ANNEX 3:
Additional Compilation of Material Relating to Counterfeit Medicines

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1 MEMBER STATES SURVEY

Introduction

1.1 This is a summary of the responses to the questionnaire for Part 1 of the study of distribution channels, submitted by the following Member States;

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c) Cyprus
d) Estonia
e) Finland
f) France
g) Germany
h) Hungary
i) Ireland
j) Italy
k) Latvia
l) Liechtenstein
m) Lithuania
n) Malta
o) Netherlands
p) Norway
q) Portugal
r) Romania
s) Slovakia
t) Spain
u) Sweden
v) UK

1.2 The following countries submitted separate responses for human and veterinary medicines:

a) Italy
b) Lithuania
c) Slovakia
d) UK

1.3 Questionnaire responses were not received for the following countries;

a) Bulgaria
b) Czech Republic
c) Denmark
d) Greece
e) Luxembourg
f) Poland
g) Slovenia

Summary of Responses

Question 1: Extent of counterfeit problem since year 2000: and expected trends

Question number	1.1	1.2	1.3	1.4	1.5	1.6
Member state	**Data (e.g. in reaction to reference data)**	**If no data is available, how and on which basis is the extent of counterfeit medicines measured?**	**Has there ever been any indication of the occurrence of counterfeit medicines in parallel trade in the past?**	**Which type of products have been counterfeited in the past and to what extent?**	**At which level of the supply chain were the counterfeit products identified and to which extent (both the legal and the illegal supply chain)**	**Is there basis for expecting the changes in the scale and nature of the problem, over (say) the next five years?**
Austria	None have been found in the legal supply chain. All counterfeit or illegal medicines were ere bought on the internet or confiscated on the black market.	Limited suspicion and information that the legal supply chain has ever been penetrated.	No	Mainly medicines against erectile dysfunctions; for neurodermitis; anabolics for body-building; and drugs for slimming. Only in the illegal supply chain. They are usually bought on the Internet or confiscated on the black market	Internet or the black market	The public continues to be warned about the risk of buying medicines over the counter.

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Belgium	2000 (4 major international cases including amoxycyllin, halofanterin, cipofloxacin), 2001 (4 minor national cases of sildenafil and 4 major cases of anabolics- in. &tablets-), 2003 8 minor national cases including sildenfil, 3 major national cases including sildenfil and 1 major case including ciclosporin capsules, 2004 3 counterfeit veterinery medicinal product (and a medicinal product for human use affecting other Member States), there have been no	There are no aimed controls related to counterfeit detection. Assuming that the penetration of counterfeits is very much dependent on a country's market characteristics it is estimated that Belgium is well protected.	No.	Amoxycyllin; halofanterin; cipofloxacin; sildenafil; anabolics; and ciclosporin capsules. See 1.a A major case means more than 100,000 units.	Illegal supply chain (illegal website acquisition and international smuggling)	Further uncontrollable internet sale explosion and black market transborder smuggle mostly for lifestyle drugs may be expected.

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	counterfeit medicinal products detected since 2000 in the regular distribution chain in Belgium. There are no data available for 2005 and 2006.					
Cyprus						
Estonia	No data	Not yet detected in licensed distribution chain.	No	Erectile dysfunction products, ordered by private persons via internet. Confiscated by customs postal services). Trade names Venegra, Viraha (packages addressed to private persons containing relatively large quantity (> 100 tablets)	Internet (illegal supply chain)	No response
Finland	No response	No response	No response	No response	Illegal supply chain (risks found in internet	No response

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					sales, and in transit traffic)	
France	No data (non found in legal supply chain)	Internet sites written in French	No	Contact lenses	Legal supply chain (e.g. opticians)	They don't know
Germany	Legal distribution chain: 1996-2007: 35 cases in the legal distribution chain. 2006: 6 cases	There are no systematic investigations that would allow a reliable estimation of the extent of the problem.	None till 2007: Currenct inevtigation 2007: recall of Casodex (R), case not finished.	Mainly illegally repacked original products involving all types of medcine. Recently it is more expensive medicines, life-style mediciation pr medicines with a high sales that are counterfieted.	Legal supply chain (retail level- none detected at wholesale level). Illegal supply chain: e.g. illegal internet trade, unlicensed internet pharmacies, illegal circulars)	Yes, total counterfeits can be expecetd to increase. Largely due to diversification of medicines, Abolishing of cost reimbursement of some medicines and greater advertisements of cheap medicines.
Hungary	1-2 detected cases.	Decrease in sales data of the original	No	Solutions, medicated premixes,	legal supply chain (e.g.	No

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	No data available.	product		1-2 products each	Veterinary pharmacies)	
Ireland	2004: 2 cases of counterfeit - amount 80 anthelmintics @ approx EUR 80 each.	N/A	No	See 1.1	Legal supply chain (e.g. retail)	No
Italy (Veterinary)	No data	see 1.1	see 1.1	See 1.1	see 1.1	see 1.1
Latvia	No data	No data	No data	No data	No data	The scale of the problem in not big and it is not expect it to increase.
Liechtenstein	No data	No big problems are known up till now	No	No response	No response	Don't know

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Lithuania (Human)	No data	Extent of problem is not big and are aware of it through information form other countries/ agencies ect. Expect imports are most likely avenue for counterfeit to enter the illegal distribution chain	No	2005 one suspected case regarding vitamins. 2006 one unlicensed product detected regarding dietary supplements.	Mainly through illegal distribution chain of illegal medicines (not registered and maybe counterfeits) in the outside market- places (without license for pharmaceutical activity), where people can buy a medicine without prescription, without advice of pharmacist.	Yes, mainly vis internet post
Lithuania (Veterinary)	No data	Mainly through information from inspections.	No data	No data	No data	No

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Malta	2006: 200 bottles of counterfeit Vicks vaporub were intercepted at Maltese customs. 2007; a case is being investigated regarded 400 packs of Plavix found in a bonded warehouse in Malta.	The extent of the problem in Malta is not significant. Both products identified above have been stopped from reaching the Maltese market.	No	None given	Products were intercepted at Customs before entering the supply chain.	Yes
Netherlands	(1) Legal distribution channel: 2004 Cialis, recalled from pharmacies: 2005 Lipitor intercepted in pharmacy prior to export to the USA. (2) illegal distribution channel: numerous cases	No valid method exists to estimate the extent of the problem. So far no accurate data, no systematic survey has been done.	Yes, Cialis case e2004 was UK livery product brought from Sweden by Dutch parallel trader.	In general life-style drugs, such as PDE5- inhibitors, anabolic steroids, weight loss products, anti-viral drugs (Tamiflu) cholesterol drugs.	Legal supply chain: Cialis: patients. Pharmacies Liptor: pharmacy acting as a wholesaler. Illegal supply chain: customs, internet based illegal operations.	No

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Norway	No data	We would look at estimates of comparable states.	No	Largely sold via the Internet. Largely costly products where the costs of the products is covered by the patient in full (no reimbursement) and/or where the licensed actions of the products are life style related (e.g.. weight loss, performance enhancement, sexual endurance etc). The well known brands seem more susceptible to counterfeiting then generic products.	So far the counterfeit drugs have been largely associated with private import of medicinal products via the internet. No legal internet pharmacies exist in Norway.	NOMA is concerned that the secondary market for medicinal products at the wholesale level seen in other member states, may develop in Norway as well. As we understand it, most cases of counterfeit discovered within the legal supply chin have originated from such secondary markets.

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Portugal	No cases	No estimates	Parallel trade was only regulated in 2006.	N/A	N/A	n/a
Romania	Illegal distribution chain: In the last 6 years 6 cases of counterfeited medicines were signalled and investigated; Legal distribution channel: no counterfeits products were detected for the last 3 years.	No response	No	Most of counterfeits referred to Romanian products which either had been authorised in the past but afterwards the marketing authorisation had been withdrawn or have never been authorized for manufacturing and marketing as medicinal products.	Legal distribution chain (e.g. private medical practices or pharmacies). No data on illegal distribution chain.	No response
Slovakia (Veterinary)	None registered since 2000	There is no basis for the estimation.	No	None given	No Response	There is a need for updating the legislation because legislation does not cover the counterfeit medicines.

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Slovakia (Human)	4 registered cases since 2000	They cannot forecast	No	Anabolics and medicines for erectile dysfunction. Extent of counterfeit can not be estimated.	Counterfeit products were sale through internet. Extent is unknown.	Slovak Republic must update its legislative act because does not have any legislative act concerning counterfeit medicines.
Spain	No data	No response	No indication.	Androgens and GH have been identified	Only at illegal supply chains.	No response
Sweden	No Data	We have no indications of cases of counterfeit medicines in the legitimate supply chain. A reason for this is good control through the monopoly of retail trade of medicinal products. Sweden has a unique	No	Legal distribution chain: Life style product/Slimming product, Acomplia (Rimonabant). Illegal distribution chain:benzodiazepines/Rohypnol, alprazolam, Anabolic steroids/different kinds, Lifestyle medicines/Viagra, Kamagra	The counterfeit product Acomplia (Rimonabant) was identified on internet sales in the illegal supply chain.	The monopoly situation of the retail pharmacy is currently under evaluation by The Ministry of Health and Social Affairs.

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		position where retail trade of medicinal products is only allowed to be run by the State owned pharmacy, Swedish monopoly position. In addition to this one-supply-chain system is applied. In the illegitimate supply chain counterfeit products have been found and seized by the police.				
UK (Veterinary)	No Data	Not aware of any cases of counterfeit medicines being made available.	Not aware of any.	Not aware of any.	We would expect industry to make us aware of such cases should they exist	No - but no data to base this on.

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UK (Human)	Legitimate Supply Chain: Since 2004, there have been 5 known cases of counterfeit medicine products reaching patients through the legitimate UK supply chain which all led to subsequent Product Recalls. Last know such case in the UK legitimate supply chain before 2004 was in 1994. Illegitimate Supply Chain: Since 2005, there have been 5 other known cases of counterfeit medicine products reaching wholesale level in the UK supply chain but not beyond as they were	See 1.1	No. In 8 of the 10 cases discussed at Qu 1.1, the counterfeit medicines were copies of the UK packaged product as licensed by the UK Medicines and Healthcare products Regulatory Agency (MHRA - national competent authority for the regulation of human medicines and medical devices) or the European Medicines Agency (EMEA) i.e. the counterfeiters	No response	(Examples give for each in the full response)	Over next 2 years a similra trend is expected. By year 3 and onwards, it is expected that the UK anti-counterfeit strategy will have reached all stakeholders on a practical level and the threat of counterfeit medicines reaching patients in the Auk through the legitimate supply chain is negated.

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	identified and intercepted at this point.		copied the UK packs. In the 2 other cases, the products were not licensed for UK or EU use – one was in French livery destined for a clinical trial and the other two were in non-UK/non-EU livery where the product was imported from outside the EU for supply outside the EU.			

Question 2: Definition of counterfeit medicines, pharmaceutical crime

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
Austria	No	No response	No response	They would be punished/fined for manufacturing, importing or distributing medicinal products without having a marketing authorisation for those medicinal products.	No, but if a person receives an injury by a counterfeit or illegal medicine criminal proceedings would be opened.	N/A	N/A
Belgium	No	N/.A	N/.A	For those medicinal products that are considered not to be in conformity with our Medicines Act, penal sanctions are foreseen (also for falsified and imitated medicinal products).	No	N/A	Since pharmaceutical crime covers different crime phenomena where medicines are involved like e.g. diversion, illegal administration and possession (doping), unregistered medicines, illegal

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							sale of scheduled substances there is no unique approach but all motioned infringements have their particular reference to law texts and sanctions involved.
Cyprus	No	N/.A	N/.A	According to Section 99 of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law, marketing a medicinal product without a marketing authorisation is an offence punishable by no more than 5 years imprisonment and/or a fine up to 50,000 Cyprus pounds.	No. However, Section 99 lists infringements punishable by no more than 5 years imprisonment and/or a fine up to 50,000 Cyprus pounds.	The legislation is appended to the questionnaire. Penal prosecution is undertaken only after the consent of the Attorney General.	See 2.1.3 and 2.1.4

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Estonia	No	N/.A	N/.A	The sanctions specified under the Estonian Penal Code include imprisonment.	See 2.1.3	See 2.1.3	See 2.1.3
Finland	No	N/A	N/A	In the case of suspected counterfeits, distribution of batches must be immediately stopped and the recall must be initiated and NAM must be informed	The interpretation could be taken implicitly (see point 2.1.3)	N.A	Sanctions specicifed under Chapter 44, section 5, of the Penal Code (39/1889) will apply.
France	No	N/A	N/A	Provisions under the general law of intellectual property (Intellectual Property Code IPC) can apply themselves to the occurrence of counterfeit medicines.	No	N/A	N/A
Germany	Yes	The Arzneimittelgestez (German Drug Law) includes the definition of counterfeit drug. Section 8	a) Imprisonment from 1 to 10 years in particularly serious instances, b)	N/A	No	N/A	N/A

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		Prohibitions to prevent deception, sub section (1) Under this defintion, counterfeits are medicines in the broadest sense(mot clarified- law is expanded in Annex 1 with the full reponse).	Imprisonment not exceeding 3 years or a fine, if the perpetrator manufactures, imports or markets medicinal products for which there is reasonable suspicion that they can cause harmful effects, c) Imprisonment for a period of not more than 1 year or an administrative fine if the perpertrator has acted wilfully or negligently (without that				

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			the medicinal product can cause harmful effects) (this is expanded in Annex 2 in the full response).				
Hungary	No	N/A	N/A	No, however, sanctions will apply under Act CLXXVI (176) 2005 on Animal Health (Act is expanded in the full response).	No, only implicitly in the general Criminal Code.	no response	Police shall be notified , sanctions according to the Criminal Code.
Ireland	No specific definition, but covered by the definition of 'prohibited animal remedy' in the Animal Remedies Act 1993	N/A	See Section 23 of the Animal Remedies Act 1993 as amended by Part 7- Section 41 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006.	N/A	No, but any branch of the Remedies Act 1993 or the Regulations made thereunder constitutes an offence punishable by law.	See 2.3	See 2.1.2

