Pro Generika e.V.,
German Association of Generic Manufacturers,

Comments on

European Commission´s

Concept Paper on

Delegated Acts on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use and its Verification

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Introduction

Pro Generika fully supports the objective to prevent falsified medicines from being handed out to patients to avoid any potential damage to health.

All statistics show that falsified medicines are a rapidly growing problem world-wide and also in Europe. The report by the EU Commissioner for Taxation and Customs published in 2010 shows that the number of confiscations of mailings following illegal online sales tripled in 2010 compared to 2009. The EU's customs statistics for 2010 show 1,800 cases of confiscation at the EU's external borders involving approx. 3.2 million falsified medicines of an estimated original value of 26.6 million Euros. The estimated number of unreported cases is much higher.

Thus all players in the German health system are warning against purchasing medicines from illicit sources over the Internet.

However one has to be aware of the fact that **falsification in the legal supply chain** – and this is the only channel the Directive is aiming at - is **insignificant**.

Around 761 million packs of Rx-medicinal products were sold by German pharmacies[1] in 2011. In total, including OTC and averaged packages dispensed by hospital pharmacies, German pharmacies dispensed 1.630.000.000 packages that year.

The **German Federal Criminal Police Office** (BKA) worked on 40 cases of falsification in the German legal supply chain between 1996 and 2008. Since then 6 cases connected with the legal supply chain are under investigation.

According to BKA most of the discovered falsifications in the legal supply chain are illegal imports in forged packages. None of them was a total falsification. That means that all fakes had original ingredients. Known up to now none of the falsified products in the legal supply chain cost less than 350 Euros and none of them was a generic medicinal product.

Thus **generics** should be exempted as a category of medicinal products with possible exceptions at high priced generics or such that are otherwise at risk of falsification.

So far any evidence-based information on the issue of falsifications in the legal supply chain is missing as becomes apparent in the response by Commissioner Dalli to a Parliamentarian Question. To not spend money at the wrong end which would eventually impact the already tight budgets of national health care systems the products that will be marked with safety features must be evaluated in a thorough and evidence-based risk assessment. As the Directive provides an adaptive system by introducing a rapid mechanism it can be adjusted if necessary. In this respect the EU-legislator is asked to put economic burdens on EU-industry only to the extent it is necessary and useful.

For the then included products the **verification system** should be as cost-effective as possible and the costs of the system should be divided in proportion to the **value of**

[1] ABDA, Die Apotheke, Zahlen, Daten, Fakten 2011

sales of the products concerned.

Pro Generika strongly feels that much more effort has to be made on awareness-building among the patients on the great risks of obtaining medicinal products via illicit channels in the internet in order to effectively prevent falsifications reaching the patients (Recital 26 of the Directive).

In detail:

Introduction A 10. - Tamper Verification Feature

The approach to leave the technical specification of the Tamper Verification Feature to the manufacturer is welcomed and in line with the Directive. The tamper verification feature is costly to a major extent. It should be apparent that the purpose of this feature is to provide a visual or other indication that a finished product has been tampered with.

A. Consultation Topic No 1: Characteristics and Technical Specification of the Unique Identifier

General remark

The use of the terms "Serialisation Number" , "Unique identifier" and "Product Code" should be consistent in future. It should be differentiated that the "Serialisation Number" is the serialised number generated for each individual pack whereas the "Product Code" is a unique (reimbursement-) number for each product. The combination of the serialization number and the product (reimbursement) code forms the "Unique Identifier" which makes every pack unique. The expression "Manufacturer Product Code" is misleading. There are many countries, such as Germany, Austria, Belgium, France, Italy, Portugal and Spain, where there is no manufacturer product code in the sense used in the Concept Paper. It should be made clear that this expression refers to a "product code" that is generated either by the manufacturer or by a national registry. Usually it is the reimbursement code.

