KPMG
cutting through complexity

October 2013

Advice on the implementation of EU-Directive 2011/62/EU

According to the European Commission, the threat to public health and safety from falsified medicinal products is on the rise. The impact assessment (2008) of the European Commission claims that by 2020, 0.05% of all prescription medicinal products dispensed through the legal supply chain will have been counterfeit products. In order to control and combat the possible threat, the EC has introduced new legislation to put in place preventive measures to improve the protection of public health. The basis for this new legislation was defined in the Directive 2011/62/EU. KPMG has conducted an independent study requested by the European Generic medicines Association 'EGA' and has concluded that with the implementation of safety features a possible risk of failure and a risk of exceeding the budgeted time and costs can arise.

The directive aims at improving the protection of public health through the prevention of the entry of falsified medicinal products into the legal supply chain in the EU.

By means of researching publicly-available information, conducting interviews and using our broad experience in the field of anti-counterfeiting, we have provided insight into the following topics:

- the background for this Directive,
- the use of the 'Risk Assessment' in the Directive,
- the most important considerations and challenges that should be addressed to ensure the successful implementation of the new legislation.

The Background for this Directive

Currently, the problem of the falsification of medicinal products in the EU is relatively small compared to the rest of the world. Additionally, the overwhelming majority of the known cases of falsified medicinal products have occurred outside of the legal supply chain, to which the Directive does not apply. In fact, very few falsified medicines have been found in the EU legal supply chain. According to an extrapolation of available figures in the European Commission impact assessment, 0.005% of medicines in the EU legal supply chain would be falsified.

Conclusion

The EU indicates that there is an alarming increase in the discovery of falsified medicines. We found that this statement is difficult to substantiate for the EU, due to inconsistent and incomplete registration. The figures that are available indicate that falsification exists, but the rate of growth is uncertain. Additionally, we found that the falsification is mainly concentrated outside of the EU or outside of the EU legal supply chain and then mainly taking place via the internet.

However, because of the potentially harmful effects of falsified medicinal products on patients, it is acknowledged that the problem merits attention and is to be taken seriously. Therefore, the EC wants to be proactive and wants to create a robust preventive system.
KPMG has identified a number of important points that should be taken into consideration when implementing safety features. In this way, the possible risks of failure of the measures and of exceeding the budgeted time or costs can be prevented. We challenge the full implementation of the safety features for all prescription medicines at once.

A Phased-in approach

Implementing the safety features initially on a smaller-scale would mean that the majority of these uncertainties could be dealt with and the additional expenditure and reputational damage possibly arising from unexpected drawbacks will remain limited. In this way, many expected and unexpected problems could be resolved during the initial phases leading to a more robust and cost effective implementation in the later phases.

Moreover, as the repository and verification systems have potential for other (commercial) uses (e.g. direct ordering, automatic reimbursement, etc.) there could be additional beneficiaries in the future. Of course, any additional costs should be borne by the participants that enjoy the benefits. Next to that the addition of "nice to have" facilities should never stress the basic functions of system. This however is a national decision as this is not a direct goal of the Directive.

> "Learn to walk before you run"

Conclusion

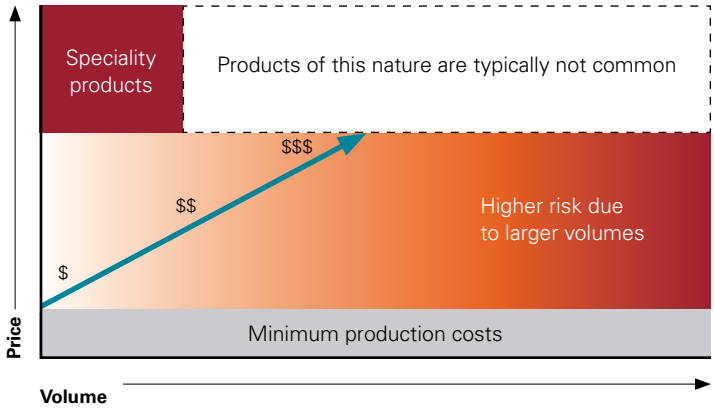
Initially, build up the system on a smaller scale, by starting with a limited number of EU member states, and only the most threatened products (to be classified using the Risk Assessment) and without the tamper verification feature packaging. By starting small and solving any arising complications on a small scale, a lot of the costs can be avoided and the credibility of the control system can be maintained.

