

## EGA Conference - How can the supply chain protect patients against counterfeit medicines in the EU?

*Tuesday 10th November, European Parliament, Brussels - 9.30 - 12.30 am*

- Conference organised by the European Generic Medicines Association and Chaired by Antonyia Parvanova MEP.

### **9.30 am: Welcome address - talking points - Antonyia Parvanova MEP**

- Ladies and Gentlemen, Dear colleagues, I would like to warmly welcome you to this conference, and to thank you all for being here with us today. I would also like to thank particularly the European Generic Medicines Association for the organisation of this conference, and I hope we will have fruitful discussions on the issue of counterfeit medicines, which should be of key interest to a wide range of stakeholders:
  - the patients first - since they should always be considered as the priority when regulating to combat counterfeit medicines,
  - the pharmaceutical industry of course - for which safety and security cannot be compromised
  - pharmacists and other distributors - as a key player in the supply chain of medicines
  - and finally national and international authorities - with a leading role to play in implementing and enforcing effective measures to combat counterfeiters
- "How can the supply chain protect patients against counterfeit medicines in the EU?", this will be the backbone of our debates today, echoing the Commission's proposal which is currently being discussed in the European Parliament. We know that falsified medicines are now threatening Europe and that measures are needed to ensure the full security of the legal supply chain. But we should also wonder where is this threat coming from?

According to the WHO, less than 1 % of medicines sold through the legal supply chain in developed markets such as the EU are counterfeited. We should therefore **look closely at the main "entry points" for counterfeit medicines**, that is to say, the main channels used by counterfeiters to reach, mislead and put at risk the lives of patients and consumers.

- I will come back to the Commission's proposal a bit later, as I strongly believe that we will not address the whole issue with this proposal. Let's be clear: **the counterfeiting of medicines is an organised crime activity and we need the right tools to fight it!** Ensuring the security of the legal supply chain of medicines is far from being enough to really fight counterfeit medicines in the EU.
  
- If we really want to achieve this essential objective, we need to **fight the illegal market of medicines**, to strengthen sanctions, and to reinforce measures to protect consumers from falsified medicinal products. It is therefore crucial that the Commission and the Council further develop their **action in the field of justice, police and customs cooperation**, specifically targeting counterfeit medicines. In addition to the current Commission's proposal, this would be an essential step to make sure we are fighting counterfeit medicines as a whole, and ensuring the highest level of protection and safety for patients and consumers.
  - **For example**, such cooperation or targeted actions exists for **tobacco or alcohol smuggling**. We should be able to further implement it for counterfeit medicines as well and create an effective task force at EU-level. I know where are here outside of the scope of the Commission's proposal but let's use all the "tool box" of the EU, and also address this issue in the **field of justice and home affairs**.

- I am glad that we have today with us representatives of national authorities, and of the World Customs Organisation, and I very much look forward to listening to them on how best we can fight counterfeit medicines as a criminal activity. This will be the topic of our first panel discussion today.
  
- Regarding the Commission's proposal, I am most pleased to have here with me **my colleague Marisa Matias, who is the Parliament's rapporteur on this dossier in the ENVI Committee**. I believe the Commission's initiative is a necessary and timely step to combat this rising health threat and to ensure the security of the legal chain of supply. But looking at it more closely, it seems that **some points need to be raised and further discussed** in order to come up with a balanced and sound proposal:
  - We first of all need a **clear definition of falsified medicinal products**, so that we can all agree on what we are fighting. It is important to remind here that we are not speaking about intellectual property rights or patent issues.
  - **The sale of medicines via Internet** should be closely looked at and properly addressed. Internet-based sales are the major source and entry point of counterfeit medicines. The proposal doesn't respond to this crucial issue, and should therefore be complemented.
    - We may not be able to address the whole problem through the current piece of legislation, but we should use this debate to open the discussion and call for the Commission to develop further initiative in this field. A crucial element to combat this situation is also to make sure that the current legislation in this field is enforced and that consumers are informed about the risk of buying medicinal

products via Internet. Awareness campaigns should therefore be considered.

- Another key point that I would like to stress on today is the **cost implications of the measures proposed by the European Commissions**. In other words, if we do intend to fight counterfeited medicines, **who will pay the price?** As already mentioned, less than 1 % of medicines sold through the legal supply chain in developed markets such as the EU are counterfeited. We should therefore be careful on what would be the financial impact of the safety features that would apply to protect products which are "at risk" from counterfeiters.
  
- I still have some doubts on the fact that the industry will be able to absorb the costs of the new safety features such as the "mass serialisation" process, and I am concerned that **such measures would lead to an increase of the price of medicines to patients**. It is therefore crucial to adopt a risk-based approach, looking at the price and cost-incidence when considering safety features, since crime organisations involved in the counterfeiting of medicines are looking at making money, and therefore they target products where they can effectively mislead consumers and make a significant margin.
  - To continue looking at the potential financial impact of the proposals, I believe that any technological feature aiming at reinforcing the security of the supply chain, should be **cost-effective and proportional**, while guaranteeing an independent management of any data collected.
  
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the entry into force of the Directive, looking at the impact it had on the price of medicines for patients and consumers, and the potential need to further extend the scope of measures -should patients' safety be at risk with a larger range of products.