Consultation item No. 1: Harmonisation versus Leaving the Choice

One should refrain from committing the specification to only one commercial or non-commercial provider as this will lead to a distortion of competition and might be legally challenged. Today´s existing standards such as the German PZN (made usable for international purposes as PPN) and for example GS1 can easily interact. It is not necessary to allow only one standard. Nevertheless the syntax of the data and their structure can be harmonized in order to ensure interoperability across EU Member States.

Pro Generika thus agrees that there should be a certain level of harmonization by legislation. Harmonization should allow future developments so that the necessary heavy investments needed for implementing the verification system will not be made obsolete by legislative developments to come.

Consultation item No 2: Manufacturer product code and pack number

Pro Generika considers that there is no "manufacturer product code" as such and that such a code does not need to be implemented in order to comply with the Directive in

a cost-efficient way. Above the level of fragmentation there is no need for a harmonization of the used product code. It is sufficient to operate with an **open standard** for a worldwide unique "product code" retaining the existing product code systems.

Technical experts have confirmed that the **interoperability of standards** can easily be generated with costs far lower than the costs of changing the whole systematics. That means that as long as the coding structure of the different systems is similar and the country of origin is recognizable in this structure the interoperability and, thus, the security of the verification system is given. In Germany the product code PZN is used for reimbursement purposes; it is possible to transform this number into an internationally recognizable code, so that the PPN can be integrated into an open standard system without effort.

It should not be part of harmonisation that a country prefix is to be used. This term is ambiguous and misleading as technical specification. The only purpose that the product code (referred to in the Concept Paper as the "Manufacturer Product Code") has to serve in respect of the FMD is– in combination with the serialization number (referred to as the "Unique identification number") – to make the package uniquely identifiable.

In this context it should be stressed that there should be **no legal endorsement of a single provider** for a product number such as in Footnote 16 that refers to a document where the GTIN is used as product code. Such an endorsement is not allowed for competitive reasons.

As far as GS1 is concerned this standard is used in several industry branches in exactly the same structure worldwide. In these markets one could speak of an existing international industry standard. It must be emphasized however that this is not true for the pharmacy market in Europe. In European markets where GS1 is used – for example in France - the generally used GTIN number is adapted to the specific French needs so it has not the internationally used GTIN characteristics anymore. Thus this GS1 number is just like any number in an open standard in the above mentioned sense. This standard could also handle the PPN or any other code with an adequate structure.

Consultation item No. 3 – Additional Product Information

The data carrier (2D or linear) (not the "serialisation number") is able to carry additional information such as batch number and expiry date. This might be helpful for the supply chain management and might even be eventually demanded by the market. However this information is not necessary to make a package unique in the sense of the Directive. The Directive is not aimed at and has **not the scope to optimize supply chain management**. So this information is not within the scope of the Directive and cannot be covered by the Delegated Acts. Apart from this these additional objectives do not require the implementation of the also very costly Tamper Verification Feature and the Repository System.

Furthermore, the inclusion has no significant impact on patients' safety. The expiry date has to appear in readable form anyhow: Firstly not all medicines are marked (like OTC and white list). Secondly, the pharmacists and, above all, the patients at home have to be able to read the expiry date in human-readable form. Thus, Art. 54 Dir. 2001/83/EC requires a human-readable batch and expiry anyway. Before dispensing a medicinal product the expiry date must be checked already nowadays by the pharmacist.

Also the inclusion of the batch number into the code does not enforce patient´ s safety but only enhances supply chain management. In case of a recall the system – for data safety reasons – will not be able to tell which patient got which batch.

It should be realized that the Directive allows the member states – and not the Commission - to extend the means of the Directive towards pharmacovigilance, i.e. recalls are not within the scope of the Delegated Acts.

This point has to be stressed since there is the possibility to **pre-print packages** with the product code and the serialization data. The installations at the manufacturers' packaging lines are reduced to camera and ejection mechanism and the packaging line controller software is simplified. This would substantially reduce the costs for the manufacturer especially when producing small quantities.

