COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Strasbourg, 15 April 2008
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PC-S-CP (2008) 09

EUROPEAN COMMITTEE ON CRIME PROBLEMS
(CDPC)

GROUP OF SPECIALISTS
ON COUNTERFEIT PHARMACEUTICAL PRODUCTS
(PC-S-CP)

DRAFT REPORT OF THE 3RD MEETING

BRIEF FOREWORD

At its third meeting, the PC-S-CP discussed the draft Final Report, taking into account the written proposals and comments made by the specialists during the written consultation procedure.

The PC-S-CP in particular:

- agreed upon the need to establish a Council of Europe convention against pharmaceutical crime, in order to create offences criminalising counterfeiting of medical products and related crimes and to provide severe penalties for anyone found guilty of these offences;

- established a non-exhaustive list of offences that a future convention should introduce;

- agreed upon the need to ensure that a broad range of sanctions is established by a future convention, which should be commensurate to the gravity of offences and sufficiently diverse to allow taking into account the specificity of each particular offence;

- stressed that criminalisation of making counterfeit medical products available via the Internet would increase the protection of the public, as it would enable the Convention on Cybercrime to apply to such offences as well;

- agreed that a future convention should enable States Parties to effectively establish their jurisdiction over offences prescribed in it and find flexible solutions in case of conflict of jurisdictions;

- put forward a number of proposals as to the possible follow-up mechanism to a future convention.

After a detailed examination of the provisions, to which the members of the Group made their comments and/or proposals, the PC-S-CP adopted the Final Report and decided to transmit it to the European Committee on Crime Problems (CDPC), which will hold its next plenary meeting in June 2008.

OPENING OF THE MEETING

1. The Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) held its third meeting in G Building of the Council of Europe, Strasbourg, on 5-7 March 2008, with Mr Claude DEBRULLE (Belgium) in the Chair.

2. The Chair reminded members of the Group that the main objective of the third meeting was to discuss and adopt the draft Final Report, prepared as the result of two previous meetings and the written consultation procedure between meetings.

3. The Terms of Reference of the PC-S-CP appear in Appendix I to this Report. The representative of the European Commission Mr Christian TOURNIE and the representative of the Parliamentary Assembly Mr Bernard MARQUET took part in the third meeting of the PC-S-CP. The full list of participants is contained in Appendix II and the agenda of the second meeting is contained in Appendix III.

ADOPTION OF THE AGENDA

4. The agenda was adopted without any modifications.

MEETING DISCUSSIONS

Discussion of the draft Final Report in the light of comments made by members of the Group

5. The PC-S-CP examined in detail the written comments made by its members to the draft Final Report prior to the meeting.

6. The Group confirmed its view that a clear distinction between counterfeiting of goods in general and counterfeiting of pharmaceutical products should be drawn. It took note of the information provided by Information Solution for Pharmaceutical and Healthcare Industries (IMS Health) concerning the volume and the value of medical products available on the market that are not protected by patent rights as well as the information from the European Generics Association concerning the market volume of generic medical products (see Appendix IV to this Report). The PC-S-CP stressed that counterfeiting of pharmaceutical products is a broad problem and its biggest threat is the jeopardy it brings to public health.

7. The PC-S-CP reiterated its conviction that the objective of a possible future legal instrument should be to create offences criminalising counterfeiting of medical products and related crimes and to provide procedural and substantive provisions against pharmaceutical crime.

8. The notion of “pharmaceutical crime”, under which specific offences could be included, found favour with the absolute majority of the specialists. However, some members of the PC-S-CP opposed using this term as they considered it to be an undefined concept, open to differing interpretations and therefore not appropriate for introducing specific criminal offences on its basis.

9. The PC-S-CP agreed that at present there is no common European and even less global standard as regards combating pharmaceutical crime. It highlighted the differences in national laws as regards criminalising this activity and stressed its increasing international character. The Group took note of a comparative study on concepts of criminal legislation, currently being carried by the Max Planck Institute for Foreign and International Criminal Law, which will be available in its final version by the end of May 2008.

10. The PC-S-CP concluded that the scope of a future convention should cover medicinal products and medical devices, including, in particular, blood and blood products and cells as well as tissues. It recognised the importance of specific expertise required to address the appropriate terminology when dealing with medical devices. As regards clinical trials, even though the majority of the Group agreed that manipulative administration or abuse of such trials could lead to danger for public health, it would fall beyond the scope of a future instrument.

11. The PC-S-CP decided to include in the Final Report a non-exhaustive list of offences that should be introduced by a new legal instrument and explained some of these introductions in greater detail. The Group indicated that the level of liability for these offences should be determined individually, taking into account the gravity of the offence in question and any aggravating or mitigating circumstances. However, the majority of the specialists agreed that the mere fact of having committed a pharmaceutical crime should constitute an offence, regardless whether any actual harm was caused.