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Italy Vet	No, However, this issue is included within the general definition foreseen for counterfeiting of goods (Legislation of reference: Italian Law 14/05/2005, n.80)	See 2.1	Sanctions include imprisonment.	N/A	There is not an explicit definition of pharmaceutical crime, this is implicitly included in the general definition of crimes.	no response	no response
Latvia	No. However, it is included in the draft of Regulations.	N/A	Administrate penalties in the field of pharmaceutical activities (Latvian Code of the Administrative Offences, Article 46, Article 78 and Article 228-responsibility of the State Pharmaceutical Inspection)- they have	N/A	No response	No response	(The full response includes a table with offences and the corresponding punishments)

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			added a table documenting offence and penalties				
Liechtenstein	No	N/A	N/A	To place medicinal products which do not conform to our legislation on the FL market [what is that?] is an offence against the law and is punished as such.	Please refer to the annex (art 47 and 48 of the Gestez uber den Verkehr mit Arzneimitteln im EWR, LR 812 103)	No response	No response
Lithuania (Human)	Yes	They have stated the conception of counterfeited medicine in Law on Pharmacy of the Lithuania Republic (2006-06-22 Ne X-709, 8 article, 14 section). The definition is similar to the WHO formulation: "a	There is no definition on counterfeit medicines in Code of violations of administrative law and penal code. (more on the legislation)	Investigation of counterfeiting is under jurisdiction of Police Department under the Ministry of the Interior, Bureau of detective-force (criminal police)-Board of crime investigation.	No	No response	No response

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		medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source".					
Lithuania (Veterinary)	No	N/A	N/A	Counterfeit veterinary medicinal products found in the distribution network should be kept apart from other medicinal products to avoid any confusion. They should be clearly labelled as not for sale and Lithuanian State Inspection on Veterinary Preparation and the holder of marketing authorisation of the original product should be informed immediately." (" Requirements and Wholesale Distributors of Veterinary Medicinal Products, Order for	Implicitly in national legislation.	Law on Pharmaceutical Activities (O.G., 2006 No. 78-3056) "Article 75: Responsibility for Infringement. Natural and juridical persons are responsible for infringements if action with pharmaceutical products and in veterinary pharmaceutical activity in accordance with the order described in legal acts of Republic	The Code of Administrative Offence (O.G., No. 1-1). " Article 109. Infringement of Veterinary Law and other legal acts regulating veterinary requirements. Infringement of Veterinary Law and other legal acts regulating veterinary requirements….., and also illegal pharmaceutical activity in veterinary-

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				Their Inspection and License Issuing" (O.G, 2006, No. 63-2355).)		of Lithuania."	induce cautionary or penalty..."
Malta	No response	No response	No response	No response	No	No Response	No Response
Netherlands	No	N/A	N/A	Any medicine, whether counterfeit or not, falls under medicines Act, based on 2001/83/EC. Illegal trade in (illegal) medicines is forbidden. In addition, counterfeiting is IP crime.	Yes (explicitly)	Any illegal activity with medicines is an economic crime which caries a high penalty. Any offence including unlicensed medicines falls under the same legislation.	6 years in prison, or fine of up to EUR 60,000
Norway	No	N/A	N/A	Trading of counterfeit medicines would a violation of the medial Products Act. The Norwegian Medicines Agency can sanction	Yes (explicitly)	Medicinal Products Act x 31 (Legemiddelloven x 31), which is not formally translated to	Fines, imprisonment or both. The penalties on the type and amount related to the

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
				violations, for example we can fine the traders.		English, says that intended or voluntary violation of the law on medical products will be sentenced by a fine/penalty, imprisonment or both.	crime. NOMA (Norwegian Mediciens Agency) may force compliance with regulations by the use of fines or revoking licenses. Criminal prosecutions are the responsibility of the Police.
Portugal	No. However, there is an article in the Penal Code whose wording can include counterfeits.	Penal procedure (this is expanded in the full response)	See 2.1.1	No response	No. However, they have an article on Pharmaceutical law that predicts penal procedure with a penalty of up to 2 years imprisonment. In situations where non authorized people	See 2.2	See 2.2

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
					dedicates to activity performed by pharmacies, wholesalers or manufactures.		

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
Romania	No response	There is no explicit definition of counterfeited medicines; the Romanian law provides sanctions for counterfeiting medicinal products: "Article 837 (a) Counterfeiting or placing on the market of medical products in violation of provisions of the Title constitutes infraction and 3 month to 3 years imprisonment shall be applied. (2) If the medicinal products referred to in paragraph (1) are hazardous	See previous answer	No Response	No explicit definition of pharmaceutical crime is provided in the national legislation.	No Response	No Response

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
		to health, 1 to 8 years imprisonment shall be applied. (3) If the deedreferred to in [paragraph (1) and (2) has resulted in disease or worsening thereof, 2 to 8 years imprisonment shall be applied: if it has resulted in death, 5 to 15 years imprisonment shall be applied."					
Slovakia	Our legislation does not include a definition of counterfeit medicines.	No response	No response	No response	Our legislation does not include a definition of pharmaceutical crime.	No response	No response

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
Slovakia (Veterianry)	No	N/A	N/A	No response	No	N/A	N/A
Slovakia (Human)	No	N/A	N/A	Cases of alleged counterfeiting were devolved upon the police.	Our legislation does not have any definition for pharmaceutical crime.	No response	No response
Spain	No, Spain uses the WHO definition.	N/A	N/A	At administrative level, the Act 29/2006, of 26th June 2006, on Guaranties and Rational Use of Medicines and Medical Devices, Article 101 says: Infringements, paragraph 2.c):Very serious infringements, point 2 states the counterfeit of medicines, penalised between 90.000 euros and 1.000.000 euros. In case it is committed a crime against the Public Health typified in the Penal Code , there will	Yes (implicitly)	The General Law 29/2006 of 26th June 2006, on Guaranties and Rational Use of Medicines and Medical Devices, Article 4: (law is expanded in the full response)	At an administrative level, the General Law 29/2006 on Guaranties and Rational Use of Medicines and Medical Devices, in Article 101 states: Infringements, paragraph 2.c): Very serious infringements, includes the placing on the market of

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
				also be a prosecution of a penal case before the Courts of Justice.			medicinal products without having obtained the mandatory health authorisation. And in paragraph 14 : the preparation, manufacturing, import, export, distribution, marketing, prescription and dispensing of products, preparations, substances or combinations presented as medicinal products without being legally recognised.

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
Sweden	No	N/A	N/A	The example referred to is the case with Acomplia (Rimonabant). Rapid Alert Notification/Counterfeit Notification has been delivered via the system for EMEO and EMEA. The manufacturing/marketing holder company has been informed about the findings at an early stage from MPA. EU commission has been informed as well. Laboratory testing in our OMCL facility has been performed to confirm the counterfeit with support from the manufacturing/MAH company. Public awareness was televised via the main news program in the specific case with	Yes (explicitly)	A medicinal product may not according to Section 5 of the Medicinal Products Act (1992:859) be sold until it has been approved for sale, been registered as homeopathic medicinal product, been registered as a traditional herbal medicinal product or is included/covered by a recognition by an approval or registration which has been granted in another Member State of the European Union. The	Any person who intentionally or negligently sells a medicinal product which has not been approved for sale can be fined or sentenced to not more than one year's imprisonment. This is according to Section 26 the Medicinal Products Act (1992:859). A prohibition may be accompanied by contingent fines according to Section 24 the same legislation. Any person deliberately or negligently contravening

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
				Rimonabant. Police reports have been delivered to the Swedish police regarding the crime against the Swedish medicinal products trading act (1996:1152).		Medicinal Products Trading Act (1996:1152) contains provisions on trading in medicinal products and on the supply of medicinal products. Retail trade in products which is mentioned in Section 4 may, except where otherwise indicated by this Act, be carried on only by the State or by a legal person over which the State has a controlling influence.	Section 4, the Medicinal Products Trading Act (1996:1152) shall be fined or sentenced to not more than one year's imprisonment if the offence is not punishable under the Penal Code. If a deliberate action indicated in the first paragraph has been committed professionally, concerns a considerable amount or value or otherwise has been of an especially dangerous kind, the guilty party

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
							shall be sentenced to a maximum sentence of two years imprisonment.
UK (Vetinary)	No	N/A	N/A	Has not occurred, so no system in place. They would expect Defra Investigation Service to deal with these on our behalf.	No	N/A	N/A

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
UK (Human)	No	N/A	N/A	The MHRA does not define counterfeiting per se because when dealing with alleged counterfeiting cases, we use a combination of the Medicines Act 1968 where the offence would be either "manufacture of an unlicensed medicine" and/or "the sale and supply of an unlicensed medicine" in conjunction with the Trade Marks Act 1994 for a trademark infringement. In addition, we would bring about money laundering charges under the Proceeds of Crime Act 2002 to confiscate money/assets attained through criminal activity. The Medicines Act contains a maximum of 2 years imprisonment	No. There are many offences within the Medicines Act covering a huge variety of types of pharmaceutical crime such as “sale or supply of an unlicensed medicine”, “manufacture of an unlicensed medicine”, “sale of a prescription only medicine not from a pharmacy”, offences for unlawful advertising, clinical trials, not adhering to	N/A	See 2.1.3

Question number	2.1	2.1.1	2.1.2	2.1.3	2.2	2.2.1	2.2.3
Member state	**Does your national legislation include a definition on counterfeit medicines?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions relating to manufacturing, importing and distributing counterfeit medicines?**	**If no, please indicate how cases of alleged counterfeiting are handled**	**Does your national legislation implicitly include a definition for pharmaceutical crime?**	**If yes, please provide details of the definition**	**If yes, what are the sanctions related to pharmaceutical crime?**
				and/or an unlimited fine. The Trade Marks Act provides for a maximum of 10 years imprisonment. The Proceeds of Crime Act has different levels of sentencing depending on the valuse of the confiscation order. A benchmnark is up to 10 years imprisonment for failure to pay a confiscation order above the value of £1million in a 12month period. It is worthy of note that prison sentences under the Proceeds of Crime Act contains no provison for bail or early release and the defendant is still liable to pay on release.	conditions of the license etc etc.		

Question 3: Provisions for import or export

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
Austria		Active substance manufacturers (like all manufacturers of medicinal products) are inspected at least every third year according to Article 67 of the Austrian Medicines Act.	No response	Manufactures of medicinal products may also export medicinal products, and need to have a manufacturing authorizations: wholesalers of medicinal products, may also export medicinal products, but also have to be in possession of distribution authorisation, regardless if the export takes place within or outside the EU.
Belgium		The Belgium Medicines Act and the Royal Decree of 14th December 2006 concerning medicines for human and vetinariry use describe the requirements for API manufacturing. The following are regarded as manufacturing operations: a partial or total manufacture, importation from third countries, packaging and repackaging, relabelling and dividing up. The manufacturers of medicinal products are obliged to use API's manufactured under	FAMPHP [Say what this is] may carry out unannounced inspections at the premises of an API manufacturer and may require a third country API manufacturer to submit to an inspection when they suspect non-compliance, also at the request of another Member State, the Commission, the Agency, EDQM (via the Commission or EMEA), or at the specific request of the manufacturer himself.	The Belgium Medicines Act and the Royal Decree of 14th December 20063 concerning medicines for human veterinary use describe the requirements for exporting . The exporter must be authorised. The medicinal products must be authorised to be on the market in Belgium or in an EU Member State. The manufacturing site must be GMP. If the medicinal product is not authorised, the Belgium legislation foresees specific requirements for the medicinal products for human use: its active(s) substance(s) must appear in an authorised product in Belgium, in another Member State, in an MRA

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
		GMP rules. So the API manufacturer must be declared GMP. This declaration is under the responsibility of the pharmaceutical manufacture's Quality Person (QP).		State, in an ICH member, in a medical product WHO's prequailified, in a medicinal product which have received and EMEA's positive advise. If not, the medicinal product cannot be exported unless one of these conditions is fulfilled.
Cyprus		There are no active substances manufacturers in Cyprus.	Imports from third countries need to be released to the market by a qualified person (QP) pursuant to Section 45 of the Law after performing the checks stated in Section 46 of the Law. The Drugs Council is empowered to perform inspections of manufacturing pursuant to Section 48 of the Law	There are no additional requirements (other than the ones on place for all medicinal products) specifically for products to exported third countries.
Estonia		The Agency is supervising local API manufacturers. National legislation- Medicinal Products Act- requires activity license for manufacture of APIs (the same principle as for medicinal products).	No response	Medicinal Products Act: paragraph 19./ Special authorisation for import and export and notification of import and export (1) for the import or export of goods requiring special authorisation: (2) authorisation for import or export third countries shall be obtained from the Sate Agency of Medicine for the import or export of such goods (more detailed requirements for the procedure are established in the Act and in the Ministry level regulations).

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
Finland		According to the Medicines Act, the term "medical product" covers also the active substances and due on that, API - manufactures in Finland are license-holders and regularly inspected by NAM. In the Medicines Act the section 77 mandates all the inspections. The section does not separate out the inspection outside the EU.	The section outlined does not separate out the inspection outside EU	The section outlined does not separate out the inspection outside EU
France		Articles L.5138-1 et L.5311-1 du code de la sante publique (CSP)	Articles L. 5138-1 et L. 5311-1 du code de la sante publique	The medicines must have been allowed in France (article L.5121-8 du CSP) or the firm must have got certificates for the respcet of good manufacturing practices.
Germany		Inspections related to decisions on licensing, offical batch release of pharmacovigilance are carried out by the competent higher Federal Athority (e.g. BfArM, PEI). This also applies to inspections involving medicinal products for which a licensing application in the framework	Inspections aimed to ascertain if the recognised standards of manufacture and quality assurance are met with respect to medicinal products or active substances that are not produced or tested in Memvber States of the EC or in other States Party to the EEA are carried out by the competent Land authority.	Generally, all medicinal products that are licensed or registered in Germany are elegible for export and, in additionl also medical products that are classed as questionable in Germany if the competant authority of the country of destination has authorised the import and is cognisant on the grounds which prevent the product's marketing in Germnay (refer to Annex 4 in the full response).

