securPharm

The German shield against falsified medicines

Thursday, 23rd of July 2015

2. securPharm European Conference on the Falsified Medicines Directive

For international stakeholders

The securPharm project:

Insights and experiences with implementation by stakeholders

www.securpharm.de

Greeting

Dear Madam or Sir,

With the so-called Falsified Medicines Directive (FMD), the European Union reacted to the globally increasing risk of falsified medicines. It introduces a set of measures for the pharmaceutical supply chain to ensure that patients are provided with safe medicines. This has created an enormous challenge to national stakeholders and their associations, because they are responsible for the set-up and management of the medicines verification system in their country. In Germany, the different stakeholders of the pharmaceutical supply chain joined forces and reacted to the FMD by establishing the organisation securPharm e.V.

Now the European Commission has announced that the adoption of the delegated act is planned for mid-July 2015. This act will set out more details about the measures laid down in the FMD as there are aspects such as the specification of the safety features as well as the modalities of verification. After publication, the member states have a transition period of three years. Our experience with the securPharm project has shown that the high degree of complexity of the FMD measures and the importance of pharmaceutical drug safety require an immediate reaction of the national stakeholders.

The 2nd securPharm European Conference on the Falsified Medicines Directive and the delegated act will offer you insights from the representatives of the EU Commission, the German Federal Ministry of Health and selected experts from the pharmaceutical distribution chain regarding the implementation of the FMD measures. We will also provide deeper insight into our activities for implementing the Directive's requirements and the impacts of the delegated act.

Together with the speakers, we look forward to your visit!

Kind regards,

Martin Bergen
General Manager securPharm e.V.

The initiative

About securPharm e.V.

securPharm e.V. is an initiative to protect patients from falsified pharmaceuticals in Germany's legal supply chain. It is sponsored by a consortium of the following pharmaceutical companies', wholesalers' and pharmacists' associations: BAH, BPI, vfa, phagro, and ABDA.
Since 2011, securPharm e.V. has been developing a protective system from falsified medicines in compliance with the requirements of the EU Falsified Medicines Directive 2011/62/EU. This system has been tested in practice since 2013. The findings derived from testing are directly used in further system development. This unique collaboration of all stakeholders in the pharmaceutical supply chain makes it possible to optimally tailor the system to the business processes of all parties involved from the outset. One important element of securPharm is the use of separate databases for manufacturers and pharmacists in order to maintain the greatest possible data privacy for patients. Today, securPharm is the leading system in Europe for the implementation of future legal requirements regarding the authenticity verification of pharmaceuticals. It is the objective of securPharm to provide a system that can be used by all market participants when the Falsified Medicines Directive becomes effective at the end of 2018.

For more information, please visit www.securpharm.de

Agenda
Thursday, 23rd of July 2015

Moderator: Thomas Brückner, Member of the board of securPharm e.V., Pharmacist, Head of Pharmaceutical Affairs/ GMP/ Pharmacopoeial Questions, German Pharmaceutical Industry Association e. V. (BPI)

8:30 **Registration and Networking with snacks and beverages, visit to the exhibitors**

9:30 **Welcome and Keynote**

- Welcome on behalf of securPharm
- Importance of the Falsified Medicines Directive and the delegated act
- Schedule till end of 2018

Dr. Reinhard Hoferichter,
Speaker of the board of securPharm e.V.,
Director Public Affairs,
Sanofi-Aventis Deutschland GmbH

9:45 **Statement of the EU Commission to the delegated act**

- Adoption planned for July 2015
- Insight in the process´s current status
- Major Topics of the delegated act

Stefano Soro,
Head of the Product and Service Safety Unit, Directorate General Health and Consumers, European Commission

Dr. Patrizia Tosetti,
Policy Officer, Directorate General Health and Consumers, European Commission

10:15 **The next three years to implement the delegated act in the member states**

- Overview of requirements included in the Falsified Medicines Directive and the delegated act
- Action items for pharmaceutical companies, wholesalers, pharmacies and national authorities in Germany

Dr. Oliver Onusseit,
Unit 114, drug development and regulatory affairs, wholesalers, clinical trial, German Federal Ministry of Health

11:00 **Question and answer session**

Thomas Brückner

11:15 **Break and Networking with coffee and beverages, visit of the demonstrator and the exhibitors**

11:45 **How implementation can work: An introduction to securPharm project**

- Overview of securPharm-Project
- Internal structures and major players
- System design and data protection

Martin Bergen,
General Manager of securPharm e.V.

12:05 **National prerequisites and their importance for a successful implementation**

- Specific national prerequisites as a secret of securPharm´s leading position
- Benefits from a national register for medicinal products
- Importance of good core principles and guidelines

Lothar Jenne,
Member of the board of securPharm e.V., Member of the board of the federal association of pharmaceutical wholesalers (PHAGRO)

