



Rif. MA 10/11

19 ta' Settembru 2011

### **Regolamentazzjoni għal mediċini li tista' tafda:**

#### ***Seminar informattiv dwar il-legiżlazzjoni tal-Farmakovigilanza u l-Mediċini Falsifikati***

L-Awtorit a dwar il-Mediċini, f'kollaborazzjoni mal-Malta-EU Steering and Action Committee (MEUSAC), se torganizza sessjoni ta' informazzjoni dwar  zewg direttivi li  gew adottati mill-Kunsill u mill-Parlament Ewropew u li dwarhom għaddej il-proċess ta' traspo izzjoni fil-legiżlazzjoni nazzjonali. Is-sessjoni se ssir nhar **it-Tnejn 10 ta' Ottubru 2011, fis-2.00 ta' waranofsinhar, f'Dar l-Ewropa, 254, Triq San Pawl, il-Belt Valletta.**

L-għan tad-Direttiva 2010/84/UE dwar il-Farmakovigilanza hu li tħares iktar lill-pazjenti billi ssaħħaħ is-sigurezza tas-sistema tal-UE għall-monitoraġġ tal-mediċini. Id-Direttiva 2011/62/UE dwar il-Mediċini Falisifikati għandha ssaħħaħ il-legiżlazzjoni tal-UE biex iċ-ċittadini jitharsu aħjar minn theddidiet serji li jgħibu l-mediċini falisifikati. Id-Direttivi u dokumenti b'mistoqsijiet u twegibiet dwarhom jinsabu fis-sit: <http://medicinesauthority.gov.mt/legcon.htm>

Għaldaqstant inti mistieden/mistiedna tattendi s-sessjoni li se tinfetaħ mill-Onor. Dott. Chris Said, Segretarju Parlamentari għall-Konsumaturi, Kompetizzjoni Ġusta, Kunsilli Lokali u Djalogu Pubbliku. Jekk tixtieq tattendi, irreġistra billi tibgħat email lil [info@meusac.gov.mt](mailto:info@meusac.gov.mt) jew ċempel lis-Sur Brian Pace fuq 2200 3300. Il-partecipazzjoni f'din il-laqgħa hija b'xejn u s-sessjoni tkun bil-Malti bil-prezentazzjonijiet tekniċi bl-Ingliż.

Dejjem tiegħek

Patricia Vella Bonanno

Kap Eżekuttiv, Awtorit a dwar il-Mediċini

Mehmuż: Il-programm tas-Sessjoni



Ref. MA 10/11

19th September 2011

**Regulation for medicines you can trust:  
*Information seminar on the transposition of legislation of Pharmacovigilance  
and Falsified medicines***

Dear stakeholder,

The Medicines Authority, in collaboration with the Malta EU Action Steering Committee (MEUSAC), will be organising an information session on two directives which have been adopted by the European Council and Parliament and are in the process of being transposed into national legislation. The session will be held on **Monday 10<sup>th</sup> October 2011 at 14:00 at Europe House, 254, St Paul Str., Valletta.**

Directive 2010/84/EU on pharmacovigilance aims to better protect patients by strengthening the EU's system for the safe monitoring of medicines. Directive 2011/62/EU on Falsified medicines aims to strengthen EU legislation to better protect EU citizens from the serious threats posed by falsified medicines. The text of the directives and question and answer documents on these directives are available on: <http://medicinesauthority.gov.mt/legcon.htm>

You are hereby cordially invited to attend the session which will be opened by the Hon. Dr Chris Said, Parliamentary Secretary for Consumers, Fair Competition, Local Councils and Public Dialogue. Kindly register your attendance by sending an email to [info.meusac@gov.mt](mailto:info.meusac@gov.mt) or else call Brian Pace on 2200 3300. Attendance is free of charge, the proceedings will be in Maltese and technical presentations in English.