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
		of mutual recognition and decentralised procedures had been filed, or in response to the request of another Member State of the EEA.		
Hungary		Art 84 (1) The supervision of the manufacture of vetinary medicinal products and third active substances, their import and wholesale as well as the handling of quality defects and pharmacovigilance reports is performed by IVMP by means of regular inspection; the control tests are performed in the OMCL laboratories of the IVMP. We do not inspect in other MSs, GMP certificates have to be submitted.	It is the responsibility of the qualified person of the manufacturer and too declare that it is in compliance with EU GMP.	Art 42 (1) Vetinary medicinal products and their active substances may be manufactured for national and community use for export only in the possession of a manufacturing authorisation.

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
Ireland		Regulation 24(4) and the Schedule 5 Paragraphs 25 and 26 of the Animal Remedies Regulations 2005	See 3.1.1	Regulation 21 of the Animal Remedies Regulations 2005 requires any manufacturer of a veterinary medicine to hold a manufactures license. Regulation 27 of the Animal Remedies Regulations 2005 provides for certification of veterinary medicines for export
Italy (Veterinary)		Legislative decree 6 April 2006, n. 193 (which implements Directive 2004/28/EC) foreseen (art 69, par.6) that the manufacturer of the active substances should be preformed in compliance to the GMP Vet inspectorate.	No inspections outside Italy are foreseen.	The manufacturing of veterinary medicinal product is subjected to the holding of an authorisation released by the ministry of Health. This manufacturing authorisation shall likewise be required for veterinary medicinal products intended for export. (Legislative decree 6 April 2006, n. 193, which implements Directive 2004/28/EC, art 46.
Latvia		The State Agency of Medicines of Latvia can inspect active substance manufactures where there are grounds for suspecting non-compliance with the principles and guidelines of good manufacturing practice. Such inspections may also be performed upon the	No response	Cabinet regulation No. 88/27.2001 " Regulation regarding the import, export and Distribution of Medicinal Products and Requirements for the Opening of Medicinal Product Wholesalers" : II Restrictions on Importation and Exportation of Medical Products

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
		request of another MS or the EU or the European Economic Area state, the EC or the European Medicines Agency.		
Liechtenstein			At the moment the directives 2004/27EC are still not part of the EE agreement. But thanks to the national legislation (which includes the Swiss Bundesgestz uber Arzneimittel und Medizinprodukte, SR 812 21), active stubstance importers in FL need to be inspected and need a license of the Kontrollstelle fur Arzneimittle (since years).	They have to conform to the provisions of the Bundesgesetz uber Arzneimittle und Medizinprodukte.
Lithuania (Human)		According to the Law relating to pharmacy of the Lithuania Republic, all pharmaceutical enterprises (manufacturers, distributors, pharmacies) are controlled by inspectors of State Medicine Control Agency in general, including purchasing, selling and storage of API there (law is expanded in the full response).	No response	No response

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
Lithuania (Veterinary)		Requirements for Manufacturer, Authorisation and Marketing of Veterinary Medicinal Products in the Republic of Lithuania (O.G., 2005, No. 134-4754). (law is expanded)	Requirements fopr Manufacture, Authorisation and Marketing of Veterinary Medicinal Products in the Republic of Lithuania (O.G., 2005. 131-4754) (Law is expanded inn the full response)	Requirements for Manufacture, Authorization and Marketing of Veterinary Medicinal Products in the Republic of Lithuania (O.G., 2005, No 131-4754) (Law is expanded in the full response)
Malta		(Laws are expanded in the full response)	(Laws are expanded in the full response)	(Laws are expanded in the full response)
Netherlands		None, only on a voluntary basis	None, only on a voluntary basis	Manufacturing for export falls under Medicines Act and requires a license.
Norway	Manufactures of API are subject to the same regulations as manufacturers of finished products. The regulations do not distinguish between API and other medicinal products. API manufacturers are therefore inspected at regular intervals (every 2-3 years). Legislation is not available in English.	Inspections of manufacturers of API within the EU are the responsibility of the Member State where the manufacturer resides. A GMP statement for the manufacturer is required before Norwegian manufactures may use the API in the production of finished products.	In accordance with the Medicinal Products Regulation x 15-1, there us a prerequisite that NOMA may inspect manufacturers of medicinal products marked in Norway. This also includes the right to inspect manufacturers of API that re used in medicinal products marketed in Norway.	The regulation for manufacture ect of products for export are the same as for products produced for EEA, Exporters of medicinal products, including API, must in all instances verify that the customer is legally entitled to import the medicinal producers before export is carried out. For products and API that are listed as narcotics, pre cursursors ect., a special export license may be required for each and every export.

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
Portugal	The requirements predicted in Directive 2001/83/EC article 47, and 111. We have no additional requirements.	No response	No response	They require a manufacturing authorisation for export only as predicted in article 40 of Directive 2001/83/EC. If the product has a Marketing Authorisation we only ask for the companies to be authorised to operate in the market as a Wholesaler of having a contract with one. We also issue a WHO certificate if required by the import country.
Slovakia (Human)	Section 66 (6) of the Act 140/1998 Coll. on medicinal products and medical devices.	Section 66 (8) of the Act 140/1998 Coll. on medicinal products and medical devices.	Section 66 (8) of the Act 140/1998 Coll. on medicinal products and medical devices.	Section 29 (3) of the Act 140/1998 Coll. on medicinal products and medical devices
Spain	The General Law 29/2006 of 26th June 2006, on Guaranties and Rational Use of Medicines and Medical Devices, Chapter I, Title IV, 64. 2. There is also under preparation a Royal Decree that will regulate the subject.	see previous answer	see previous answer	The export of medicines of human use and medicines of veterinary use is regulated in the General Law of Guaranties and Rational Use of Medicines and Medical Devices, Article 73, and in the Royal Decree 109/1995 of Veterinary Medicines. Basically, the manufacturer must be authorised and comply by NCF (GMP) for any medicine and must be authorised for the marketing in Spain, or in its defect, obtain and express authorisation of manufacturing for export.

Question number	3.1	3.1.1	3.2.2	3.2
Member state	**What are the legal provisions in your Member State to inspect active substance manufacturers ?**	**What are the legal provisions in your Member State to inspect active substance manufacturers a) inside the EU?**	**What are the legal provisions in your Member state to inspect active substance manufacturers b)outside the EU?**	**What are your requirements for export of medicines to third countries (outside the EU)?**
Sweden	The legal base is determined by Community Directives 2001/83/EC and 2001/82/EC and amended by Directives 2004/27/EC and 2004/28/EC. No national legislation is in place.	The practical performance to inspect active substance manufacturers inside and outside EU, are done according to the guidelines Doc.Ref. EMEA/5028/2005	See 3.1.2.(According to EU Directive 2001/83 as implemented in national legislation.	The same requirements are valid regardless if the product will be used within EU or if the product will be manufactured for export only.
UK (Veterinary)	No response	This is covered in Regulation 33 and in Schedule 2, paragraph 7 of the Veterinary Medicines Regulations 2006.	This is covered in Schedule 2, paragraph 12 of the Veterinary Medicines Regulations 2006. The text is lengthy so I have attached the website address to the Veterinary Medicines Regulations 2006.	Export is covered in Regulation 30 of the Veterinary Medicines Regulations 2006. The text is lengthy so I have attached the website address to the Veterinary Medicines Regulations 2006.

UK (Human)	No response	The provisions of Article 111(1) for Directive 2001/83/EC as amended, on medicines for human use, allowing the competent authority of a Member State to carry out inspections of starting material manufacturers has been transposed into UK legislation by The Medicines for Human Use (Manufacturing Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 [SI 2005/2789]. Paragraph 9 of Part 1 of Schedule 5 to these Regulations amends section 111 of the Medicines Act 1968 as amended to allow rights of entry for the purpose of the third sub-paragraph of Article 111(1) of the 2001 Directive.	The provisions of Article 111(4) for Directive 2001/83/EC as amended, on medicines for human use, allowing a Member State to require a manufacturer established in a third country to submit to an inspection as referred to in paragraph 1 of Article 111 of the same Directive, has been transposed into UK legislation by Regulation 3(a) of the Medicines for Human Use (Manufacturing Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 [SI 2005/2789], requiring an importer of a medicine from a third country to comply with GMP and section 19 (3) of the Medicines Act 1968 as amended on factors relevant to determine an application for a licence for a medicinal product imported from a third country	Persons that manufacture or assemble a medicine for human use are required to hold a manufacturer's licence (Section 8(2) of the Medicines Act 1968) even if the medicines are intended for export. All manufacturers of medicines for human use are required to comply with the relevant provisions of the Medicines for Human Use (Manufacturing Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 [SI 2005/2789]. Persons that export unlicensed medicines for human use to a third country are required to comply with The Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations [S.I. 2003/1680] which apply the European Commission's 'Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human medicinal products', and any future updates of this guidance, generally to unlicensed medicines. This excludes all unlicensed herbal remedies, Traditional Chinese and Ayurvedic Medicines.

Question 4: Distribution

Member state	Are there any specific regulatory requirements for tracking and tracking medicines in your member state from manufacturers to patient distribution?
Austria	No
Belgium	The Belgium Medicines Act and its different Royal Decrees cover the entire distribution chain of medical products and allows the legal monitoring (by bookkeeping on paper or computer) of volumes through the distribution chain. However, this doe4s not completely cover the integrity of the product itself and can only be guaranteed through better barcode systems.
Cyprus	Pursuant to Section 84 of the Law, and authorised wholesaler may only procure medicinal products and active substances from other authorised wholesalers and only distribute them to authorised persons. The wholesaler has to maintain records of traceability of the products he procures and distributes.
Estonia	Traceability in the legal distribution chain is provided by legal requirements for document activities- compulsory data necessary on distribution documents by wholesalers/local manufacturers to pharmacies: wholesalers can accept products from suppliers only on the basis of consignation documents: wholesalers are obliged to notify the Agency about cross-border sales of notational medicinal products, including importer/exporter. Dispensing from pharmacies naturally can be traced back only in case of prescription only products.
Finland	According to the Medicines Act Para 36, medicinal product wholesalers must keep records of imports, procurement, storage and sale of medicinal products. The records must be stored for a minimal of 5 years. According to the Medicines Act Para 57 a, pharmacies must keep records if prescriptions. - there is not tracking and tracing system at individual package level/
France	Article L. 5124--3 et suivants, articles R. 5124-1 et suivant du CSP (wholesaler_ Good Distribution Practices L. 5125-1 et suivants (pharmacists).
Germany	No. However, there is an obligation to track and trace deliveries from a mail order pharmacy to consumer or patient.
Ireland	Regulations 28,30,31 and 33 of the Animal Regulations 2005 provide that only holders of licenses may sell veterinary medicines. Regulation 34 specifies record keeping requirements for veterinary practitioners and pharmacists. Regulation 43 species record keeping requirements for farmers.

Member state	**Are there any specific regulatory requirements for tracking and tracking medicines in your member state from manufacturers to patient distribution?**
Italy (Veterinary)	Legislative decree 6 April 2006, n.193 (which implements Directive 2004/28/EC) foreseen (art 89) the application, on each pack sizes of the veterinary medicinal product commercialised of a bar code system for tracking and tracing them. This provision has effect from 1st of January 2008.
Latvia	Cabinet Regulation No. 88/27/2001 " Regulation regarding the import, export and Distribution of Medicinal Products and Requirements for the Opening of Medicinal Product Wholesalers" : (legislation is explained in the full response)
Liechtenstein	The manufactures, distributors have to follow the GNP guide/ the Good distribution Practice. Therefore they need to have a system in place by which the products can be traced.
Lithuania (Human)	According to the Good Manufacturing practice rules in respect of medicinal products and investigational medicinal products, approved by the Order No V-268 of 23 April. (law is expanded in the full reposnse)
Lithuania (Veterinary)	Requirements for Manufacture, Authorization and Marketing of Veterinary Medicinal Products in the Republic of Lithuania (O.G., 2005, No. 131-4754) (Law is expanded)
Malta	No provisions like specific labelling are in force but Legal notice 386 of 2005 states in article 8. (law is expanded in the full response)
Netherlands	Yes. From manufacturer to wholesaler the batch number must be recorded. From wholesaler to pharmacy this is done on a number of companies.
Norway	There is no requirement to track and trace specific batches of medicinal producers to the retail of patient level. The amount, type of products and date of sale to a pharmacy is however mandatory for wholesalers. At the pre-wholesale level there is a requirement for track and trace systems for specific batches.
Portugal	We have transposed the GDP approved in Directive 92/25/EC.
Romania	National Medicines Agency has no responsibility regarding the regulatory requirements for distribution of medicines. Regulatory requirements for the distribution of medicinal products have been established by the Ministry of Health. Art. 12 of the Annex 1 of Order of the Minister of Public Health no. 893/2006 provides that: “The authorisation for the activity of wholesale distribution of medicinal products involves the public service obligation of the wholesaler, as well as the obligation to comply with the following: (law is expanded in the full response)
Slovakia (Veterinary)	Act 140/1998 Coll. On medicinal products and medical devices in wording f its later amendments: (law is expanded in the full response)

Member state	**Are there any specific regulatory requirements for tracking and tracking medicines in your member state from manufacturers to patient distribution?**
Slovakia (Human)	Section 30 (1)d), section33(1) c), Section 36(2) e) of the Act 140/1998 Coll. on medicinal products and medical devices; Order Ministry of health Slovak Republic No.274/1998 Coll. On GMP a GWP
Spain	The General Health Law 14/1986, of 25 April 1986, in Article 103, and the General Law 29/2006, of 26th June, on Guaranties and Rational Use of Medicines and Medical Devices states that the safeguarding, storage and dispensing of medicinal products shall be the responsibility of a) legally authorised community pharmacies and, b) the pharmacy departments of Hospitals, Health Centres and the Primary Care structures in the National Health System for their use within the said institutions or for those which require a specific surveillance, supervision and control by the multidisciplinary team of health care. The Law on Guaranties and Rational Use of Medicines and Medical Devices introduces in Chapter V, Title VI, a tracking system for all medicines, from the manufacturer till the final user.
Sweden	Tractability of batch number including the wholesaler chain is applicable.
UK	Manufacturers, wholesale dealers and retailers are required to keep records to enable Veterinary Medicinal Products to be tracked and traced as required by Directive 2001/82/EC as amended. This is covered in Part 3 of the Veterinary Medicines Regulations 2006, Regulations 17 - 24. The text is lengthy so I have attached the website address to the Veterinary Medicines Regulations 2006.
UK Hum	No. However, under Article 80 of Directive 2001/83/EC, as Amended, Title VII, Wholesale distribution, holders of the distribution authorisation must keep records for any transaction to include at least the date, name of the medicinal product, the quantity received/supplied and the name and address of the supplier/consignee. Therefore, in the case of a recall or need to trace a product's), a cascade system is used to inform all in the supply chain. Each distributor is required to contact who they sold the particular product to instruct them to subsequently check their stock for the product and also contact the customers that they sold the product onto to ensure the message is passed down the supply chain.

