Response to the European Commission Concept Paper Submitted for Public Consultation on the Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its Verification

This response is made by Teva Europe B.V., a stakeholder association and medicinal products manufacturer.

Introduction

Teva recognises the importance of the aims of the Falsified Medicines Directive (Directive 2011/62/EU, referred to hereafter as "the Directive") and supports the European Commission in its aim to reduce the number of falsified medicines that enter the legal supply chain and to prevent them from reaching patients. However, Teva has a number of concerns with the proposals for the delegated act on the rules for the unique identifier and, in particular, the proposals for the "white list".

Low cost generic drugs are a critically important tool in constraining the cost of medicines, and consequently national health budgets, in the EU. As currently contemplated, the proposals make it extremely difficult, if not impossible, for generic drugs to get on the white list, not for any reason related to patient safety, but due to the large sales volumes that many generics drugs enjoy. In contrast to the spirit of the Directive, the proposal do not appear to recognize that generic products are simply not a target for counterfeiters due to their low prices and ready availability from a number of different manufacturers; this view is supported by the fact that generic medicines are not currently falsified in Europe. The imposition of the proposed unique identifier obligations on generic manufacturers will add significant costs to the production costs of generic medicines which will inevitably lead to a reduced availability of medicines across Europe without providing any benefit to patients. Our concerns are set out in detail below.

Generic products on the white list

<u>The Directive contemplates that generic products could go on the white list</u>

Teva is concerned that the Commission has, prior to carrying out the consultation, formed the view that generic medicines should not be put on the white list and so should not be excluded from the requirement to bear the safety feature. At paragraph 84 of the concept paper it is stated 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 feature".*

The Directive, however, expressly contemplates that broad categories of medicinal products could be excluded from the scope of the safety feature requirement. In fact, generic medicinal products are stated to be an example of such a category of medicinal products in recital 11.

It is clear from the Directive that the general principle that all prescription medicines should bear the safety feature is the *starting point* for analysing whether a particular product or category of products should be required to bear the safety feature. There is nothing in the Directive that supports the proposition that the criteria for allowing exemptions from the requirement should be interpreted narrowly. If anything, recital 11 suggests that the possibility for exemptions should be interpreted broadly since it is clearly contemplated that generic medicines as a category could be exempted.

Generic products are low risk

Generic products should be put on the white list as they are not a target for counterfeiters. This is mainly because the prices of generic medicines are low and volume is split over a number of different manufacturers. There is very little, if any, incentive for generic medicines to be falsified and Teva is firmly of the view that generic medicines are not currently falsified in Europe and will not be in the future.

In fact, Teva has never received any reports of falsified versions of its medicinal products in the EU. Teva is one of the largest producers of generic medicinal products in Europe and produces a wide range of different generic products. As such it would be expected to have received reports of falsified medicines if generic products really are being falsified in the EU. The fact that it has received none is strong evidence that generic products are at very low risk of being falsified.

Generic products should be treated in the same way as OTC medicines

If OTC medicines are to be excluded from the requirement to bear the safety feature then generic medicines should also be excluded. The report on the impact assessment carried out by the Commission in order to assess the economic, environmental and social impacts of the proposals for the Directive found that the risk of falsification was similar for OTC medicines and generic products. The report found that this was because both are far less costly than innovative drugs and so are typically not a target for counterfeiters. The impact assessment also found that both OTC-producers and generic manufacturers are disproportionately affected by the obligatory safety feature, particularly with regard to the cost and burden of regulatory compliance (see pages 40 to 43 of the impact assessment report).

In fact, generic medicines may be at an even lower risk of falsification than many OTC medicines. OTC medicines are often higher priced than generic products at the point at which they enter the supply chain as discounts are not usually offered. In addition, many OTC medicines are well known products which are branded and are familiar to consumers and may therefore be more likely to be attractive to counterfeiters.

There is no reason why generic products should be required to bear the safety feature if OTC medicines are not. There is little difference between them in terms of the risk of falsification; if anything, generic medicines are less likely to be falsified than OTC medicines. Overall, neither are particularly attractive to counterfeiters and, as far as we are aware, there have been no reports of either type of product being falsified in the EU.