During the discussion of the Concept Paper the reasoning was put forward that the involvement of the pack manufacturer into the processing of serialized cartons would pose a security risk. In fact this reasoning would be just as valid for external IT-providers who generate the numbers for smaller manufacturers or for the in-house specialists or any other involved person and would put any of them under general suspicion of committing serious crimes. There is no indication that carton manufacturers are less reliable than other involved persons.

Consultation item No 4 - National Reimbursement Number

At the beginning it should be emphasized that the Directive at no point hints at the introduction of a new number. It speaks of "safety features" or a "unique identifier". The necessary uniqueness can be achieved with the existing reimbursement numbers and the serialization number.

Due to the fact that the reimbursement system in Germany legally requires the use of the national product number, the PZN, it would be an enormous effort in administration and cost to replace that number. Thus in Germany and in other countries using a product number the Manufacturer Product Code and the national product (reimbursement) number would be the same. As far as Option 1 foresees the replacement of the numbers this is neither necessary nor cost-effective as shown below.

There are different codes possible like IFA, GS1, ISBT etc.. They can be integrated in a new interoperable product code. The integration can either be achieved as in the Concept Paper with a fifth element or as an integrated number in a national system (e.g. with a national prefix). Consequently option 2 is only one of the possible options.

Pro Generika strongly urges that the necessary harmonization can be reduced to the requirement of an **open standard**. The objective of interoperability is achieved without option 1 or option 2. As all existing numbers can be used in an open standard they are easily compatible to each other.

Other stakeholders argue that an overall fully harmonized approach in the form of a new product number would be the best way to manage supply chains or they go even further and state that it would help to pallet aggregation. This argument applies possibly to wholesalers and pharmacists. On the other hand it would certainly increase the financial and administrative burden for the manufacturers. This concerns not only the printing process as mentioned above. It relates even more to pallet aggregation as this needs another full set of new machinery on the production lines additionally to the new machines required for the verification process. Again it has to be made clear

that neither the Directive aims at facilitating the supply chain nor is it in the scope of the Delegated Acts to do so.

With respect to the generic industry which in Germany accounts **for 65 % of total packages but only 22 % of the sales volume based on ex-factory-price** in the statuatory health insurance market these costs are substantial and cannot be forced on the manufacturers by way of the Delegated Acts.

To summarize:

- Different codes in an open standard are internationally compatible. Patient safety is not affected by using an open standard that allows different code-formats to interoperate.
- A fully harmonized manufacturer product code that replaces or complements (fifth element) the national reimbursement numbers is thus not necessary in terms of the objectives of the Directive.
- Batch number and expiry date are not within the scope of the Delegated Acts.
- As far as a fully harmonized approach of a product number would only facilitate supply chain management this is not within the scope of the Directive. Pallet aggregation would substantially increase the burden on manufacturers without increasing patients' safety.

Consultation item No 5 – Technical characteristics of the carrier

Option 2.2.1 – Linear barcode

As the unique identification number consists only of the product (-reimbursement-) number and the serialization number the linear code would be capable of carrying this information. Using the linear code would fulfill the requirements of the Directive and would minimize the costs especially for small and medium sized companies as most of them have already installed the equipment required for linear coding. In Germany it is the common carrier.

Seen from this light it is not necessary to install as a legal requirement another data carrier instead of the linear carrier that is widely used by manufacturers and pharmacists alike.

Option 2.2.2 – 2D Barcode

It might be considered as useful in some countries or required by the markets to use Data Matrix. However as it is not necessary to fulfill the requirements of the Directive (that is serialization) it should not be made mandatory to use the Data Matrix.

Option 2.2.3 – Radio-frequency identification (RFID)

RFID is much too expensive and does not comply with data protection legislation as it can be read even outside the pharmacy by any passer-by. The protection level for patients in respect of falsifications is not higher than with other solutions. This should not be an option.