Question 5: Trade via the Internet

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
Austria	No response	No to both	No response	According to the Austrian Medicines Act, dispensing of medicinal products by self-service and mail order is forbidden.	Act 59 (9) Austrian Medicines Act
Belgium	No response	Prescription: No. Non-prescription: No yet (legislation is in preparation, it will be allowed in the near future)	Only by pharmacies with a site open for the public.	Yes	The person buying the medicines though the internet can be punished when buying medicines not in conformity with the Belgium legislation. Also, the pharmacist selling is responsible for the conformity for the medicines he sells.
Cyprus	No response	No to both	N/A	no explicit provisions are in place.	N/A

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
Estonia	No response	No to both	no response	Yes	See 5.1.1 Medicinal Products Act: Para 29 (2) Pharmacy services shall be provided only in pharmacies holding a corresponding activity license and structural units, taking account of the restrictions established for different categories of pharmacies. (Ministry regulation establishes requirements for physical pharmacy premises). Para 25 Medicinal products for personal use (3) Mail order sale of ,medicinal products as well as delivery by post or express service pf medicinal products ordered through the internet is prohibited.

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
Finland	No response	No to both	Licensed pharmacies may use internet in their activities but there is also legal requirement that when supplying of medicinal products from pharmacies and subsidiary pharmacies, efforts must be made to ensure that the users of the medicinal producers are aware of the correct and safe use of the product.	No	The Decree on personal import of medicines states that personal import by mail is allowed from EEA counties only. Medicinal products must have a marketing authorisation in the country of supply, and the supplier must be a legitimate retailer. Additionally, a valid prescription or doctor's attest is required in personal import of prescription only medicines. there are certain maximum amounts allowed to import.
France	No response	No to both		Only pharmacists "with a shop" are allowed to sell medicines.	No response
Germany	Yes, and so too are pharmacies from other EU countries (prerequisites for this are outlined in the full response).	Prescription: Yes (providing submition of a prescription) Non-prescription: Yes (pharmacy-only/ OTC drugs)	There are a number of prerequsites for a pharmacy to sell medinces over the internet, including; a) Simultaneous operation of mail order and community pharmacy,	No	N/A

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
			2) A quality assurance programme (these are expanded in the full response).		
Hungary	No response	No to both	No conditions yet.	No	N/A
Ireland	No response	No to both	Regulation 37(3)(a)&(b) of the Animal Regulations 2005 provides for a license regime for internet selling.	Regulation 31 of the Animal Remedies Regulations 2005.	See 5.3
Italy Vet	Medicinal products in Italy can only be sold exclusively by pharmacies. Exceptions are foreseen for pre-mixes for medicated feeding stuffs that can be deposited directly from wholesalers to breeders and vmp for external use having	No response	no response	No response	No response

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
	antiparasiticide and disinfectant can be sold in pet shops.				
Latvia	No	Prescription: No, Non-prescription: Yes	Regulation regarding the import, export and Distribution of Medicinal Products and Requirements for the Opening of Medicinal Product Wholesalers" : VI Requirements for Distribution of Medicinal Products (Legislation is explained in the full response)	No response	No response
Liechtenstein	No (under discussion)	No to both (under discussion)	No response	No response	No response
Lithuania (Human)	There are no regulations for this. However, the basis of the main says that the dispensing	Only presentations of some pharmaceutical services or products and advertising of some medicines is allowed via the internet.	No response	No response	No response

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
	(selling) of medicines to patients in general should be performed only through pharmacies: this means that physical dispensing, including pharmaceutical services, consultations should be done directly to patients in pharmacy. Only presentations of some pharmaceutical services or products, advertising of some medicines is allowed via the internet.				

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
Lithuania (Veterinary)	National legislation does not describe the trade of veterinary medicinal products via the internet. Ways of distribution of veterinary medicinal products described in national legal acts do not include the internet.	No to both	N/A	N/A	N/A
Malta	No	No to both	No response	No	No response
Netherlands	No response	Yes to both	Prescription only medicines may only be delivered after a patient has submitted a valid prescription.	No	No response

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
Norway	Selling medicinal products via the internet is not explicitly regulated by the Medical Products Act. These following provisions will affect the possibility of selling medicinal products via the internet: 1) As a main rule in Norway, only authorized pharmacies are allowed it retail medicinal products. The Norwegian Medicines Agency has not authorized any "internet-pharmacies". 2) According to the Pharmacy Act, the pharmacies are given limited rights to send/post medicinal	See 5.1	See 5.1	No	No response

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
Portugal	No	No to both	N/A	Yes. There is a rule saying that medicines can only be sold through pharmacies ion the case of prescription medicines and only in legal authorised places in the case of non-prescription.	No response
Slovakia (Veterinary)	No	N/A	N/A	No	No response
Slovakia (Human)	Our legislation does not regulate sell of medicines through internet.	No response	Our legislation does not regulate sell of medicines through internet.	No	No response
Spain	No response	Prescription: No. Non prescription: Yes (with conditions)	The mentioned Law 29/2006, in the Article 2.5 states:" It is forbidden the sales by correspondence and through telemetric via of medicinal products and medical devices of prescription. The secondary law will regulate the types of sales of prescription medicines and with respect to non-	No response	The Law 29/2006, in Article 2, paragraph 5, it considers it as a "Very serious infringement" (number 11$^{th)}$.

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
			prescription medicines, with the guaranty in any case that they dispensed in an authorised pharmacy, with the intervention of a pharmacist, and with the previous personal assessment, following the Articles 19.4 and 84.1 of this Law, and to comply the applicable legislation to the medicines subject of sale".		
Sweden	Yes	Yes, the only one allowed to sell products via Internet is the State owned pharmacy, due to the Swedish monopoly situation.	None	Yes	Plan for mapping/information to public and police reports

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
UK (Veterinary)	Yes	Yes to both	The legislative provisions governing the supply of Veterinary Medicinal Products apply to UK internet sales equally as they do to other retailers. The supply of veterinary medicine is covered in Schedule 3 of the Veterinary Medicines Regulations 2006, there are no specific conditions for internet sales. The text is lengthy so I have attached the website address to the Veterinary Medicines Regulations 2006.	No	The supply of veterinary medicine is covered in Schedule 3 of the Veterinary Medicines Regulations 2006, there are no specific conditions for internet sales. The text is lengthy so I have attached the website address to the Veterinary Medicines Regulations 2006.
UK (Human)	Yes	Yes to both	The sale and supply of pharmacy and prescription only medicines for human use via the internet must be made in accordance with the	Yes. Pharmacies that sell medicines over the internet must have a physical premises that can be inspected by the Royal Pharmaceutical Society of Great Britain (RPSGB). In addition such internet operations must	In the UK the Medicines Act 1968 makes no distinction between non-internet pharmacies and internet ones – see 5.2

Question number	5.1	5.1.1 & 5.1.2	5.2	5.3	5.3.1
Member state	**Does your member state allow medicines to be sold via the internet?**	**Does your member state allow medicines to be sold via the internet? (prescription and Non-prescription medicines)?**	**What are the national conditions for internet sales of medicines, if any?**	**Does your member state specific national previsions to avoid illegal trade with medicines via the internet?**	**If yes, plus provide details**
			Medicines Act 1968. Medicines law in the UK imposes strict controls on the sale, supply and advertising of medicines and these controls apply without distinction to medicines offered for sale via the Internet and by mail order. The UK policy is that supply to the general public through electronic media is regulated in the same way as supply from any other retail outlet and is therefore subject to the same control.	display the name, address and contact details of the physical pharmacy that runs the operation. The RPSGB is currently piloting a logo system where if successful, they will consider that all UK internet pharmacies must have one. The MHRA Enforcement & Intelligence group conducts 2-3 Internet Days of Action (IDA) a year to target a number of suspect websites based in the UK on a single day of activity. The aim of this action is to efficiently tackle such illegal activity and promote warnings to the public of the risks associated with purchasing medicines over the internet. In addition, the media coverage of the robust action taken against perpetrators is aimed at deterring criminals from such activity.	

Question 6: Analytical testing to identify counterfeit medicines since year 2000

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
Austria	Aprrox 10 per year, the majority are illegal medicines, e.g. food supplements to TCMs boosted with APIs	Police inspections, pharmacists., patients and medical doctors.	Yes (as part of annual market surveillance plan)	Yes	Viagra and Tamiflu from the internet, Calis from the legal supply chain. Viagra and Tamiflu were mainly counterfeits. Cialis were okay.	No response
Belgium	No data	All sources	No	No	No response	Priority, specific knowledge, staff, lack of collaboration with industry, cost, laboratory equipment, etc.
Cyprus	None	No response	No	No	N/A	N/A
Estonia	Venegra analysed and found sub potent and classified as counterfeit, no analysis conducted. See also 1.4.	Customs (postal services)	Yes (but not detailed specifically for identifying counterfeits)	No	No response	no response

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
Finland	Totally 2 counterfeits were analysed and identified (Viagra and Kamagra)	Customs	Yes	No	No response	No response
France	No response	No response	No response	No response	No response	No response
Germany	240 counterfiets, mostly from the illegal supply chain. Among these were; Viagra, Levtra, Cialis, Propecia, Xenical, Reductil, Orfiril and Testosterone derivatives.Sibtramine	Police, customs and inspection services.	Yes.	Yes. 2007 project for checking internet supply chain.	Programme: a) Public private partnetship with consumer health protection organisations; Finished project in slimming products in 2.2007, Planned project on body builder products in 7.2007. b) Ongoing co-operation with the German Federal Police; targeted sampling of the internet supply chain. Outcome: a) 16/17 samples	Lack of coordination betrween the police and custsoms in making internet sampling possible by the OMCL.

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
					from the project were identified as counterfiets and/or illegal products. b) 50 per cent of the suspect samples were identified as counterfeits.	
Hungary	One product (not named)	MAH of the authorised veterinary medical product	Yes (annually)	No	N/A	Very low number of cases up till now.
Ireland	Anthelmintics- one product	Department of Agriculture and Food veterinary inspectorate.	Yes	No	N/A	N/A
Italy Vet	No response	No response	No response	No response	No response	They have not data on this issue, samples for analysis are sized and picked by police forces under the supervision of the judicial

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
						authorities.
Latvia	Since 2003, 206 products have been identified (testing for quality and counterfeit) 95 % of them were injection solutions, infusion and solutions and eye drops.	Only the Sate Pharmaceutical inspection gives samples for analysis.	Yes. Not less often than yearly the State inspection takes on the analysis from each distributor a minimum on one position of injections, infusions and eye drops.	No (but Latvia but we are members of the EDQM (European Directorate for the Quality of Medicines) CAP programme.	Centrally Authorised products (CAP); Outcome; 2004-Tamiflu, 2005-Cialis, 2006-Stalevo, 2007--Apidra	No response
Liechtenstein	None	Nobody	No (they are included in the Swiss system)	No	No response	no response
Lithuania(Human)	See 1.4	The samples provided to the Medicines control laboratory of SMCA are submitted by SMCA inspectors.	Yes (both spot and random checks)	The new program of quality control of medicinal products is prepared yearly by the Work Group of different experts from SMCA (Inspection, Laboratory, Marketing	No response	Sampling in conducted according sampling program is performed by SMCA inspectors. Samples of medicines,

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
				Authorisation divisions etc) taking into account tests described in the documentation of authorisation of medicinal product which are necessary to ensure the quality of medicinal product, monographs of pharmaceutical substances described in European Pharmacopoeia (if not described- monographs described in Pharmacopoeias of EU Member States) See also article 6.3.		forfeited by forces of Police or Customs often are not submitted to SMCA laboratory for testing.
Lithuania (Veterniary)	None	N/A	Yes	Taking into account that counterfeit veterinary medicinal products were not	N/A	N/A

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
				identified in our country, such program was not prepared.		
Malta	None	No response	Yes	No	No response	Costs, identifying possible sources.
Netherlands	Viagra, Cialis, Letitra, Liptor, Tamiflu, Rohypnol, Xenical (a detailed list is included in the full response)	Dutch Health care inspectorate	No	No response	OMCL Network Surveillance Programme	No response
Norway	2004: Corticosteroids (dexamethasone) in 2 herbal products were detected; 2005: sildenafil derivatives in 4 herbal products were detected. The herbal products concerned were not classified as medicinal products as such, but their content of undeclared active substances made them medicinal. Whether they	The samples of herbal products were submitted by health professionals and the public. Police, customs, inspection services did not submit any samples.	Yes (annually)	No (However, NoMA sent samples of Cialis from the Norwegian market for the EDQM(European Directorate for the Quality of Medicines)/EMEO campaign in 2005)	No response	No response

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
	should be considered as counterfeit medicines is obviously open for discussion, but they were certainly "deliberately and fraudulently mislabelled with respect to identity". No other counterfeit medicines have been identified					
Portugal	None	None	no	no	No response	Insufficient information concerning the Analytical methods.
Slovakia (Human)	Vega; Kamagra, Viagra, and Somathohorm	Customs	No	No	No response	Lack of funds and labour.
Slovakia (Veterinary)	None	N/A	No	No	N/A	Lack of fund
Spain	There have been found several androgens as well as somatropin products. See attached a	The National Security Force ("Guardia Civil").	No	No response	No response	No response

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
	list of potential counterfeit medicines, according to the analytical results and the origin of the samples.					
Sweden	See enclosure with full response	See 6.1	Products included in the regular control programme of the Swedish OMCL, are usually ordered from local pharmacies. Two pharmaceutical wholesalers, Tamro and KD (Kungliga droghandeln), supply the retail pharmacies.	Yes	The source and the results of the products controlled during 2000-2006, are listed in the tables attached to the full response. They conducted a campaign for weight reduction products, searching for i.e. ephedrine content. The samples were ordered from Internet in collaboration with the police. Ephedrine, pseudoephedrine, synephrine and	The personal identity number that is required for Internet purchases serves as an obstacle for campaign testing. In order to solve this obstacle the Internet products are now ordered via Police, who uses assumed identity numbers.

