



The Danish Generic Medicines Industry Association (IGL) comments on the concept paper on the delegated act for a unique identifier for medicinal products for human use, and its verification.

The Danish Generic Medicines Industry Association (IGL)

Introduction

The Danish Generic Medicines Industry Association (IGL) 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 chain¹ 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, 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 demand², especially targeting well-known brands. But there are no reports of counterfeit generic medicines in the EU at all and especially not in the legal supply chain. 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, which are unattractive for counterfeiters.

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.

Economical consequences

The EGA 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:

- € 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.

¹ recital 29 - Directive 2011/62/EU

² OECD, "The Economic Impact of Counterfeiting and Piracy"

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.

Different objectives

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*, IGL 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.

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.

Implementation costs

- 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.

Falsified products

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 be verified.

To ensure that this can be done proportionately, without involving major costs for the stakeholders, the IGL 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.

Competition is important for costs

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.

Whatever system is adopted, IGL 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.

Risk assessment approach

IGL 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).

Generic medicine lower the prices

IGL 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.

IGL considers that the approach for quantification of the classification criteria should be weighted in the following order of importance:

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

About The Danish Generic Medicines Industry Association (IGL)

The Danish Generic Medicines Industry Association (IGL) is a trade association founded in 2002. The association today counts 11 member companies, which are all engaged in the sale and marketing of generic medicines for the Danish market. Some of the companies also manufacture generic medicines.

IGL is working to promote the sale of generic medicines in Denmark and thereby limit drug costs to consumers and society.

Until 2002 largely all pharmaceutical companies in Denmark were members of the Danish Association of the Pharmaceutical Industry (Lif). However, research-based pharmaceutical companies and generic pharmaceutical companies have different interests. First and foremost this applies to issues such as patent rights and other rules and conditions that directly affect which drugs are sold in Denmark. This is the reason the generic drug manufacturers broke away from LiF and created IGL instead.

IGL acknowledges and respects the principle that pharmaceutical companies, which invest in research and development of new medicines, are entitled to protection against unfair competition. Patent protection is an absolute precondition for the industry's being able to produce new and better medicine for the treatment of diseases.

Inversely, IGL believes that it is important that those rights not be so extensive that they actually prevent drug competition. All Danes should have access to good, effective and inexpensive medicine from the very moment the patents on the original medicines expire. This not only benefits the generic drug manufacturers but also patients and Danish society, which today are so heavily burdened by rising drug costs.



IGL is working to ensure that the laws, rules and practice in the Danish health system will continue to address opportunities for offering Danes good, effective and inexpensive generic medicine. IGL will continue to contribute to the public debate on medicines and drug expenses, just as the association sees it as its task to influence politicians, authorities and actors in the Danish health system to think about what provides 'most possible health for the least amount of money,' as far as medicine is concerned.

Best regards,

Lone Darket

Chairman of the board

IGL