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Commissioner Dalli delivers speech on 'Ensuring the safety of the supply chain in a global market'

John DALLI, European Commissioner for Health and Consumer Policy, addresses the European Institute

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SPEECH

ENSURING SAFETY OF THE SUPPLY CHAIN IN A GLOBAL MARKET

Introduction

I am very pleased to be here in Washington today to address the European Institute on the broad topic of the safety of the supply chain, a cross-cutting theme in my area of responsibility: health and consumer policy.

I would like to use this opportunity to set out where the European Commission currently stands as regards the safety of supplies in the main policy areas for which I am responsible.

Specifically, I will focus on the safety of the supply of medicines, medical devices, consumer products and food.

Medicines

Let me start with medicines where the European Union is actively stepping up the fight against falsified medicines.

The illegal supply of fake and counterfeit medicines has increased markedly in recent years – helped in no small part by the distribution opportunities offered by the relative anonymity of the internet.

This illegal activity is not limited to so-called lifestyle drugs. Even some cancer drugs have been falsely represented, which poses a real threat to the safety of citizens.

Our new European legislation on falsified medicines introduces obligatory safety features on the outer packaging of medicines.

This safety feature will include 2 parts:

- A unique identifier to verify that a medicinal product is authentic and to identify the individual pack; and

- A device to verify if the outer package has been tampered with.

These safety features will be mandatory on prescription medicines, with the possibility of certain exceptions. Over the counter medicines will, however, be exempted.

The European Commission is now working towards setting detailed rules for the establishment and control of the unique identifier. In particular:

- What information should be encoded in the unique identifier? – for example: product code, batch number, or expiry date… ?

- How should this information be carried? – for example: a linear barcode, or a 2D barcode? And

- Who would be required to verify the unique identifier –wholesalers or retailers?

The outcome of a public consultation showed that a full track and trace system might lead to unnecessary costs. A check at the point of dispense could be much more cost effective.

Other important questions are:

- Who will manage and access the system? and

- Do we envisage stakeholder governance, EU or national governance?

The Commission must also take due account of the legitimate interests to protect information of a commercially confidential nature.

The recent consultation on the modalities of the unique identifiers will help to address all these critical questions.

The Commission will now start working on assessing the impact of each possible policy option, the results of which will be ready in 2013.

A delegated act for the unique identifier is planned for adoption in 2014.

Finally on this issue, we are also taking forward other rules to secure medical supply chains – namely, a common EU-wide logo to identify legal online pharmacies.

This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union.
A public consultation on a potential logo will be published later this year.

Equally important, we are planning to publish a consultation paper related to checks of medicines introduced into the EU and re-exported to third countries.

As part of our strategy to fight against falsified medicines, the Commission is also reinforcing the rules for the import of active pharmaceutical ingredients and strengthening record-keeping requirements for wholesale distributors.

We are, for example, revising our guidelines for good distribution practices to ensure the storage and distribution of medicinal products under appropriate and secure conditions.

Medical devices

Allow me now to turn to the issue of traceability of medical devices. Traceability is one of the key elements of the forthcoming revision of the European medical device legislation – for which the Commission will adopt proposals shortly after the summer.

Traceability of medical devices is not currently regulated by the European medical devices legislation. This has prompted some European countries to impose traceability requirements on economic operators at national or sometimes even regional level.

The forthcoming revision of the legislation will seek to introduce a Unique Device Identification (UDI) mechanism for medical devices at European level.

This UDI system – based on globally accepted guidance – is the result of a close and fruitful international cooperation where both the United-States and the European Union have played a leading role.

It will allow the unambiguous identification of a specific device on the market, which will considerably enhance patient safety.

- First, it will enhance the effectiveness of the post-market safety of medical devices, due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities;

- Second, it will optimise patient care, by reducing medical errors;

- Third, it will lead to better control of the supply chain, since all economic operators will be obliged to identify who supplied them and to whom they have supplied medical devices;

- Fourth, the UDI system will increase transparency, mainly through the establishment of a UDI database, acting as a central repository for all devices present on the European market; and

- Finally, it will contribute to the fight against counterfeiting.