To summarize:

The data carrier should be left open as regards to linear or data matrix. Thus, it would be possible, on one hand, to continue to use existing data carriers and on the other hand, to react to new developments when mutually agreed upon by the stakeholders.

B Consultation Topic No 2 – Modalities for Verifying the Safety Features

Consultation Item No 6 – Other points of dispense

Consultation Item No 7 – Wholesalers

Policy Option No 2/1 – Systematic check-out of the serialization number at the dispensing point

The objectives of the Directive are to avoid risks to the health of patients arising from the use of falsified medicinal products. Thus, it has to be prevented that such falsified medicinal products are handed over to patients. This risk is to be minimized by checking the medicinal product out at the point of dispensation, that means at pharmacy level (in Germany Rx-medication can only be dispensed by pharmacies not by retailers).

However, it has to be taken into account that there is – especially with clinical pharmacies – a considerable amount of medicinal products delivered directly from the manufacturer to the clinical pharmacy. In these cases a check-in/check-out procedure is obviously not necessary.

Policy Option No 2/2 – additional random verification at the level of the wholesalers

There is no reason why the wholesaler should not have access to the system for checking, e.g. if there is a suspicion. When choosing this option as Pro Generika´s preferred option we assume however that "random verification" in the sense of the concept paper does mean: having the possibility to take control samples; it does not mean and this would not be favored by Pro Generika that the taking of samples is mandatory.

Policy Option No 2/3- additional systematic verification at the level of the wholesalers

This option is in line with the title of the Directive. As aggregating on the pallet cannot be installed by way of the Delegated Acts the wholesalers would have to check every single pack. This would delay the delivery process of medicinal products up to a major extent. Thus this option is only feasible if only a fraction of medicinal products is wearing the safety feature.

C. Consultation Topic No 3 – Provisions on the Establishment, Management and Accessibility of the Repository System

Consultation Option No 8 – Management of System

Policy Option No 3/1 – Stakeholder Governance

Pro Generika clearly favors a stakeholder governance as this implies several advantages which, at the same time, are disadvantages of the other policy options:

1. A Stakeholder model is – with the following exemptions - by nature the most cost-effective one as it is run by the same entities that pay for the system. Thus the requirement of the Directive for cost-effectiveness is best met.
2. The partners in the market have the most day to day experience with all kinds of supply chain eventualities.
3. Almost all data processed during the verification process is confidential as trade secret information of the one or the other stakeholder. Thus, it is in the very own interest of every 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 (Art. 54 (3) (b) (c)).

4. As the check-in/check-out is a legal requirement it does not make a difference whether the system is stakeholder or otherwise driven. Each actor in the chain has to comply with the legal framework as far as it exists.
5. The undelayed response from the repository system is imperative for the business operation of any pharmacy. As the pharmacists are stakeholders in the system (as in the German securPharm project) it is in their own interest to enable the system in the appropriate way.

Pro Generika has been involved in the **securPharm project**. This initiative was founded by the German associations of the pharmacists, of the wholesalers and the four associations of manufacturers. It is open to all interested parties.

The objective is the joint development of a product verification system to be run by the national and EU-wide stakeholders. This project will move into a practical pilot phase in Q 1 2013. For the practical pilot several manufacturers will mark some or all of their products. The serialized products will be loaded into the verification system and then randomly dissolved in the market. The participating pharmacies will check the marked products out of the system. With this pilot the practical functioning of the verification system will be proven.

The technical frame of the project is to install two databases: one managed by the manufacturers and one by the pharmacists. Manufacturers upload their data into the manufacturer´s database. Upon dispensation the pharmacist checks the package via the pharmacist´s database. This database starts a request at the manufacturer´s database for verification of the package. Wholesalers will have access for the purpose of checking the verification via the pharmacist´s database.

