recently more counterfeits are found of Avastin[10®]

4. Sales volume
   a) Single source patented medicinal products are high risk
   b) Multi-source off-patent medicinal products are low risk

5. Seriousness of the disease: this is not a driver for counterfeiters however for matters of patient safety, lifesaving products should be graded the highest.

As the concept paper points out in paragraph 6: since the impact assessment for the proposal for Directive 2011/62/EU, the figures may now be partially outdated, the EGA would like to confirm that still no falsified generic medicines have been found in the EU legal supply chain. The difference between falsified medicines and IP infringement also needs to be noted.

13. 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.

In order to carry out a cost-effectiveness study, the Commission should in its preparations of the delegated act, carry out a clear and detailed analysis of the main driving forces of counterfeits in the legal supply chain, define the weak points where counterfeit medicines enter the legal supply chain, and identify the type and number of products found falsified in the EU legal supply chain. The original impact assessment failed to do this and the response by Commissioner Dalli to the Parliamentary question clearly indicates that there is a critical lack of information. The Commission should not undertake major regulatory provisions with significant costs to be borne by stakeholders and healthcare systems without first assessing the cause and nature of any problem (see Annex 1: Parliamentary questions (14 December 2011)).

[10] http://in.reuters.com/article/2012/04/04/avastin-fake-idINDEE8330EU20120404

3. Annex 1: Parliamentary questions (14 December 2011)

Question for written answer to the Commission

Subject: Application of the Amending Directive 2011/62/EU on the Community code relating to medicinal products for human use

In order for policymakers to get a better understanding of the application of Directive 2011/62/EU on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, could the European Commission provide up-to-date information on the numbers of medicines being falsified in the last five years, both in terms of total volume and also brand of product?

- Could the Commission complement its response by answering the following questions:
- How many of these seized falsified products were found via the Internet?
- What is the estimated number of falsified medicines offered for sale on the Internet?
- What is the ratio of the number of seized falsified medicines found via the Internet to the total of seized falsified medicines?
- How many cases of falsified medicines were found in the illegal supply chain?
- How many falsified medicines were found in the legal supply chain?
- For falsified medicines found in the legal supply chain, can the Commission say which stages of the supply chain have been mostly affected?
- What is the ratio of the number of falsified medicines in the legal supply chain to the number of falsified medicines in the illegal supply chain?
- Could the Commission provide a full list of medicines which have been falsified, including brand names and their therapeutic class? Could the Commission provide the number of falsifications per product found per annum?
- Could the Commission provide a comparison between the number of brand medicines and generic medicines that have been falsified in the legal supply chain?
- In addition, and in order to facilitate the implementation of Directive 2011/62/EU on the Community code relating to medicinal products for human use, has the Commission undertaken a detailed analysis of the key drivers of the counterfeiting of medicines? Where are the weak points of entry of these products?

Answers given by Mr. Dalli on behalf of the Commission

The most recent information available to the Commission and the latest analysis undertaken are contained in the Commission impact assessment report of 2008 which was published alongside the Commission proposal for Directive 2011/62/EU.

Regarding the third question, there is no estimated number available. According to the World Health Organisation, in over 50 % of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be falsified.

The current availability of precise data on falsified medicines is limited, as falsification is illegal and traceability and identification of packages was difficult. In response, the directive foresees that five years after the adoption of the delegated act setting out a unique identifier for medicinal products, the Commission will submit a report to the Parliament and to the Council. This report will include, where possible quantitative data, of the trends in the falsification of medicinal products in terms of: categories of medicinal products affected, distribution channels including Internet sales, the Member States concerned, the nature of the falsifications, and the regions of provenance of these products.