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
					caffeine were found in several products. About 40 products were tested. Some other planned and ongoing activities are listed below: Nutritional supplements; Potency drugs; Herbal products; Internet: On-line pharmacies; and Medical self-tests.	
UK	N/A	N/A	Distributors are inspected regularly and must hold a Wholesale Dealers Authorisation	No	N/A	Resources issues

Question number	6.1	6.2	6.3	6.4	6.4.1.1 & 6.4.1.2	6.4.2
Member state	**Which and how many products were identified to be counterfeit via laboratory testing in your member state?**	**Who submitted samples for analysis?**	**Does your member state have a programme of random or spot checks of pharmaceutical stocks in the hands of distributors**	**Does you Member state conduct targeted (campaign) sampling and the testing with the objective to identify counterfeit medicines?**	**If so, please describe the programme and the outcome**	**What are/could be the possible obstacles for campaign testing to identify counterfeit medicines?**
UK Hum	Cialis; Viagra; Lipitor; Reductil; Celebrex; Propecia; Plavix; Xenical; and Levitra.	MHRA enforcement officers (these are occasionally provided by police or customs officers)	Yes	Yes	A list of products with the greatest risk of being counterfeited has been identified. For each product survey, samples are collected from community pharmacists, wholesale dealers and manufacturers. Analytical data for market samples are compared with authentic batches of product from the UK manufacturing site(s). To date five surveys have been completed and no counterfeit product identified	(a) Cost of samples;(b) Laboratory resources for the analysis of large numbers of samples (c) Ensuring coverage of all areas of the supply chain.

Question 7: Co-operation structures to combat counterfeit medicines

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
Austria	No response	The AMEG (Austrian Medicines Enforcement Group) combines all authorities involved in combating the illegal pharmaceutical market in Austria. Its members are the medicines market surveillance group of the Medicine Agency, the Official Medicines Control Laboratory, the Ministry of Health Family and Youth, the Ministry of Justice, the Customs, the Federal Bureau of intelligence of the ministry of Interior, the Anti Doping Committee. The group meets twice a year and discusses open cases and works on preventing strategies against illegal medicines.	No response	No response	No response	No response	More exchange between inspectors dealing with these cases.	No response	More exchange of analytical data (projects already started)	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
Belgium	No response	Mostly limited to ambulatory and voluntary collaboration; Customs play a major role in detecting but lack experience, training and knowledge.	See 7.1.1	None	No response	No response	Network and SPOCS, databases	Convention or at least a legal framework	Univoque intelligence gathering	Public and political awareness
Cyprus	No response	None	None	None	None	No response	No response	A call for action by the WHO	An FU database for all member states to report counterfeit medicines seizures etc.	No response
Estonia	No response	No response	No response	Internal electronic database used to store basic data about cases of counterfeit: documents about cases of counterfeit archived separately	No response	No response	No response	No response	No response	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
Finland	No response	Contacts have been established between National Agency for Medicines and customs/police	None (yet)	No	no response	Establishing a contact network with relevant authorities and interest groups (Para industry, wholesaler and retailers) for sharing information, increasing awareness and for operational and legislative issues.	Networking with authorise, planning and constructing methods to combat and detect counterfeits.	Networking with authorise, planning and constructing methods to combat and detect counterfeits.	No response	No response
France	No response	Cooperation between police, custom service, justice, health ministry, competent authority (AFSSAPS).	No response	No response	No response	No response	No response	No response	No response	The creation of an Administration employing policemen, customs, pharmacists, all useful people who would work together freely. A specialist judge would be

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
										working only on this kind of case.
Germany	Both counterfeit and suspect medicines must be reported at every step of identification to the competent Federal or Land authority and documented. Section 68 of the Drug Law lays down these	Co-operation between the customs authorities, Bundeskriminalamt- BKA (Federal Criminal Police Office) and the supervisory authorities of the Federal Lander is laid down by law. Relevant provisions are included in the sections 68 and 74 AMG that were implemented in section 13 (3) and (5) of the 'AMGVwV (General Administrative Regulation on the Implementation of the Drug Law (see Annex 7).	Responsibility for the pharmaceutical supervision of industry lies with the supervisory authorities and the Lander based in AMG- Section 64 Conducting Surveillance, sub-section 1 and 3 (see Annex 5).	A database is needed which provides officials such as customs, inspectors, police, and public prosecutors with information about known illegal medicines. Work on creating one is intended to start in 2008.	Establishment of a national network (SPOC) for information exchange.	a) improved awareness of counterfeit medicines throughout the supply chain, b) improved consumer education on counterfeit drugs and their sources, c) establishment of specialist police units and public prosecutors (in pharmaceutical crime), d) Further training of supervisory and	Revise the EU legalisations such that: e.g. a) a harmonised definition for counterfeit drugs is agreed upon, b) any counterfeit medicine licensed in any EU country shall be seized in any EU country wherever it appears. (More	E.g. a) Support any international activity aimed at the suppression if counterfeited medicines, b) Extension of an international network to enhance information, c) Harmonisation of the counterfeit medicines reporting form. (More examples are provided in the full response)	The creation of a central European database with national supplements to deal with specific local needs.	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
	obligations (the legislation is expanded in the full response). Reporting beyond national cases takes place via the Rapid Alert System (RAS) that includes not only EU Member States but also Sates Parties to the EEA and other states on the basis of corresponding arrangements					customs officials.(More examples are provided in the full response)	examples are provided in the full response)			

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
Hungary	No response	Contract for cooperation	Regular contact with industrial organisations	No response	Working group organised by the human agency involving all interested authorities.	Finances for targeted sampling campaigns. Organised and regular cooperation with all interested parties	More regular cooperation through Rapid Alert System	International cooperation not only with MRA partners	No response	No response
Ireland	No response	Department of Agriculture and Food Veterinary inspectorate have ongoing liaison Customs, Police, Irish Medicines Board, Veterinary Council of Ireland and Pharmaceutical Social of Ireland.	Department of Agriculture and Food Veterinary inspectorate have ongoing liaison Customs, Police, Irish Medicines Board, Veterinary Council of Ireland and Pharmaceutical Social of Ireland.	Department of Agriculture and Food Veterinary inspectorate have ongoing liaison Customs, Police, Irish Medicines Board, Veterinary Council of Ireland and Pharmaceutical Social of Ireland.	Department of Agriculture and Food Veterinary inspectorate have ongoing liaison Customs, Police, Irish Medicines Board, Veterinary Council of Ireland and Pharmaceutical Social of Ireland.	Current measures appear to be satisfactory.	A forum for sharing information	See 7.2.2	Sharing of databases would be useful.	Need to continue to strengthen c-operation between market supervision authorities inn National, European and international level.

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
Italy (Veterinary)	No response	No response	No response	No response	No response	No response	No response	No response	No response	No response
Latvia	No response	Cabinet Regulation No. 88/27.02.2001 " Regulation regarding the import, export and Distribution of Medicinal Products and Requirements for the Opening of Medicinal Product Wholesalers" (legislation is explained)	No response	No response	No response	No response	No response	No response	No response	Need to continue to strengthen c-operation between market supervision authorities inn National, European and international level.
Liechtenstein	None (they are included in the Swiss structure	See previous	See previous	See previous	See previous	As they are such a small country they need the cooperation with bigger organisations/countries on European level.	N/A	N/A	N/A	N/A

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
Lithuania (Human)	The SMCA doesn't have an Enforcement unit, so we have prepared mutual agreements for cooperation in fight against counterfeits and the control of illegal pharmaceutical activity between SMCA and Department of Customs and Department of Police under the ministry of	No response	No response	No databases	No response	More cooperation between SCMA (inspectors laboratory) and Police or Customs. Problem is insufficient cooperation with enforcement bodies. Lack of effective strategy and change of information between different institutions.	No response	No response	No response	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
	interior. SCMA participates in EMEO (European medicines enforcement officers group) meetings. (legislation is expanded in the full response).									
Lithuania (Veterinary)	No. Only general co-operation between appropriate state institutions exists.	See 7.1	See previous	See previous	See previous	No response	No response	No response	No response	No response
Malta	No response	No, but a good liaison has been established between the police, customs and	Awareness has been increased in Malta and	The Medicines Authority has access to the 4IPR database	No response	No response	A clear legislative basis is required	No response	No response	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
		regulatory authority.	Inspections are now taking into consideration the problem of counterfeiting.							
Netherlands	No response	No. Co-operation is ad-hoc	No. co-operation is ad- hoc	No. co-operation is ad- hoc	No response	Clear police of Inspectorate: adequate organisational structure.	There is already a well established co-operation group in EMEO, HMA WGEO	The Netherlands are active in Council of Europe ad-hoc working group on counterfeit medicines and WHO IMPACT	No response	No response
Norway	No response	NoMA has frequent contact with customs officers in import cases involving medicinal products. However, there is currently no formal cooperation or forum that involves both NoMA and customs/police with regard to combating counterfeit medicines.	NoMA holds regular meetings with both pharmacy and industry organisations on a variety of questions, including counterfeit	They have a national database for spontaneous reported adverse drug reactions. We are collecting only ADRs from health care professionals into the database, receiving about 2000 reports yearly. Most reports	No response	No response	Continuation of the European Directorate for the Quality of Medicines EDQM recently established a system for information exchange of counterfeit/illeg	No response	No response	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
		Contact is established on a case by case basis. NoMA has recently taken an initiative towards establishing formal cooperation with customs/police.	medicinal products and issues associated counterfeit medicines, such as personal import of medicinal products via the internet.	concern prescription medicine, but. The spontaneous reporting system will have difficulties capturing ADRs related to counterfeit medicines, as all medicines might have side effects or might give lack of effect in certain patients. An ADR report will not give suspicion of a possible counterfeit drug unless the reaction is highly different from what is expected. In fact, the spontaneous reporting system is not a tool to capture cases of counterfeit medicines. However, the situation with			al medicines in the network for Official Medicines Control Laboratories.			

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
				herbals is a bit different. For these drugs, we do not expect a pharmacological effect or noly a monoer one or adverse effect. If such drugs give adverse reactions other then allergy, there might be because they contain unlabelled substances and as such can be classified as a counterfeit drug. About 0.02% of the reports to or national database are related to herbal drugs that are not marketed as medicines.					
Portugal	No response	We have established a network of contacts between Police, Customs;	No response	No yet as there are no cases to insert.	No response	Less bureaucracy, increase of competences to	Legal environment to share	See previous	No response	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
		public prosecutors and national medicines agency to work on the area of pharmaceutical crime.				have access to information and safe network for sharing information.	information and safe network			
Slovakia Hum	No response	No response	No response	No response	No response	Our legislation must be updated and resources must be provided.	Tracking and tracing of medicines must be improved. Balance of	See previous	No response	No response
Spain	No response	No response	No response	No response	In Spain there is a strong cooperation between the Security Forces (Guardia Civil and Policía Nacional) and the Spanish Agency of Medicines and Medical Devices to combat	No response	No response	No response	No response	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
					counterfeit medicines. In particular: (1) The participation of technical experts of AEMPS in the operations performed by the Security Forces. (2) Reports of AEMPS on risks for Public Health of confiscated medicines by Security Forces, derived from its consume. (3) Analytical identification of the					

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
					confiscated medicines (on previous judicial petition).					
Sweden	No response	MPA has regular discussions (e.g. seizures, test purchases) with the customs and police. The police perform the test purchase of products from Internet to MPA.	MPA has regular discussions with the industry (e.g. regarding action plans to combat counterfeit medicines)	N/A	N/A	Further active networking which includes Counterfeit to be put on the political agenda. Active discussions with patient organisations.	Working with HMA Working Group of Enforcement Officers, HMA WG EO	Working with HMA Working Group of Enforcement Officers, HMA WG EO	Databases Tool for rapid information in addition to Rapid Alert	N/A
UK (Veterinary)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Greater resource required at all levels.