In case of an alert a third datasystem is involved to investigate the alert. This datasystem is managed by the securPharm initiative.

A **central European Hub** mandatorily involved in every transaction, as proposed by other stakeholders, is, however, **not needed**. As known so far the costs of such a European Hub would substantially increase the costs of the system per package.

For transaction on a national level only it is sufficient to have the above mentioned data bases which communicate directly with each other. For small and medium sized companies that do mostly national transactions this solution would be by far the most cost-effective one.

For international transactions the databases of the manufacturers would have interfaces with the other national databases. Even to date manufacturers are connected to a variety of databases either of their own group or to different country databases as those from Turkey or France.

This interconnectivity would be substantially cheaper than the installation and management of a European hub.

A European hub if introduced should in any case be optional and could be used for international transactions, multinational packs or by countries that do not want to run their own systems. However it has to be stressed that the Hub is not necessary as national concepts like securPharm can achieve all these objectives.

Policy Option No 3/2 – EU-Governance

A pan-European repository system in EU-Governance has all the disadvantages listed in the Concept Paper. The sheer mass of processed data has several risks e.g. breakdowns, central hacking etc.. The more complex the system is, the more expensive it is. This is not in line with the requirement of cost-effectiveness as stipulated in the Directive.

The advantage mentioned of having only one contact point does not seem convincing in the light of the technical possibilities developed by securPharm.
A central entry point can – in specific cases where it seems desirable for the connected manufacturers – be put up by the manufacturers themselves.
A central system might be less responsive to specific national characteristics such as reimbursement.

Policy Option No 3/3 – National Governance

The interconnectivity of national systems has to be ensured also in Option 3/1. This is, however, more cost-effective when done by the stakeholders.

The specific national characteristics of the distribution system will be taken into account also by a stakeholder driven model because otherwise the system will not work in the specific national surrounding and, thus, will not be cost-effective.

As the Directive leaves the possibility to involve national authorities for certain purposes the Delegated Acts can leave it to the discretion of the member states to define their involvement in the system. At this point it must be stressed that the Directive confines the national authorities to certain objectives such as information for reimbursement purposes, pharmacovigilance or pharmacoepidemiology. Apart from this, to stay in line with the Directive the accumulated information may not be used.

Based on information received from different hardware and software providers, the EGA has performed **cost calculations** to implement the new features. 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 additionally the financial 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.

Depending on the European Commissions' interpretation of the Directive 2011/83/EU these costs will have a different impact on the different manufacturing authorisation holders: Small manufacturers will have proportionally higher costs than larger manufacturers.

In any case Pro Generika strongly argues that whatever system is adopted **the division of costs** should be proportionate and relative according to the value of sales of the products. Lower priced products should contribute to the costs of the system in a relative way compared to high priced products.

Consultation item no 9 – Other issues

Pro Generika agrees that there has to be a high level of data protection. This is also the objective of the securPharm project and the reason why it foresees two separated databases for the manufacturers and the pharmacists. Thus it is ensured that relevant information from one stakeholder side is not disclosed to the other.

In the case of an alert the securPharm system managed jointly by all stakeholders will have access to both databases to ensure the effectiveness of the system and the patient safety. This can also be operated for recalls as far as traceability goes.

But again: The Directive allows member states to extend the scope of the system to e.g. pharmacovigilance whereas the scope of the Delegated Acts is narrower. Thus the system must serve foremost to prevent falsified medicine reaching the patient. Objectives such as supplementing existing recall processes are not in the scope of the Delegated Acts.

Consultation item no 10 – Protection of Personal Data and Repackaging

Pro Generika fully supports adequate protection of patient data in the Delegated Act.

Parallel distributors are obliged to replace the mandatory safety features. In the securPharm approach the parallel distributor checks out the serialization number in the country of origin of the products and checks in a new serialization number in the import market. That is exactly what the provision of Art. 47a of the Directive is stipulating the parallel distributor to do.