- As you can see, whether we speak about the fight against counterfeit medicines within the legal or the illegal chain of supply, we have a lot to do, and therefore a lot to debate! So, please allow me to open this conference and start with our first session, which will focus on the new development on the fight against counterfeiting in the international arena, with:
  - **Dr. Domenico Di Giorgio**, from the Secretariat of the Italian Anti-Counterfeiting Task-Force
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- Thank you again to all of you for being here with us today, and now let's debate! Dr Di Giorgio, the floor is yours!

## EGA Conference - How can the supply chain protect patients against counterfeit medicines in the EU?

*Tuesday 10th November, European Parliament, Brussels - 9.30 - 12.30 am*

- Conference organised by the European Generic Medicines Association and Chaired by Antonyia Parvanova MEP.

### **9.30 am: Welcome address - talking points - Antonyia Parvanova MEP**

- Ladies and Gentlemen, Dear colleagues, I would like to warmly welcome you to this conference, and to thank you all for being here with us today. I would also like to thank particularly the European Generic Medicines Association for the organisation of this conference, and I hope we will have fruitful discussions on the issue of counterfeit medicines, which should be of key interest to a wide range of stakeholders:
  - the patients first - since they should always be considered as the priority when regulating to combat counterfeit medicines,
  - the pharmaceutical industry of course - for which safety and security cannot be compromised
  - pharmacists and other distributors - as a key player in the supply chain of medicines
  - and finally national and international authorities - with a leading role to play in implementing and enforcing effective measures to combat counterfeiters
- "How can the supply chain protect patients against counterfeit medicines in the EU?", this will be the backbone of our debates today, echoing the Commission's proposal which is currently being discussed in the European Parliament. We know that falsified medicines are now threatening Europe and that measures are needed to ensure the full security of the legal supply chain. But we should also wonder where is this threat coming from?

According to the WHO, less than 1 % of medicines sold through the legal supply chain in developed markets such as the EU are counterfeited. We should therefore **look closely at the main "entry points" for counterfeit medicines**, that is to say, the main channels used by counterfeiters to reach, mislead and put at risk the lives of patients and consumers.

- I will come back to the Commission's proposal a bit later, as I strongly believe that we will not address the whole issue with this proposal. Let's be clear: **the counterfeiting of medicines is an organised crime activity and we need the right tools to fight it!** Ensuring the security of the legal supply chain of medicines is far from being enough to really fight counterfeit medicines in the EU.
  
- If we really want to achieve this essential objective, we need to **fight the illegal market of medicines**, to strengthen sanctions, and to reinforce measures to protect consumers from falsified medicinal products. It is therefore crucial that the Commission and the Council further develop their **action in the field of justice, police and customs cooperation**, specifically targeting counterfeit medicines. In addition to the current Commission's proposal, this would be an essential step to make sure we are fighting counterfeit medicines as a whole, and ensuring the highest level of protection and safety for patients and consumers.
  - **For example**, such cooperation or targeted actions exists for **tobacco or alcohol smuggling**. We should be able to further implement it for counterfeit medicines as well and create an effective task force at EU-level. I know where are here outside of the scope of the Commission's proposal but let's use all the "tool box" of the EU, and also address this issue in the **field of justice and home affairs**.

- I am glad that we have today with us representatives of national authorities, and of the World Customs Organisation, and I very much look forward to listening to them on how best we can fight counterfeit medicines as a criminal activity. This will be the topic of our first panel discussion today.
  
- Regarding the Commission's proposal, I am most pleased to have here with me **my colleague Marisa Matias, who is the Parliament's rapporteur on this dossier in the ENVI Committee**. I believe the Commission's initiative is a necessary and timely step to combat this rising health threat and to ensure the security of the legal chain of supply. But looking at it more closely, it seems that **some points need to be raised and further discussed** in order to come up with a balanced and sound proposal:
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- Another key point that I would like to stress on today is the **cost implications of the measures proposed by the European Commissions**. In other words, if we do intend to fight counterfeited medicines, **who will pay the price?** As already mentioned, less than 1 % of medicines sold through the legal supply chain in developed markets such as the EU are counterfeited. We should therefore be careful on what would be the financial impact of the safety features that would apply to protect products which are "at risk" from counterfeiters.
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## EGA Conference - How can the supply chain protect patients against counterfeit medicines in the EU?

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  - The question of cost implications should also be considered when it comes to the **overall scope of the proposed directive**, and I would support the idea of an implementation report to be developed following

the entry into force of the Directive, looking at the impact it had on the price of medicines for patients and consumers, and the potential need to further extend the scope of measures -should patients' safety be at risk with a larger range of products.

- As you can see, whether we speak about the fight against counterfeit medicines within the legal or the illegal chain of supply, we have a lot to do, and therefore a lot to debate! So, please allow me to open this conference and start with our first session, which will focus on the new development on the fight against counterfeiting in the international arena, with:
  - **Dr. Domenico Di Giorgio**, from the Secretariat of the Italian Anti-Counterfeiting Task-Force
  - **Mr Myeong-ku Lee**, from the World Customs Organisation
  - **Mr Mick Deats**, from the UK Medicines and Healthcare products Regulatory Agency
  
- Thank you again to all of you for being here with us today, and now let's debate! Dr Di Giorgio, the floor is yours!