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
UK (Human)	No Response	No Response	The MHRA (leader of the UK anti-counterfeit strategy for human medicines) holds and chairs a 6-monthly Anti-counterfeit Stakeholder meeting for Police, Customs, The Royal Pharmaceutical Society of Great Britain and the UK trade and industry associations to discuss a watchlist of	No response	The MHRA has a stand-alone database, which records all reported incidents of pharmaceutical crime that have taken place in the UK. The information held is classified in data security terms according to the nature of the status of an investigation. When stakeholders feed	No response	No response	Currently the UK MHRA participates and contributes to counterfeiting initiatives by the European Commission, the Council of Europe and the World Health Organisation (IMPACT). The MHRA is keen to ensure duplication is avoided, but because of the global threat of counterfeit medicines, the MHRA is keen to synthesise the different work streams across	Having an agreed counterfeit reporting form for all international groups to use. Currently in the middle of a counterfeit incident crisis, an organisation is faced with 4 or 5 different counterfeit reporting forms to complete for the different bodies it belongs to	No response

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
			'high risk' medicines that are most likely to be counterfeited for UK supply. A Single Point of Contact is established at each of these organisations. In addition, the MHRA hosts a national Law Enforcement Officers open day to discuss pharmaceutical crime and counterfeit medicines with Police, Customs, Royal pharmaceutica		information in to the MHRA about a suspected breach of the medicines Act, it is entered onto this system.			these groupings to ensure that good quality intiatives/workstreams and best practice may be shared across the groups to maximise the ability to protect public health.		

Question number	7.1	7.1.1	7.1.2	7.1.3	7.1.4	7.2 & 7.2.1	7.2.2	7.2.3	7.2.4	7.2.5
Member state	**Please describe national co-operation structures to combat counterfeit medicines in you Member State.**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and customs**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Pharmaceutical supervision and industry**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Databases**	**National co-operation structures to combat counterfeit medicines in your member state; Specifically; Other**	**What would be the needs for enhanced co-operation with respect to; a) National level?**	**What would be the needs for enhanced co-operation with respect to; a) European level?**	**What would be the needs for enhanced co-operation with respect to; b) International level**	**What would be the needs for enhanced co-operation with respect to; c) Databases**	**What would be the needs for enhanced co-operation with respect to; d) Other?**
			l Society of Great Britain, General Medical Council, the National Health service Counter Fraud and Security Management Services, the Serous Organised Crime Agency (SOCA), trading standards officers and mail couriers.							

Question 8: National Programmes for Raising Public Awareness of illegal trade in medicines

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
Austria	No response	If there is a serious health risk , the professional bodies of Pharmacists, doctors (chamber of doctors, chamber of pharmacists) are informed and they have to inform their members.	See previous	See previous	They are already working in GEON + ILFCM
Belgium	No response	Website of the Federal Medicines Agency	Very rare but effective media coverage (TV, press)	Not specifically (warning on the website for the sale via internet)	Yes. Media approach and specific (harmonized) awareness programs directed towards the patient and professionals.

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
Cyprus	No response	No	No	Not systematically. Occasional articles have appeared in the mass media.	Yes. Since the issue may affect all member states, it may be prudent that any initiatives be spearheaded by the Commission.
Estonia	No response	On its homepage, the Agency has published in national language WHO guide "Medicinal products and the Internet".	No response	The Agency publishes information about relevant cases on its homepage (for example about counterfeit Tamiflu sold via the internet) in the form that can be used by the press.	Yes. Training material to be used by national authorities to train police and customs, international training activities for police and customs.
Finland	No response	Media releases by NAM, information ion authorities' websites, public awareness raising information in media; a campaign programme for public is being planned for 2008.	See previous	Media releases by NAM, information ion authorities' websites, public awareness raising information in media; a campaign programme for public is being planned for 2008.	Yes. Initiatives at a European level might complete and support national activities.

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
France	No response	Communications from the AFSSAPS, newspapers	See previous	New communication campaign in June 2007	No response
Germany	No response	If illegal drugs are discovered, the Federal Land concerned warns the public. These alerts are usually taken up by the local and/or regional press and further disseminated. BfArM are currently developing a website what will provide general warnings concerning illegal activities on the internet.	Press rel;eases, media (e.g. radio and TV) are used for consumer information.	By publication of a press release or the websites of the competent authorities when counterfeit medicines are discovered.	Batch traceability from the manufacturer to the pharmacy should be among the golas on the European level and rely on a standardised track system for all medicines in the EU. There should also be (independent of the track and trace system) the introduction of randomised serial numbers for each drug pack.

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
Hungary	No response	No response	This would be the case, if necessary	No practice up to now	More regular cooperation, feed back and information dissemination at European Level.
Ireland	Circulars targeted at farmers.	No response	No response	See previous	Yes
Italy (Veterinary)	No response	no response	no response	Patients in general are warned through the media (television , newspapers).	no response
Latvia	No response	There are 2 internet sites: Official site of State Pharmaceutical Inspection (1) and the special internet site for pharmacists (2) where all identified potential legal drugs are mentioned.	In special cases we send a rapid alert to distributors and representations.	See 8.1.1 and 8.1.2	Their needs from European level are: to perform practical training course how to prevent the distribution of illegal medicines and counterfeit medicines.

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
Liechtenstein	They are informed via the media.			We are informed about all legal imports by the customs office. We contact people when they import medicines brought by internet pharmacies and inform them about the risks.	Yes
Lithuanian (Human)	Information for the general public is provided through the media (newspapers, internet sites of Police or SCMA: television broadcast etc).	See 8.1	See 8.1	See 8.1	No response
Lithuania (Veterinary)	At the moment we do not have such a national program. However we would foresee to inform public via internet and then via type of	See previous	See previous	N/A	They welcome initiatives at a European level as they do not have any experience in this field.

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
	mass media.				
Malta	No response	No response	No response	Press releases, circulars	Yes
Netherlands	No response	Warning letters in inspection website	None	Warning letter in inspection website	Yes, it needs to be clear that this is a common problem
Norway	Patients and consumers are alerted to potential of illegal trade medicines via internet in Norway.	See 8.1	See 8.1	See 8.1	If problems related to counterfeit authorised medicinal products are raised because of risk for potential adverse drug reactions, we would expect a discussion in PhVWP/CHMP/EMEA resulting in recommendations on national or harmonised European activities.
Portugal	No response	INFARMED's website provides specific information to the public and Press releases,	No response	Although there is no case of counterfeited medicines reported in Portugal. INFARMED issues public awareness through press releases and conferences/workshops. Consumers associations, health	Yes

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
		especially on the illegal selling of medicines through the Internet of the selling of medicines without Marketing Authorisation.		professionals' organisations and Pharmaceutical industry also take some initiatives to raise awareness on this topic.	
Slovakia (Human)	They are alerted through press, TV and Radio.	Yes, we inform public on our web pages	They are alerted through press, TV and Radio	See 8.1.2	Yes. They expect initiatives at a European level
Spain	No response	Consumers and patients may find the pharmaceuticals alerts in the webpage of the Spanish Agency of Medicines and Medical Devices.	The Spanish Agency of Medicines and Medical Devices send the Pharmaceutical Alert notifications to several organisms and institutions to inform all patients and consumers at different levels. Between others:	No response	No response

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
			(Laws are expanded in the full response)		
Sweden	No response	Information on MPA´s website. To warn/inform the public of the dangers of acquiring the products in question via Internet. Information in media, newspapers, radio/TV	Information will be made through media, newspaper and radio/TV. An information campaign is planned to start during 2007	Information on our website through media and pharmacies. We haven't detected any counterfeit in the legal distribution chain.	Internet Day of Action, Campaigns arranged by MHRA are good examples of European initiative. Initiatives/activities discussed at HMA WG EO meetings are expected.
UK (Veterinary)	They are not directly alerted. Presentations, articles and journals briefly touch on the issue.	They are not directly alerted. Presentations, articles and journals briefly touch on the issue.	They are not directly alerted. Presentations, articles and journals briefly touch on the issue.	They are not directly alerted. Presentations, articles and journals briefly touch on the issue.	Yes

Question number	8.1	8.1.1	8.1.2	8.2	8.3
Member state	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; a) via the internet?**	**How are patients and consumers alerted to the potential of illegal trade in medicines in your country; b) via other distribution channels?**	**How are patients and consumers alerted for the potential of counterfeit medicines in your country?**	**Would you expect initiatives at the EU level to complement any activities at a national level?**
UK (Human)	No response	The MHRA warns people not to buy prescription only medicines from the internet without a prescription. Some initiatives in this area include: (these are expanded in the full response)	See 8.1.21 for illegal channels which are predominantly the internet. For the legal supply chain, see 8.2.	MHRA promotes its enforcement action against counterfeiters via its website and through media press releases. Key messages include: (1) no supply is impenetrable (2) statistically the chances of receiving a counterfeit medicine through the legal supply chain are extremely remote (3) the risk of receiving a counterfeit medicine is significantly increased when medicines are purchased over the internet (4) MHRA has a well-developed anti-counterfeit strategy based on education, collaboration and regulation to safeguard UK members of the public. In addition, the MHRA and RPSGB has developed guidance for pharmacists on the subject including what to do when a suspected counterfeit product is encountered. Currently MHRA and RPSGB are compiling similar guidance for members of the public. The MHRA is setting up a hotline for members of the public to report suspected counterfeit medicines incidents. This will be a 24-hour facility.	Yes. It is hoped that such efforts are synthesised and not unnecessarily duplicated or contradictory. Generic European-wide messages can be used as well as member state specific ones to tailor the individual country needs and situation

Question 9: Relevant Studies

Question number	9.1.1	9.1.2
Member state	**Have any studies been made in your Member sate and/or used by government of either on a) the costs and benefits of policies to combat counterfeit medicines?**	**Have any studies been made in your Member state and/or used by government of either on b) the benefits (including but not limited to patient health) of preventing the use of counterfeit medicines?**
Austria	No	No
Belgium	No. However, they have largely contributed to the CoE anti counterfeit survey which has resulted in the HARPER study.	no
Cyprus	No	N/A
Estonia	No response	No response
Finland	No	No response
France	No	No
Germany	N/A	N/A
Hungary	No response	Not in the veterinary field
Ireland	No	No
Italy vet	we have no data on this issue	No
Latvia	No response	No response
Liechtenstein	No	No
Lithuania (Hunman)	No	No response
Lithuania (Veterinary)	N/A	N/A
Malta	No	No
Netherlands	Yes, "Counterfeits and imitation of Viagra and Cialis tablets: trends and risks to public health" (L.Blok-Tip et al., RIVM report nr. 267041001/2005	See 9.1
Norway	No	No
Portugal	No	No
Romania	No	No
Slovakia	No	No
Slovakia Hum	No	No
Spain	No	No
Sweden	No	No
UK	Not aware of any	Not aware of any

Question number	9.1.1	9.1.2
Member state	**Have any studies been made in your Member sate and/or used by government of either on a) the costs and benefits of policies to combat counterfeit medicines?**	**Have any studies been made in your Member state and/or used by government of either on b) the benefits (including but not limited to patient health) of preventing the use of counterfeit medicines?**
UK Hum	Not in such terms, but we have conducted risk assessment about this issue that notes key areas where harm may be caused by counterfeit medicines reaching patients through the legitimate UK pharmaceutical supply chain, which are listed in priority order: (these is expanded in the full response)	See 9.1

2 SUMMARY OF STAKEHOLDER RESPONSES TO OPEN CONSULTATION

Introduction

2.1 This document summarises the responses of industry to the European Commission's DG consultation on counterfeit medicines. Aspects of counterfeit medicines related to parallel trade are also addressed here.

2.2 The consultation process was open to patient, health care professional and industry organisations. Several trade associations responded, and in addition Pfizer and Sanofi-Aventis decided to contribute separately for their companies.

AEGATE

2.3 There was a 100 per cent increase in the number of counterfeit medicines seized at the EU borders between 2004 and 2005 (560,000). Recent estimates suggest that the number of counterfeit medicines seized in the same way in 2006 was 1.5 million. This represents a 300 per cent increase between 2005 and 2006.

2.4 Counterfeit medicines are able to enter the supply chain (both legal and illegal) at any point despite strict pharmaceutical regulation in the EU. EU figures indicate that there have been 27 confirmed counterfeit cases in the legal supply chain and 170 in the illegal supply from China over the past five years.

2.5 In developed countries, medicines with the greatest risk of being counterfeit are those that tend to be sold in large volumes or those of well-known brands. In developing countries, 25 per cent of the medicines on the market are counterfeit and these tend to be centered on medicines linked to diseases (e.g. malaria, HIV, and tuberculosis).

2.6 The impacts of counterfeits is significant, especially when taking a medicine that contains no active ingredient, wrong or toxic ingredients can result in side–effects, serious illness, or death.

2.7 As recognition of the problem, Aegate welcomes the recent EU and international policy on medicine counterfeiting. In particular, it welcomes the DG Enterprise consultation in 'Distribution Channels' with the aim of developing policy options to address the counterfeiting problems discussed.

2.8 Aegate believes that a EU solution to the problem should be assessed according to the following criteria:

- Increases in patient safety;
- Flexible technology;
- Fully integrated solution; and

- Regulatory compliance.

2.9 With regards to the various EU policy solutions beings proposed, Aegate is of the view that the EU institutions and Member States should consider the following:

- Addressing what is a growing problem in both the EU and in developing countries;
- Considering the merits of medicine authentication at the point of dispensing as an effective method in the prevention of counterfeit medicines;
- Considering an EU-wide unique serialization of the medical products under the EU's pharmaceutical legislation as a means of improving identification and authentication; and
- Identifying the urgency of the issue by taking immediate action (e.g. by thoroughly limiting unnecessary lengthy discussions by stakeholders etc).