D. Consultation Topic No 4 – Lists Containing the Medicinal Products or Product Categories

Consultation item no 11 – Risk Factors and Identification Criteria

At this point Pro Generika refers to the introduction of this comment. We strongly believe that a cost effective system as put forward by the Directive has to be based on a thorough risk assessment.

The costs for the system for those manufacturers in the supply chain who deliver the highest volumes with the least costs for the health insurances, and that are the generic manufacturers, are significantly lower if only a fraction of their products has to be marked.

As evidence at the same time shows that firstly generic products and secondly low price products have not been falsified yet in the legal supply chain it is reasonable to see those criteria as strong factors in the risk assessment.

In detail:

Exemptions of the application
With respect to the basic considerations again the fact must be stressed that recital 11 of Dir. 2011/62/EU clearly states that there has to be taken due account of the particularities of certain medicinal products or categories of medicinal products, such as generic medicinal products. This means that the general rule can be adapted inline with the Directive to the possibility to leave one category of medicinal products, such as generics, out altogether even if this is a broad category.

Price:
Pro Generika agrees that a price of a product is an important factor. However the suggested price of 2 Euro is by no means a high price in the sense of the Directive. Even if it is obviously possible to form items that look like pills and put them into blisters and put those blisters in cartons for 2 Euros these are by no means the costs for which such a package can be smuggled into the legal supply chain and by no means profitable for the falsifier.

For smuggling the falsified product into the **legal supply chain** the involved persons must develop enough criminal energy to risk heavy punishment and ruination of career in order to acquire the product and process it in the legal chain. For this the criminal person must receive an interesting profit margin which, of course, cannot be achieved with 2 Euro.

The findings of the German Federal Criminal Authority (BKA) that found only six cases in the last four years with the cheapest product found costing **350 EURO** are in line with this approach.

Completely different from this situation is the situation in the **illegal supply chains**. The costs for criminals in this sector are indeed mainly the costs of production of a fake package plus the costs of putting up an internet selling network. The overall operating expenditures for these channels are considerably lower as are the risks of being detected. Prices for products being found there are hence significantly lower as proven by the findings of the competent authorities such as customs and investigation authorities.

Thus, Pro Generika suggests a price of 100 Euro ex-factory (excluding VAT and discounts) as an expensive product.

Sales Volume:
The approach that large volumes are at a higher risk disregards the fact that in order to get higher volumes into the market more people and more packages and more patients are involved. This increases the risk of detection and lowers the margin of everybody involved in the criminal part of the process. Thus the criteria of volume have to be differentiated evidence-based and cannot be used as done the concept paper.

Number and frequency of previous incidents
This criterion grounds on evidence. However, Pro Generika wants to emphasize that the observation of previous incidences has to **solely focus on the legal supply chain** as this alone is the objective of the Directive. It must be differentiated between products found in the legal supply chain and products found in the illegal one as the struc-

ture of the sales, the buyers and the approach of the falsifiers are decisively different.

At this point it must be noticed that according to the answering of the Commission and the Agency (EMA) to a parliamentary question neither has an evidence-based view on this subject.

Pro Generika strongly suggests that the commission **interrogates the actual situation** in a more detailed way before putting heavy burdens on the manufacturers and eventually on the health insurance systems. The preparation of the Delegated Acts gives time to gather evidence on the actual situation.

Also only similar developed markets can be compared. The WHO points out that the share of falsified products in developing countries with scarce implementation of controls can be very high but this does not apply to the EU. So **only developed markets** can be considered.

Incidences from illegal sources have to stay out of the assessment as these sources are having a completely different structure.

The specific characteristic of the product

One specific criterion of any product is the price as mentioned above. Another criterion is the fact whether the product is generally known. This is the case with branded products whereas the names of generics as these are usually INN are widely unknown.

The seriousness of the conditions treated

Falsifiers in the legal supply chain do not target diseases but products.