Consumer product safety

Let me turn now to the safety of consumer products.

In the European Union, our legislation on non-food consumer product safety is aimed at ensuring the safety of all products regardless of their origin.

And while we have made great strides forward in protecting consumers from dangerous products, we are continuously seeking to improve our systems.

Product safety has a huge global dimension and our objectives cannot be achieved in isolation.

Trade in goods is increasing; supply chains are becoming more complex; and the same products are often marketed across the globe.

In recognition of the increasingly global nature of the market, the European Commission has been actively pursuing international co-operation for many years.

A key issue for me in the context of supply chains is to work closely with the EU's main trading partners to ensure safety at source – so that only safe products are produced for our market in the first place.

Moving further along the supply chain, we also work on strengthening product safety customs controls to prevent dangerous products from entering the EU.

We are also working on improving the feasibility of tracking where dangerous products are coming from. Plus, if dangerous products reach our market, we have the EU rapid alert system between EU Member States in place (the RAPEX system) to help locate, isolate and eliminate these products.

In the international field, our two most important partners in the consumer product safety area are the United States and China.

With China we have set-up a very effective information exchange system which enables the Chinese authorities to directly follow-up any unsafe products found in the EU coming from China.

Together with the US Consumer Product Safety Commission (CPSC) and the Chinese authorities, we have also taken trilateral action to improve the health and safety of consumers.

Over the next two days, the third trilateral EU-US-China consumer product safety summit will take place. I am looking forward to making further progress during the discussions in this forum.

We also have very good bilateral cooperation with the US CPSC. Unfortunately, however, due to restrictions in place in US legislation, we have not yet managed to conclude a formal EU-US agreement on consumer product safety.

This obstacle limits how we can work together both bilaterally and trilaterally.

Nevertheless we have very good informal contacts in place and we work together as much as legally possible at bilateral as well as multilateral level.

Food

Finally – the safety of food supplies.

The EU is the biggest importer and exporter of food products in the world. The safety – and quality – of EU products are a major selling point. This is possible thanks to the bedrock of our food safety regulatory framework.

The EU integrated approach to food safety aims to assure a high level of safety within the European Union through coherent farm-to-table measures and adequate monitoring, whilst ensuring the effective functioning of the EU internal market and enhancing our exporting capacity.

This regulatory framework allows live animals, food and feed to move freely throughout the EU, and for them to be exported under safe conditions.

The publication of a White Paper on Food Safety in 2000 sparked a series of measures which transformed the EU food safety system. The General Food Law, the Hygiene Package and the Food and Feed Control Regulation are cornerstones of the EU Food Safety system.

Other essential elements of our system are the Rapid Alert System for Food and Feed, which enables swift and effective action to be taken when problems arise, and the Better Training for Safer Food project, which trains Member State and third country control staff in our food safety rules.

Whilst we are satisfied with the results from the implementation of this framework:

- we continue to take firm action to counter risks to the food chain;

- we continue to retain and strengthen the credibility of the EU framework;

- and we continue to ensure that the regulatory framework remains modern and risk-based.

We are currently working on a series of initiatives to further fine-tune our rules, taking account of the experience gained in recent years. Let me only mention three topics:

1. the review of the official food and feed controls;

2. the review of the hygiene package, and

3. the modernisation of EU meat inspection system.

This enhanced framework will continue to facilitate our trade with key partners, such as the US, in line with international agreements.

Finally the EU is, of course, an active key partner on the international scene, in particular in multilateral fora such as the Codex Alimentarius, OIE and WHO.

We contribute to internationally accepted standards in global health and world trade, and a greater push for better global governance on food safety.

Conclusion

Ladies and Gentlemen,

I have given just a very quick "whistle-stop" of current initiatives in relation to the safety of the supply chains in relation to medicines and medical devices, consumer products and food.

I now look forward to hearing your views and addressing any questions you may have.

Thank you.

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