Yours sincerely

Patricia Vella Bonanno  
CEO, Medicines Authority

Encl.: Session programme



## Regolamentazzjoni għal mediċini li tista' tafda:

### *Seminar informattiv dwar il-legiżlazzjoni tal-Farmakovigilanza u l-Mediċini Falsifikati*

**Data:** 10 ta' Ottubru 2011

**Ħin:** 14:00

**Post:** Dar l-Ewropa, il-Belt Valletta

#### PROGRAMM

13:30	<b>Registrazzjoni u kafè</b>	
14:00	<b>Diskors ta' merħba</b>	Dott. Diane Saliba <i>Kap – Politika u Legiżlazzjoni tal-UE MEUSAC</i>
14:05	<b>Diskors tal-ftuħ</b>	Dott. Chris Said <i>Segretarju Parlamentari għall- Konsumaturi, Kompetizzjoni Ġusta, Kunsilli Lokali u Djalogu Pubbliku</i>
14:20	<b>Seven Years of EU Medicines Regulation in Malta</b>	Dott. Patricia Vella Bonanno <i>Kap Eżekuttiv Awtorità dwar il-Mediċini</i>
14:40	<b>Directive 2010/84/EU:</b> Strengthening and rationalising the current system for monitoring the safety of medicines	Dott. John Joseph Borg <i>Direttur Post-Licenzjar Awtorità dwar il-Mediċini</i>
15:00	<b>Diskussjoni</b>	
15:45	<b>Directive 2011/62/EU:</b> Protecting patients and consumers from the serious threats posed by falsified medicines	Is-Sur Mark Cilia <i>Direttur Spettorat u Nfuzzar Awtorità dwar il-Mediċini</i>
16:05	<b>Diskussjoni</b>	
16:45	<b>Diskors tal-għeluq</b>	Dott. Ray Busuttil <i>Awtorità tal-Licenzjar</i>



**Regulation for medicines you can trust**  
***Information seminar on the transposition of legislation of Pharmacovigilance  
and Falsified medicines***

Date: 10<sup>th</sup> October 2011

Time: 14:00

Venue: Europe House, Valletta

13:30	<b>Registration and welcome coffee</b>	
14:00	<b>Welcome Address</b>	Dr Diane Saliba <i>Head – EU policy &amp; Legislation MEUSAC</i>
14:05	<b>Opening Address</b>	Dr Chris Said <i>Parliamentary Secretary for Consumers, Fair Competition, Local Councils and Public Dialogue</i>
14:20	<b>Seven Years of EU Medicines Regulation in Malta</b>	Dr Patricia Vella Bonanno <i>Chief Executive Officer Medicines Authority</i>
14:40	<b>Directive 2010/84/EU:</b> Strengthening and rationalising the current system for monitoring the safety of medicines	Dr John Joseph Borg <i>Post-Licensing Director Medicines Authority</i>
15:00	<b>Discussion</b>	
15:45	<b>Directive 2011/62/EU:</b> Protecting patients and consumers from the serious threats posed by falsified medicines	Mr Mark Cilia <i>Inspectorate and Enforcement Director Medicines Authority</i>
16:05	<b>Discussion</b>	
16:45	<b>Concluding Address</b>	Dr Ray Busuttil <i>Licensing Authority</i>



## Registration Form

### Regulation for medicines you can trust *Information seminar on the transposition of legislation of Pharmacovigilance and Falsified medicines*

10 October, 2011

Name of Person(s) attending:	
Organisation:	
Address:	
ID No. ( <i>ID nos of all persons attending must be provided</i> ):	
Tel:	Fax:
Email:	

I would like to register for this Information Session, being organised by MEUSAC and the Medicines Authority at Europe House, 254, St Paul Street, Valletta, at 14:00 on 10 <sup>th</sup> October, 2011.
I have/ have not attended for activities organised by MEUSAC in the past <i>(delete as applicable)</i>
I would like/ would not like to be added to MEUSAC's database and to continue receiving information about future activities and any e-Updates issued by it <i>(delete as applicable)</i>

Kindly send this form back to MEUSAC by email to email [info.meusac@gov.mt](mailto:info.meusac@gov.mt)

Please note that the I.D. Card is to be presented for entry to Europe House.