Other potential risks to Public Health

Pro Generika agrees that other potential risks might be identified in the future.

Rapid Alert System

As far as the Concept Paper draws a time horizon of around two years for amending the Delegated Act this timeline does not apply to medicinal products being excluded from or included in white or black lists. These lists are only annexes to the Delegated Acts and, thus, can be adapted to new assessments much faster. This is in line with Art. 54a 2. (c) that requires the Commission to put up a rapid system for evaluating and deciding on such (national) notification for the purpose of applying a risk assessment.

Optional Use of the Safety Features

With regard to the scope of the safety feature Pro Generika cannot identify a provision in the Directive that would hinder a manufacturer to use the safety features voluntarily. Also the rationale of the Directive to increase patients safety is in line with the optional use of a safety feature. Already today many manufacturers use features voluntarily that are comparable to the tamper verification feature.

Identification Criteria

One of the four identification criteria put forward in the Concept Paper might not stand for itself to single out the categories. The combining of elements could be helpful.

However it should be taken into consideration that the name of the API is not a valuable criterion as those names are usually not known whereas the branded product con-

taining this API might be known. In these cases the branded product might be in risk for falsification whereas the generic product – usually named using the INN – is not.

However it is clear from Recital 11 of the Directive that a product category can be generic medicines in general.

Other Considerations

In the discussion on the Delegated Acts the reasoning was put forward that the exemption of a medicinal product from the marking requirement might make it susceptible to falsification. This reasoning is not solid as the product still has to fulfill the criteria that make it worthwhile for falsifiers to take up the risks of smuggling a falsified product into the legal supply chain. Apart from this the reasoning might also be applied to any OTC-product that as a general rule is not marked.

It also had been put forward that it is easier for the manufacturers to mark all their products. This is obviously not valid and especially not for high volume manufacturers such as generic manufacturers. On the one hand the manufacturer does not have to mark its OTC-products (except when black-listed) i.e. the manufacturer has to make a differentiation anyway. On the other hand, it decisively decreases the manufacturers costs when products have not to be marked. Firstly, there is no need for the manufacturer to invest in all of his production lines what he would have to do if all or almost all products have to be marked. Secondly, it decreases the cost burden significantly when less data has to be generated and managed.

Giving consideration to the handling at the dispensing point: It should be pointed out that the pharmacist must differentiate with regard to OTC-products anyway. To tackle this problem the code on a pack can be marked with a visible icon if this code has to be verified. This procedure would make it easy for the pharmacist to differentiate between those products that have to be verified and those that carry codes for other reasons.

Consultation item no 12 – Risk Factors and Identification Criteria

Applying the criteria as put forward by the Concept Paper would mean that every product costing more than 2 Euros would have to carry the safety features as it cannot have less than 6 points in the proposed risk assessment.

Approach a)

Only in case that some kind of risk assessment approach as the one put forward in the Concept Paper will be pursued in the Delegated Act Pro Generika proposes an assessment which as a first step of the assessment incorporates a **weighting of the different criteria**. A weighting is a declaration of a certain 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 in form of a value.

In this procedure previous incidents of falsification in the legal supply chain in regulated markets and price should be taken into account as the most important and highest weighted risk factors. The target for counterfeiters is profit only; high priced products should therefore be considered in the Delegated Act as those priced at 100 Euro or higher ex-factory or more. The other criteria should have significantly less weight as they might need more details to be effective.

By weighting the criteria in respect to their impact on the possibility of falsification the objectives of the Directive to carry out a risk assessment would be taken into account.

Approach b)

Another approach which would have the advantage of clarity and easiness in terms of handling would be to **exempt all medicinal products having a price of less than 100** Euros (as a category of products) and then, if necessary, reinsert specific products into the list according to the listed criteria.

This would significantly help to meet the requirement of the Directive to make the system as cost efficient as possible.

Pro Generika would strongly support the latter approach.

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