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12:25	**The separate database model of securPharm and its benefits** ↗ Data protection by design as one of the main principles ↗ What benefits can be gained ↗ What´s that supposed to mean to stakeholders	**Dr. Eckart Bauer,** Member of the board of securPharm e. V., Head Department Economic and Social Affairs, ABDA-Federal Union of German Association of Pharmacists
12:45	**Why competition is good – coding as an example** ↗ PPN: Transfer of national numbers into international unique product codes ↗ Costs for implementing the product codes	**Paul Rupp,** Member of the board of securPharm e. V., Expert Auto-ID
12:55	**Question and answer session**	**Thomas Brückner**
13:10	**Break and Networking** **Lunch, visit of the Demonstrator and the exhibitors**	
14:10	**How to embed a national system in a European context** ↗ How to set up a successful team ↗ Cooperation with the European Hub ↗ What an MAH must do to connect and ways to upload data	**Peter Krug,** Member of the board of securPharm e. V., Director Human Resources / Finance Research-Based Pharmaceutical Companies (vfa)
14:25	**Verification of Medicinal Products in Europe** ↗ Introduction of the European Stakeholder Model ↗ The National Blueprint approach ↗ European roll-out	**Monika Derecque-Pois,** GIRP, The European Association of pharmaceutical full-line wholesalers, Director General & EMVO Board member
14:50	**Cost estimation of securPharm** ↗ Different components to consider ↗ Current calculation	**Martin Bergen**
15:00	**Question and answer session**	**Thomas Brückner**
15:30	**Break and Networking** **with coffee and beverages, visit of the demonstrator and the exhibitors**	

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16:00	**System security and what it means for the user legitimation** ↗ Registration and legitimation of users as requirement for a safe medicines verification system ↗ A short insight will provided how this will be handled in the securPharm approach	**Dr. Hermann Kortland,** Member of the board of securPharm e.V., Deputy general manager of German federal association of pharmaceutical manufacturers (BAH)
16:15	**Challenges for marketing and manufacturing authorisation holder** ↗ How to implement the requirements of the falsified medicines directive in a pharmaceutical company ↗ Tasks, feasible timelines and who has to be involved	**Klaus Egner,** Merck KGaA, Engineer Engineering & Maintenance Pharma, Logistics, Downfilling Site Operations | Engineering and Maintenance
	Verification: valuable lessons learned by wholesalers ↗ Integration into everyday business routine ↗ Experiences and solutions	**Lutz Schütte,** Head of ZSB Technik / Organisation / Innovation, Phoenix Pharmahandel GmbH & Co. KG
	Impact on the business in pharmacies ↗ Effects on the everyday business in pharmacies ↗ Challenges and Experiences	**Dr. Hans-Peter Hubmann,** Member of the board of ABDA, Chairman of the Bavarian Pharmacists Association
	Question and answer session	**Thomas Brückner**
	Closing session and final statement	**Dr. Reinhard Hoferichter**
17:15	**End**	

Speakers

Dr. Eckart Bauer,
Member of the board of securPharm e. V.,
Head Department Economic and Social Affairs,
ABDA-Federal Union of German Association of Pharmacists

Martin Bergen,
General Manager of securPharm e.V.

Thomas Brückner,
Member of the board of securPharm e.V., Pharmacist, Head of Pharmaceutical Affairs/ GMP/ Pharmacopoeial Questions, German Pharmaceutical Industry Association e. V. (BPI)

Monika Derecque-Pois,
GIRP, The European Association of pharmaceutical full-line wholesalers,
Director General & EMVO Board member

Klaus Egner,
Merck KGaA, Engineer Engineering & Maintenance Pharma, Logistics, Downfilling
Site Operations | Engineering and Maintenance

Dr. Reinhard Hoferichter,
Speaker of the board of securPharm e.V.,
Director Public Affairs, Sanofi-Aventis Deutschland GmbH

Dr. Hans-Peter Hubmann,
Member of the board of ABDA, Chairman of the Bavarian Pharmacists Association

Lothar Jenne,
Member of the board of securPharm e.V.,
Member of the board of the federal association of pharmaceutical wholesalers (PHAGRO)

Dr. Hermann Kortland,
Member of the board of securPharm e.V., Deputy general manager of German federal association of pharmaceutical manufacturers (BAH)

Peter Krug,
Member of the board of securPharm e. V.,
Director Human Resources / Finance Research-Based Pharmaceutical Companies (vfa)

Dr. Oliver Onusseit,
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German Federal Ministry of Health

Paul Rupp,
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Lutz Schütte,
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Stefano Soro,
Head of the Product and Service Safety Unit,
Directorate General Health and Consumers, European Commission

Dr. Patrizia Tosetti,
Policy Officer, Directorate General Health and Consumers, European Commission

Organisational issues

Registration

For Registration please follow:
www.securpharm.de/en/events
Submission deadline is the 7th of July 2015

Contact

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Location

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www.kapeuropa.de
Getting there:
www.securpharm.de/en/events/directions

Host

securPharm e.V.
Hamburger Allee 26-28
60486 Frankfurt am Main / Germany
www.securpharm.de

Conditions of participation

The participation is exempt from charges for national and international stakeholders and representatives from the pharmaceutical companies, wholesalers and pharmacies. We reserve our right to limit the number of participants. Any liabilitiy is excluded.

Get together

We like to offer you the opportunity for a meet & greet of your national and international colleagues.

Wednesday 22nd of July 2015
19:00 to 21:00
At Kap Europa
Costs 59,50 Euro (included VAT) per person.
For registration please follow:
www.securpharm.de/en/events

ABDA · BPI Bundesverband der Pharmazeutischen Industrie e.V. · PHAGRO · Bundesverband der Arzneimittel-Hersteller e.V. B.A.H · vfa. Die forschenden Pharma-Unternehmen