GIRP AISBL (The European Association of Pharmaceutical Full-Line Wholesalers)

2.10 Groupement International de la Repartition Europeenne (GIRP) is the European umbrella organization of pharmaceutical full–line wholesalers and represents the national associations of over 600 pharmaceutical full-line wholesalers.

2.11 This paper puts forward a number of proposed legislative and regulatory measures and self-regulation proposals from the perspective of its members. It also outlines some technical issues that need addressing at the EU level.

2.12 GIRP defines the activity of pharmaceutical full-line wholesaling as consisting of the purchase, warehousing, storage, order preparation and delivery of medicines (the full range of products).

2.13 The internet and mail order sales of medicines ordered through the internet and delivered by mail are regarded as high-risk areas with regards to counterfeits entering the supply chain, as it is impossible for the authorities to control these areas. GIRP stresses the need for urgent action in order to inform both patients and consumers of the dangers of purchasing medicines from websites or mail order (where there is no pharmacist involved).

2.14 GIRP identified links between the risk profile of a country and the likelihood of counterfeit drugs entering the supply chain. Countries that are characterized by a low level of risk appear to be associated with the following:

- Highly regulated markets;
- Absence of internet sales of ethical products from non-certified sources;

- Limited number of wholesaling licenses;
- Distribution of medicines only through full-line wholesalers;
- Strict and frequent control of wholesalers' licenses;
- A strongly interlinked supply chain between full-line wholesalers and pharmacies; and no shortages of medicines on national markets; and
- A large number of medicines in national markets.

2.15 Given the concern of full line wholesalers about the risks of counterfeit medicines penetrating the legal supply chain, GIRP members have contributed towards the endeavor to prevent counterfeit medicines from entering the legal supply chain through a number of measures taken to minimize the risks. Some of these measures include: establishing supplier approval procedures; proactive auditing; product approval procedures; quality assurance staff undertaking sample checks against reference products; increasing corporate awareness; and sharing market intelligence.

2.16 The GIRP members are committed to a zero tolerance approach to the risk of counterfeit medicines in the legal supply chain and they highlight the need to fully co-operate with all supply chain partners. With this in mind, the GIRP, together with manufactures and pharmacies, established a 'Safe Supply' chain coalition in 2006. Developed within this are a number of proposed self-regulatory measures (in addition to legislative and regulatory measures) and include the following:

- A certification system for the supply chain partners;
- A code of conduct for the supply chain partners;
- Transparency and information sharing between the supply chain partners; and
- Joint training activities and awareness rising campaigns.

2.17 This paper highlights the GIRP's concerns over distribution licensing procedures. The paper points out that despite the EU regulatory backdrop of pharmaceutical wholesaling, many Member States do not issue specific licenses for pharmaceutical full-line wholesalers as many fail to draw a distinction between distribution licenses. Thus, for these countries there exists no differentiation between specific types of distribution activity, the license creates the scope for a wide variety of players and diverse licenses in the distribution of medicines in Member States. Some the countries used to illustrate this point include, Denmark, Hungary, Italy and the Netherlands.

2.18 The GIRP argues that increased consistency in the approaches taken with regard to the issuing of licenses be regarded as a fundamental step in developing measures to mitigate the risks of counterfeit drugs from penetrating the legal supply chain.

2.19 This paper outlines GIRP's views on a number of future legislative and regulatory measures that might be taken in this regard.

- **Future legislative measures** – The EC should aim towards creating a set of harmonised high-level standards for the distribution of medicines throughout the Member States by outlining a state of detailed requirements for obtaining licenses. This could be achieved, for example, by amending chapter VII of Directive 2004/27/EC or as an amendment to the Guidelines on Good Distribution Practices. The latter should also be reviewed with regards to the integration of anti-counterfeit measures and setting inspection and enforcement standards (an example being the 'Gold Standard'; of GIRP's UK member association BAWP). The EC should also consider the legal 'upgrade' of the GDP to the same level of GMP to ensure that measures are implemented completely and in a timely fashion as the current legal status of the GDP does not ensure this (implementation into national law is not obligatory).

- **Strengthened regulatory implementation** – Obtaining and keeping a distribution license should depend on full compliance with GDP, which must be regularly checked by the relevant authorities in Member States. GIRP endorses the setting up of the "EudraGMP" database to ensure the validity of manufactures and importers in the EU. The aim of the database should be that of establishing a framework that ensures all players in the supply chain only buy and sell from certified sources and that pharmaceutical full-line wholesales should have full access to the information on the EudraGMP database.

- **Communication and early warning systems** – GIRP underlines the willingness of its members to contributing towards the creation of a system of early and information to be utilized by all authorities and supply chain partners. This could be jointly elaborated with the Council of Europe through its "Ad-hoc Group on Counterfeit medicines'' employing a form developed by the latter for the sharing of information and as a checklist to compile information relevant to decisions over public health. This should be complemented by a respective reporting toll that would enable the inclusion of information regarding suspicions of counterfeiting and points of contact.

2.20 GIRP's members have to employ sophisticated information technology and physical infrastructure to cope with the logistical challenges of distribution where times are short and flows are continuous. GIRP's members are committed to collaborating with the authorities and supply chain members to establish a harmonised solution to track and trace medicinal products in Europe, something that Europe is currently lacking.

2.21 In fulfilling the objectives of establishing harmonized and machine readable data on all medicine packaging, GIRP requires its members to provide the national product identification number, the expiry date and the batch number in a machine readable format on all packaging. GIRP members seek a solution that addresses the specifics of the pharmaceutical supply chain, thus allowing for the following:

- The smooth integration of national product identification, expiry data and batch number;
- Speed of delivery;
- European wide technological harmonisation; and
- Competitive costs of implementation.

GS1 HUG (The Global Healthcare User Group)

2.22 GS1 HUG is a voluntary and open group formed by 40 leading pharmaceutical and medical devices companies, wholesalers, hospitals and trade associations from around the world. Its primary objective is to enhance patient safety worldwide through accurate and standardised product identification.

2.23 This paper puts forward the case for the establishment of a standardised and unique coding of healthcare products across the world built around global standards. This would include the assignment of a unique identity to a product that would remain constant from the point of manufacture to consumption. While recognizing that country-specific regulation might be necessary for addressing the specific needs of those countries, GS1 HUG advocates a global approach to standardization in a context of cross-border movements of products throughout the global supply chain.

2.24 GS1 HUG identified three key ways in which improving the accuracy of healthcare product identification:

- Avoiding medication errors by ensuring that the right drug is delivered to the right patient;
- Preventing the use of counterfeit drugs and medical devices; and
- Allowing the traceability of medical products.

2.25 The most widely used numbering and data carrying system used globally is the GS1 System of Standards, and has been adopted by more than 1 million users across 145 countries and across more that 24 industries.

2.26 In developing global standards, the HUG's members have created a roadmap for the completion of the final ADIC Application Standards of Healthcare enabling the health care industry globally to work with one standard. This roadmap consists of the following:

- Creating the GTIN Allocation rules (in its final stages of approval) which describes the procedures in assigning a product number and when to assign new ones etc;
- The Auto-ID Data Team have identified the relevant data that will be required by business to support their objectives for patient safety (e.g. serial number, expiry date);

- Defining of the appropriate Serialization schema for healthcare products, establishing how and where is the use of mass serialization most appropriate; and

- Agreeing upon a global standard for data carriers with regards to giving direction as to where and when to use various types of bar codes.

EFCC (European Fine Chemicals Group) APIC (Active Pharmaceuticals Ingredients Committee) cefic

2.27 This response came in four parts:

- Position Paper: ''Impact of API Fraud, Counterfeiting and Severe Non Compliance on EU Medicines'' (Submitted by EFCG, APIC and cefic);

- Joint Position Paper: "Uneven Enforcement Leads to Sub–par Drugs and National Security Risk" (submitted by EFCG and the SOCMA);

- Extract from the Pharmeuropa Journal Vol.15 April 2003, "Composition and Impurity Profile of Multi-source Raw Material of Gentamicin – a Comparison"; and

- A note "No Safe Medicines without Safe Ingredients" (submitted by APOC Sector Group of Cefic).

1. Position Paper: "Impact of API Fraud, Counterfeiting and Severe Non Compliance on EU Medicines" (Submitted by EFCG, APIC and cefic)

2.28 The majority of APIs on the EU market are now sourced from China and Asia (the number of manufactures ranges between 10,000 and 15,000 but how many supply the EU is unknown) who are not subject to having to comply with strict regulations for the manufacture of APIs.

2.29 The strictness of EU API regulations for the manufacture of API's has increased, namely as a result of new measures introduced in 2005 requiring API manufacturers to comply with GMP/Q7A. This paper argues that increasing the stringency of compliance regulations has the tendency to increase the prevalence of non-compliant (e.g. not complying with GMP) and counterfeit API's on the market as non-compliant manufacture become as form of competitive advantage.

2.30 The University of Wurzburg (at the request of the German Health Authorities BfArM), began an "analytical fingerprinting" in 2002-2003 to gather evidence of the nature of counterfeiting of APIs. Within this, they estimated that approximately 33 per cent of older, off-patient APIs that enter the EU via traders and brokers are counterfeit.

2.31 This main argument put forward in this paper is that the development and implementation of the EU system for inspection and enforcement of compliance with regulations is not adequate as it does not address the global means through which APIs are sourced.

2.32 Thus, a robust system of rigorous inspection of compliance of imports of APIs from outside of the EU or even to prevent the entry of known non-compliant APIs into the EU is lacking and thus exacerbates the risks exposure of patients in the EU.

2.33 This paper argues that the most viable solution for protecting patients from the risks of counterfeit and other illicit APIs is to implement an API enforcement program that establishes a regime of inspection and monitoring that is equally applied to API manufacturers, traders and brokers in the EU as well as those located outside the EU.

2.34 This paper also highlights that the forthcoming Communication on the future Single Market in the pharmaceutical industry should be view as a unique opportunity to both address the fundamental problem identified and to develop and implement the most effective solution.

2. Joint Position Paper: "Uneven Enforcement Leads to Sub–par Drugs and National Security Risk'' (submitted by EFCG and the SOCMA)

2.35 This paper calls for the relevant health authorities in the US and the EU to be provided a mandate to ensure that the level of quality standards of foreign manufactures of API is the same as those found in the EU and the US.

2.36 Similar to the case in the EU, there are limited systems in place in the US for the rigorous inspection and enforcement of cGMP regulations for manufactures of APIs located outside of the US. SOCMA thus called upon the US Food and Drug Administration in 2006 to ensure that the FDA better managed risks posed by foreign manufacturers, for example by including a 'foreign facility' in the list of risk factors taken into consideration when ranking the priority of facilities to be inspected.

2.37 SOCMA supported its position by highlighting a number of key statistics, including:

- 80 per cent of APIs used by US manufactures originate from abroad, and approximately half of this comes from China and India;
- In 1992, 242 APIs that were imported into the US from manufactures in 36 countries may have entered the US market without having been subject to FDA inspection; and
- In 2005 9 per cent of the inspections carried out on foreign API manufacturers by the FDA were in China and 14 per cent were in India. This is not proportionate to the quantity being imported from these sources.

2.38 The scope for non-compliance places EU and US citizens at risk in two key ways: patient safety and national/regional security.

2.39 Globalization has not only exacerbated pressures on prices and margins and driven generic and OTC companies to buy from the lowest costs sources, it has also increased the complexity of the global supply chain, increasing the scope for contamination,

mislabeling or substitution of substances. This tends to escalate the risks posed to patient safety.

2.40 With regards to the risk of national/regional security, an uneven playing field in terms of the stringency of compliance regulations and inspections may result in the detriment of domestic companies where greater compliance costs put them at a competitive disadvantage (it is estimated that the savings from non-compliance may be as much as 25 per cent of operating costs). This poses risks in the form of job losses, lost tax revenue, and reduced financial rigor etc. The potential for compromising national/ regional security may also arise where reducing the secure capacity of domestic production (both in the EU and the US) renders the EU and the US more dependent on foreign sources of APIs for their pharmaceutical requirements.

3. Extract from the Pharmeuropa Journal Vol.15 April 2003, "Composition and impurity Profile of Multi-source Raw Material of Gentamicin – a Comparison''

2.41 This background document specifies the factors that the legal framework should be based on that the EU must create to harmonise standards for all API suppliers to the EU market. These include the following:

- A mandatory and effective system of inspection that serves to verify the manufacturing processes and controls conform with the relevant regulations (e.g. ICH/Q7A GMP Guidelines);
- A sampling process to ensure quality surveillance of medicines and their API;
- A compulsory requirement to include to the producer of the API a Certificate of GMP compliance issued by the EU inspectorate with every Marketing Authorization; and
- Periodic follow-up inspections to reconfirm the validity of the GMP Certificate.

EAEPC (European Association of Euro-Pharmaceutical Companies)

2.42 EAEPC is the professional and representative voice of pharmaceutical parallel distribution in Europe, encompassing over 70 firms from 18 countries in the EEA. Its members are either licensed wholesalers ("parallel exporters") or both licensed wholesalers and pharmaceutical manufacturers ("parallel importers/distributors").

2.43 EAEPC's contribution focuses on delivering evidence and recommendations on the issue of the safety of medicines in Europe. It also draws attention the efforts made by the parallel distribution industry to prevent the penetration of substandard or counterfeit products into the supply chain.

2.44 The primary aims of the EAEPC are:

- Safeguarding the free movement of medicines;

- Promoting and co-operating in the development of parallel distribution as a means of providing innovative medicines to all Europeans at affordable price;
- Ensuring that social polices of Member States both accept and benefit from professional and regulated parallel trade; and
- Ensuring the integrity of the pharmaceutical supply chain.