A Robust Risk Assessment

A Risk Assessment is provided for in the Directive as a tool to determine which products are in or out of scope with regard to bearing the safety features. The most important criterion for this Risk Assessment is the ratio of price and volume as it is an indicator for the potential profit for the counterfeiter (see illustration). The criteria mentioned in the Directive that refer to the number and frequency of previous cases of falsified medicinal products and the severity of the conditions intended to be treated appear to be good indicators at first sight, but are difficult criteria to apply. Only comparable markets can be included and a clear distinction between legal and illegal supply chains in these markets should be made.

Conclusion

As an initial assessment we suggest focusing on products that score high on the 'price-volume' scale, and additionally, we suggest that the criteria should be weighted.



Doubtful tampering verification feature

Additionally, KPMG estimated that the implementation costs for tamper-verification packaging could be approximately €500 million per year (approximately € 150K per packaging line), plus the additional time required for implementation. Also, tampering with the packaging of medicinal products is currently not considered as a major threat. During the phasing-in period, the EC can research whether an anti-verification feature is necessary, based on the developments within the supply chain.

Conclusion

We advise the EC to postpone the requirement for tamper verification packaging, as implementing an effective tamper verification feature is a difficult and costly task, which may even lead to the risk of creating a false sense of security.

Cost-effectiveness

When establishing the safety features, due consideration shall be given to their cost-effectiveness. In general, taking the cost-effectiveness into account when setting up a project that introduces new measures is important, as the investment should lead to notable benefits. Besides this, the addition of "nice to have" facilities should never stress the basic functions of the system. This however is a national decision as this is not a direct goal of the Directive

KPMG addresses a number of challenges and considerations that the EC will face when implementing the system.

When implemented for 90% of medicinal products subject to prescription incl. tamper evident packaging within the suggested time scale we consider the chance on:

Patient safety:	Medium
Cost-effectiveness:	Low
Successful implementation:	Very low

When started well prepared with 40% of prescribed medicinal products in a limited number of countries (growing to all member states) and excluding tamper-evident packaging we attain:

Patient safety:	Medium
Cost-effectiveness:	High
Successful implementation:	Medium

Scope & outline report

The resulting report is publicly available. A URL to a digital copy is present at the back.
The Directive covers a wide range of topics aiming to improve the protection of the public.
While conducting our independent study, we have specifically focused on the following topics:

- Unique identifiers (Article 54.o of the Directive);
- Repository and verification system (Article 54.a.2.e of the Directive);
- Risk assessment (Article 54.a.2.b of the Directive);
- Tamper-evident packaging (Article 54.o of the Directive).

The findings and conclusions in this leaflet are based on our detailed report "Advice on the implementation of EU-Directive 2011/62/EU". As a consequence these findings and conclusions should be read in conjunction with that detailed report.

KPMG Counterfeit Risk Services (CRS) is the service that assists brand owners to mitigate the risks of counterfeited products. Instead of relying exclusively on legal protection, investigation and enforcement, CRS can assist brand owners in developing and implementing advanced holistic prevention concepts. For more information, please visit www.kpmg.com.

European Generic medicine Association (EGA)
The generic medicines industry represents 50% of the medicines that are dispensed in the EU while only using 18% of the total pharmaceutical budget. EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, including a large number of SMEs. For more information, please visit www.egagenerics.com.

Report Advise on the implementation of EU-Directive 2011/62/EU.

For a full digital copy of the report, please visit http://www.kpmg.nl/eu-directive2011-62.eu

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