Proportionality

The Commission must act in accordance with the principle of proportionality when adopting the delegated act. Recital 33 of the Directive states:

> *"In accordance with the principle of proportionality, as set out in [Article 5 of the Treaty on the European Union], this Directive does not go beyond what is necessary in order to achieve that objective"*

The objective referred to is the overall objective of the Falsified Medicines Directive which is:

> *"to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicines".*

Therefore the Commission must not go beyond what is necessary to achieve the objective of the Directive when supplementing its provisions through the adoption of delegated acts. The current proposals contained in the concept paper for the delegated act risk going beyond what is necessary to achieve the aims of the Directive and, as such, are arguably disproportionate.

According to the Directive, whether a particular medicine must bear the safety features should be determined according to the risk of it being falsified. The Directive therefore offers some flexibility in the scope of application of the safety feature system. Indeed, it is clear from the documentary record of the development of the Directive that a certain level of flexibility in the regulatory framework was intended. This is because when the Directive was being developed it was unclear (and in fact it remains unclear) what the scope of the problem of counterfeit medicines really is and the most effective way to deal with it.

The Commission would be going far beyond what is necessary to achieve the objective of the Directive if the rules it made in the delegated act had the effect of requiring medicines at low risk of falsification to be included in the safety feature system. The safety feature requirement should only apply to those medicines that are at the highest risk of being counterfeited in order to provide an additional measure over and above the other measures aimed at tackling falsified medicines that are set out in the Directive. It should not be forgotten that the other measures for combating counterfeit medicines that the Directive and other new legislation introduces may be the most effective way to achieve the objective of protecting the public from falsified medicines. These include measures such as requirements directed towards medicines sold over the internet, imposing stiff penalties on counterfeiters, and raising consumer awareness about the dangers of counterfeit medicines.

In fact, in our view, the most effective way to reduce the number of counterfeit medicines that reach consumers via the legal supply chain may be the measures in the Directive that increase the oversight of different entities in the legal supply chain. This will reduce the number of "weak links" and increase the integrity of the legal supply chain overall. These measures in combination are likely to be effective in achieving the aim of the Directive. As a result, and in accordance with the principle of proportionality, the safety feature only needs to be viewed as one of the many different measures available to protect the public, and one which only has particular utility with regard to those medicines that are at the highest risk of being falsified.

The risk assessment

Applying the classification criteria

The Directive requires that certain criteria must be taken into account when assessing the risk of, and arising from, falsification of medicinal products. As discussed above, the risk of falsification of generic medicines is extremely low. Therefore, carrying out the risk assessment by applying the classification criteria should result in all generic medicines being included on the white list.

As explained previously, Teva is concerned that the Commission has already decided that there should be very few exceptions to the requirement to bear the safety feature. This is further illustrated by the proposals for applying the classification criteria at paragraph 87 of the concept paper. Under the proposals, a medicine can only be put on the white list if it scores the lowest possible score in each of the six categories (although there are only five criteria, criteria 1 actually contains two categories: price and volume). Under this system a medicine which is of a low price, that treats a condition that is not severe, for which there have been no incidents of falsification and which in fact has characteristics that indicate that there is no risk of falsification would still be not be put on the white list if it was sold in volumes that were not regarded to be "low". Such a medicine would clearly be at very low risk of falsification, but, as the proposals for the risk assessment currently stand, it would still not be eligible for being included on the white list. As stated above, refusing to allow low risk medicines, such as generic medicines, to be included on the white list would run contrary to achieving the objective of the Directive in a proportionate and cost-effective manner.

If the framework proposed for the risk assessment makes it very difficult for a medicine to get on the white list then that proposal is not in accordance with the Directive. The Directive makes it clear that risk must be taken into account in order to determine which products or classes of products can be excluded from the safety feature requirements. If the risk assessment procedure is such that it is almost impossible for a medicine to qualify for the white list regardless of the real risk of falsification, then the Commission will be going beyond the power delegated to it in the Directive by making rules that conflict with provisions contained therein.