2.45 EAEPC's members assume their full responsibility as players in the European pharmaceutical supply chain to:

- Ensure reliable and safe sources of supply within the EE;
- To fully comply to all national and European regulatory and legal requirements;
- Take the appropriate action when counterfeit products are detected/suspected; and
- Co-operating with stakeholder and regulators in ensuring the safety of the supply chain.

2.46 While emphasizing the robustness of Europe's pharmaceutical supply chain, Europe's growing trade relations with high risk countries such as Russia, China and India and the parallel increase in Europe's exposure to the risks of counterfeit medicines is a growing concern for EAEPC's members.

2.47 EAEPC initiatives given the above includes the following:

- **EAEPC Guidelines for Good Parallel Distribution Practice** – a condition on EAEPC membership is the acceptance and compliance with the EAEPC's Good Parallel Distribution Guidelines (GDP Guidelines), which entail requirements in addition to the regulatory framework and regulations in the area of parallel distribution in Europe.
- **EAEPC engagement with the Council of Europe (COU)** – EAEPC was accepted as a member of the ad-hoc Working Group on Counterfeit Medicines in 2005. Since then they have actively participated and contributed to projects which aim to identify additional actions market participants might take to ensure the safety of the supply chain.
- **Participating in the broader dialogue on supply chain safety** – engaging in a number of conferences and seminars with the aim of discussing with stakeholders and educating them on the efforts of the parallel distribution towards improving the safety of the supply chain.

2.48 Like other players in the pharmaceutical supply chain, parallel distributors face the same concerns regarding, for example, the assurance that ingredients are sourced from reliable and safe sources, the reliance on a robust and reliable licensing regime for wholesalers

and manufacturers and ensuring the safe transport of products/active ingredients throughout the whole supply chain.

2.49 Underlying the EAEPC's guidelines is the 'know your supplier' principle. Thus, parallel distributors (and importers) may only purchase medicinal products with marketing authorisations from authorised wholesalers or manufactures in other EEA countries. Similarly, parallel distributors are only permitted to sell or supply medicinal products with marketing authorization to authorised wholesalers, registered pharmacies etc.

2.50 Parallel distributors/importers also serve in protecting the security of the supply chain from counterfeits through their internal Standard Operating Procedures (SOP) through having the diction of defective medicines and counterfeits as a regular component of the quality control procedures.

2.51 With regards to the safety of technologies, the EAEPC would welcome any technological innovation that would further the aims of supply chain safety and efficiency such as track and trace technologies (e.g. 2D barcodes).

2.52 EAEPC's calls for the development of mass serialization technologies that make available information about the movement of all products throughout the supply chain and while at the same time is implemented in a manner that does not compromise the protection of private data (e.g. information of a commercial nature or that concerning individual patients).

2.53 EAEPC's also stresses the need for there to be some level of regulation regarding access to information by members of the supply chain as a means of safeguarding competition and the free movement of goods in the Single Market. This is to prevent the occurrence of discriminatory practices between national and cross-border distribution that the unregulated availability of information may encourage.

2.54 The regulatory environment surrounding the safety of medicines includes a number of requirements placed on parallel distributors in the following areas:

- The maintenance of the integrity of the supply chain;
- Control of incoming stock;
- Re-labeling/repackaging;
- Final release of products;
- Batch recalls;
- Regular inspections; and
- Pharmacovigilance.

2.55 With regards to the safety record of the parallel supply chain, the EAEPC claims that despite the rhetoric, there have been no proven cases of counterfeit medicines having penetrated the European supply chain as a result of parallel trading. This is largely attributed to the regulatory checks that parallel distributors are obliged to conduct and the fact that they have to employ a European Qualified Person (QP) to ensure these checks are effective and are of the right quality.

2.56 EAEPC provides some empirical evidence of counterfeit cases as proof to support that claim that parallel distribution channels are not the point of entry for counterfeits, including the following cases:

- The Cialis/Fisher Farma Case in the Netherlands; and
- The Plavix case in France and the UK

2.57 Parallel distribution also provides an additional layer of safety with regards to ensuring quality of products distributed. This is through the potential to detect defective products as a result of the requirements placed on distributors and importers, who repack or re-label products, to open each pack thereby providing an additional level of optical inspection in the supply chain.

2.58 EAEPC does however, point out that there are two involuntary restraints with regards to parallel labeling. First, in most cases, parallel distributors are obliged to apply multiple stickers on an original box and second, the parallel distributor is not able to attach any additional security devises (e.g. its own tamper proof seal). In theory, these restraints might be at risk of exploitation by counterfeits as it may be more difficult to tell the difference between true and falsified parallel import packaging than fake from real original pack. Thus, EAEPC argues that to the extent that overstickering might serve as a potential obstruction to the defense against counterfeits, then the prevailing obligation on re-labeling warrants a review, on grounds of both counterfeiting and medicines safety.

2.59 EAEPC supports the view that co-operation with the industry, governments and regulatory bodies are key to combating counterfeits, establishing working relationships with regulators to alert them to any potential counterfeit risks on the market. Experience shows that authorities in some countries take a proactive approach to the issue, i.e. by providing information to parallel distributors directly, thus increasing the speed with which counterfeits are detected (e.g. Ireland, Netherlands, Poland and Germany). Authorities in some other countries, however, take a more passive approach (e.g. Italy).

EFPIA (European Federation of Pharmaceutical Industries and Associations)

2.60 The submission from the EPIA came in three parts:

- EHPIA's position paper;
- Separate submission by Sanofi-avantis; and

- Separate submission by Pfizer.

1. EFPIA response

2.61 EFIPA represents the pharmaceutical industry operating in Europe and has a direct membership of 30 national associations and 46 leading pharmaceuticals.

2.62 EFIPA believes that although the primary responsibility for the prevention and control of counterfeiting resides with national authorities and international organizations, the pharmaceutical industry has an important role to play in contributing to this.

2.63 Counterfeit medicines are encountered at all stages of the supply chain and the nature of the problem is local, regional and global. Historically, while the recorded incidence of counterfeits is greatest in countries outside of the EU (e.g. Russia (12 per cent), China (15 per cent), India, and Mexico), there is evidence to suggest that it is becoming a growing problem in the EU.

2.64 EEPIA is of the view that there are five key factors that warrant both highlighting and examining to account for the increase in counterfeit incidence in the EU:

- The increased availability and uncertainty that exists when purchasing medicinal products over the internet;
- The increased use of Europe as a transit location for counterfeits;
- The challenge of EU enlargement;
- The existence of a grey market as a result of difference in government fixed prices in Europe; and
- The opportunities, provided by the combination of complexity and the fractured nature of the parallel trading system with a rapidly expanding grey market, for counterfeits to enter the legal supply chain.

2.65 EFIPA data shows that despite the fact that a vast array of therapeutic categories that are the type most commonly counterfeited, the latter can also be observed in life saving pharmaceuticals (e.g. antibiotics, antidepressants, anti-diabetics, cardiovascular, oncology, pulmonary disease, viral disease etc).

2.66 With regards to the issue of models of co-operation to combat counterfeit medicines, EFIPAs members are co-operating with the relevant regulators and other stakeholders in a number of ways, the aims of which are:

- **Ensuring the integrity of the legal supply chain** – The EFIPA Board has decided to recommend to its members the adoption of the 2D matrix barcodes system coupled with randomized mass serialization with the aim of moving towards a more harmonised coding system throughout the Member States and thus help reducing

production costs and improving production speed. EFIPA emphasizes the need for a collaborative approach between EFIPA and Member State governments in both developing and supporting the implementation the right regulations/standards.

- **Strengthening current laws and enforcement to deter counterfeits** – EFIPA has urged for the adoption of legislative measures to improve the supply chain and criminal prosecutions, and have called for the imposition of stronger penalties. EFIPA have also fostered public/private partnerships with a number of authorities (e.g. trading standards officers, police, national customs etc) including the participation of EIFPA's members in the training of officials on issues relevant to counterfeiting. Thus strong and open co-operation with the health authorities facilitates the appropriate actions where counterfeits are detected in the legitimate supply chain.

2.67 Raising awareness of the general public should be carried out by suitable public authorities (i.e. targeted mainly via specialized media and healthcare experts in order to contribute towards balanced reporting), as means of maintaining confidence in the sector.

2.68 With the encouragement of EFIPA, national public authorities have developed a number of pro-active initiatives to raise consumer awareness of the importance of purchasing medicines from certified sources.

2.69 With regards to the issue of counterfeits in the context of parallel trading, EIFAP argues that repackaging by parallel traders interrupts the safe supply chain and the authenticity of products can no longer be guaranteed. They thus suggest that banning the repackaging of products by parallel traders in addition to taking appropriate action on the sub-standard regulations that currently govern parallel trading would serve to mitigate the risks of counterfeits.

2.70 Other suggestions put forward include;

- Certification of mail order pharmacies;
- Auditing of the supply chain;
- Establishing an alert system; and
- Increased collaboration with the customs authorities.

2. Sanofi-avantis

2.71 The contribution from Sanofi-avanits is in the form of presentation slides which outlines the commonly counterfeited drugs, countries mainly concerned and includes a number of counterfeit cases in Taiwan, Germany, Hong Kong and on the internet.

2.72 The main counterfeited products cited are:

- Plavix (Thrombotic diseases);

- Stilnox/Ambien (Central nervous system; hypnotic);
- Clexane/Lovenox (Thrombotic diseases); and
- No-spa (in Russia), Neo-melubrina (in Mexico) (Antihistamine, Analgsics).

2.73 The main countries of concern highlighted in Asia are China, Hong Kong, Russia and Taiwan. In the Middle East it is Iran. In Latin America it is Mexico and in Europe it is the UK.

3. Pfizer

2.74 Pfizer also gave a separate contribution which outlines its main concerns about parallel trading and the implications for the safety of medicines. It's also provides some recommendations to address these concerns.

2.75 With regards to parallel trading and the implications for the safety of medicines, Pfizer have four main concerns:

- It provides an entry point for counterfeits to penetrate the legal supply chain in Europe. The fragmented and porous supply chain reduces the conduciveness of medicines trading to regulation and is convenient to counterfeiters, as a means of cover, seeking to penetrate the legal supply chain in Europe;
- It can lead to a shortage of medicines and thus deny patients access to their medicines as a result of being able to strip the exporting country of supply;
- The repackaging process (e.g. the removal of safeguards and the replacement of the original patient information leaflet by that in the language of the country of destination) and the scope for human error is such that parallel trading has the potential to result in the provisions of wrong or outdated PIL's, discrepancies between pack label and pack contents and incorrect batch numbers. Such factors would make a necessary and effective batch recall problematic; and
- Total compliance of parallel traders to regulatory procedures is lacking.

2.76 Pfizer highlights what they view as two worrying counterfeiting trends that have recently emerged in the EU:

- Counterfeit Pfizer medicines have been discovered in the majority of EU Member States. Not only have they been found in the legitimate supply chain, but they have also been dispensed to patients; and
- Counterfeits are increasingly adapting quickly and effectively to new anti-counterfeiting measures; counterfeits are thereby becoming increasingly sophisticated and extremely difficult to detect. Pfizer is now discovering counterfeit

packaging, inserts and holograms as well as counterfeit medicines and active ingredients.

2.77 With these concerns in mind and with Pfizer's belief that the regulatory framework governing parallel trading is inadequate with respect to ensuring patient safety, it proposes a number of recommendations as a means of improving supply chain security and public confidence in medicines:

- Temporary suspension of parallel trading of medicines;
- Prohibiting the grey trade of medicines;
- Prohibit the repackaging of medicines;
- Introduce medicines "pedigree" legislation and track and trace technologies;
- Strengthen current licensing regulations and enforcement of medicine trading; and
- Aid the Commission in creating a European Taskforce to co-ordinate communication activities on medicine safety and anti-counterfeiting.

PGEU (PHARMACEUTICAL GROUP OF THE EUROPEAN UNION)

2.78 PGEU is the European association representing community pharmacists in 29 countries including EU Member States, EEA countries and EU applicant countries, overall representing over 400,000 pharmacists.

2.79 This paper advocates precautionary approach top action at Community level as the correct one to combating counterfeit medicines in Europe, stressing that counterfeit medicines are not confined to medicines and generic medicines, but also medical devices, cosmetics and veterinary products.

2.80 PGEU regards two aspects of the current European climate that may come into conflict with supply chain security imperatives:

- The requirements to push for cost containment; and
- The relative ease with which medicines can be traded between Member States, facilitated by the internal market.

2.81 The principles upon which the recommendations provided by PGEU in this response are based are the fullest possible range of medicines to the public and are not compromised by any measure introduced to increases the security of the supply chain. Second, such measures should not adversely affect the ability of pharmacists to provide advice, medicines management and respect patient confidentiality.

2.82 PGEU broadly supports the adoption of track and trace technology. Pharmaceutical companies have been experimenting with a range of new technologies such as radio frequency identification technology (RFID) and optically variable devices (OVDs).

2.83 Overall, PGEU does not identify a specific preference for one particular technology providing the following principles are adhered to:

- Technology facilitates the identification and reporting of suspect medicines at pharmacy level and that fully integrated reporting mechanisms are in place to ensure quick and effective action is to be taken once a suspect item is identified;
- Technology is user friendly and practical and above all is not an impediment to the efficiency of the pharmacy; and
- Technology does not impose disproportionate costs burdens in the pharmacy.

2.84 With regards to the sale of pharmaceutical sales via the internet, PGEU stresses that the European Commission should continue to support the current position of European Law, that the prohibition of internet sale of prescription medicines is compatible with the internal market.

2.85 A number of supply chain innovations (e.g. altering its configuration), have been tried with the aim improving the security of the supply chain. However, PGEU have viewed these developments with some concern as they potentially pose risks to the level of efficiency and comprehensive supply of medicines that is characteristic of the current system in Europe. PGEU argues that the most appropriate approach would be to focus more on the coordinating activities of supply chain partners rather than reshaping current supply chains.