Practical considerations

Teva is also concerned that the concept paper does not give any indication as to how the risk assessment process will work in practice. Assessing every prescription medicine on the market in the EU will be a time-consuming and costly process. It is not clear whether manufacturers are required to carry out a risk assessment themselves for each of their products, or whether an EU body will be responsible for carrying out the risk assessment. Teva estimates that it would cost it around €400 per product to carry out a straightforward risk assessment.

If the risk assessment is carried out by an EU body, what will the procedure be? Whether or not a product is put on the white list as a result of the risk assessment will have an impact on the manufacturer of that product and, since they will be affected by what is effectively a 'decision' of an EU body, the manufacturer ought to have procedural rights in relation to that decision including a right to be heard by the body making the decision and a right to appeal. In these circumstances it would seem that the decision to include a medicine on one of the

lists (or not include it) would also be a reviewable act that could be reviewed by the General Court of the EU and the Court of Justice of the European Union (CJEU) in judicial review proceedings.

If the risk assessment was carried out by a self assessment procedure there would presumably need to be rules on how it would be enforced and what the consequence of not complying with the relevant rules would be. Again, it would seem that a decision made by an EU body on, for example, the enforcement of a penalty for carrying out a risk assessment incorrectly would also necessitate procedural rights for the affected party.

Another practical point is that the Commission concept paper does not address how the risk assessment system and white list will deal with products that come onto the market between delegated acts.

Cost

The Commission is required, under Article 54a(3)(d) of the Directive, to give due consideration to the cost effectiveness of the measures relating to the safety feature system it sets out in delegated acts. The best way to achieve a functional and cost-effective system will be to use a suitable risk assessment procedure to exclude low risk products and identify those products at high risk. This will allow the measures designed to prevent falsification of medicines to be targeted to those medicines (and therefore patients) that are most at risk.

The European Generics Association has estimated that, if generic medicines are not put on the white list and all generic medicines are required to bear the safety features, it will cost the average generic manufacturer over €50 million in implementation costs in terms of changing production lines and facilities as well as software changes and other costs, and a further €10 million per year for the verification system. These are costs that pharmaceutical companies will have to pass on to already stretched national health funds.

Teva is significantly larger than the average generic manufacturer and we estimate that it will cost Teva €100 million per year to comply with a requirement to place the unique identifier on every pack of prescription medicine it produces. This is bound to affect the prices of Teva's generic products. We estimate that in countries such as the UK, where there is a free market for prescription medicines, the average price of a generic medicine would increase by at least 4%.

In fact, generic manufacturers may be forced to discontinue many high volume low price products if those products are forced to bear the unique identifier. The additional cost associated with the unique identifier will simply mean that those products are not viable. This would undoubtedly lead to shortages as well as price rises for medicines which are often the mainstay or gold standard therapy for many European national health services.

Impact on the supply of generic medicines in the EU

It therefore follows that imposing the safety feature requirement on all generic medicines will not only be disproportionate and costly, it will also have an impact on the supply of generic medicines in the EU in the following ways:

- **Price increases**: the high cost of the system to the manufacturers means that the prices of generic medicines are likely to increase. A conservative estimate puts the price increase at at least 4% in countries where there is a free market for prescription medicines.

- **Reduced availability**: the changes that would need to be made by manufacturers in order to comply with the proposed requirements would be time consuming and could impact the availability of generic medicines in the EU. Some generic products may be withdrawn from the market altogether.

Conclusions

Whilst Teva supports the aims of the Directive, the current proposals for the implementation of the safety feature are disproportionate in the following ways:

- There is no realistic way in which prescription medicines can be placed on the "white list". The proposals make the risk assessment provisions in the Directive redundant.

- As yet there is no practical proposal as to how all products currently on the market can be assessed in a timely fashion.

- No consideration has been given to the cost of the implementation of these measures across all generic products in the EU as measured against the likely benefit to consumers.

Viewed in the context of the limited discretion the Commission has under the Directive and its duty to use only proportionate measures, Teva considers implementation of the current proposal would exceed the powers conferred on the Commission to implement the safety feature measure by means of a delegated act. Teva would like to stress once again that the safety feature is only one of many measures in the Directive that aim to combat counterfeit medicines.