12. To successfully prevent counterfeiting of medical products and pharmaceutical crime in general, the PC-S-CP indicated that a criminal justice system should dispose of a variety of measures and sanctions, which should be proportionate to the particular offence and have a dissuasive effect on the offender in question as well as any future offenders. The sanctions and measures could usefully include confiscation of the instrumentalities and the proceeds from crime, destruction of medical products endangering public health, a ban on exercising entrepreneurial activity, revocation or annulment of professional diplomas or licences etc.

13. The PC-S-CP emphasized however, that a future instrument will not aim at criminalizing the production of substandard pharmaceutical products by licensed manufacturers, when there is no criminal intent. Such violations should be left to the pharmaceutical regulatory sphere.

14. Given the international character of pharmaceutical crime the PC-S-CP considered it vital that a future convention allows states to establish jurisdiction over the offences prescribed in it, regardless of the place of commission of these offences. The Group noted that some of the already existing Council of Europe instruments contained provisions that enabled states parties to determine their jurisdictions according to different criteria. One of the most important aspects to be taken into account was being able to criminalise an act when it was committed on the territory of a state that does not criminalise that act. In determining jurisdiction for such a complex type of crime as pharmaceutical crime some additional criteria could apply, such as victim-related criteria, for example.

15. For an international instrument to function effectively, international co-operation, including exchange of information between relevant authorities, is essential. A separate chapter, devoted to these matters, was included by the PC-S-CP in the Final Report.

16. The specialists of the Group considered that along with penal sanctions, preventive measures, including administrative measures, could be very helpful in combating pharmaceutical crime. Drawing up lists of good manufacturing practices, good distribution practices and other appropriate standards should be promoted. The PC-S-CP agreed that the victims of pharmaceutical crime would need to avail themselves of necessary legal remedies and compensation rights, given the possible deteriorating effects that counterfeit medical products sometimes have on deceived patients.

17. The PC-S-CP decided to include the three major monitoring mechanisms for a future convention, characteristic to the Council of Europe legal instruments, as they appear in the Final Report, and agreed that it was not for the PC-S-CP to identify the most appropriate. However, the specialists reiterated their conviction that it would be useful to allow for a monitoring mechanism that envisages on-site visits to states parties to a future legal instrument.

18. At the end of the meeting the PC-S-CP adopted the Final Report, leaving it to the Chair of the Group to make any editorial changes that might be necessary, and decided to transmit it to the CDPC.

FOLLOW UP TO THE PC-S-CP'S CURRENT WORK

19. The PC-S-CP took note of the proposal, expressed at the CDPC Bureau meeting on 16-18 January 2008, concerning the possible continuation of the work of the Group, should the CDPC decide at its meeting in June 2008 to proceed with the drafting of a convention.

20. Mr Carlo CHIAROMONTE, Head of the Criminal Law Division, informed the PC-S-CP of the departure of its current Secretary and that a new Secretary should be appointed to the PC-S-CP for it to continue its work in an effective manner. Mr CHIAROMONTE expressed his hope that that an appropriate solution will be found in due course to faciltate the eventual preparation of a new Council of Europe legal instrument against pharmaceutical crime.

APPENDIX I

TERMS OF REFERENCE
OF THE
GROUP OF SPECIALISTS ON COUNTERFEIT PHARMACEUTICAL PRODUCTS
(PC-S-CP)

1. Name of Committee: Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP)

2. Type of Committee: Ad hoc Advisory Group

3. Source of terms of reference: Committee of Ministers, on the suggestion of the European Committee on Crime Problems (CDPC)

4. Terms of reference:

Having regard to:

- the Declaration and Action Plan adopted by the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), in particular concerning the issue related to the security of citizens;
- Resolution Res(2005)47 on committees and subordinate bodies, their terms of reference and working methods;
- Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security;
- reply adopted by the Committee of Ministers on 6 April 2005 concerning Recommendation of the Parliamentary Assembly 1673 (2004) on "Counterfeiting: problems and solutions" and Recommendation 1794 (2007) on "The quality of medicines in Europe";
- the survey report on counterfeit medicines prepared by the Partial Agreement in the Social and Public Health field and the conclusions of the Seminar on counterfeit medicines (2005);
- the Declaration on "Combating IPR piracy and counterfeiting", adopted by Heads of State and Government at the G8 Summit meeting, St. Petersburg on 16 July 2006;
- the International Conference on "Europe against counterfeit medicines" (Moscow, 23-24 October 2006) and the declaration[1] adopted by its participants;
- the conclusions of the High-level Conference of the Ministries of Justice and of the Interior on "Improving European Co-operation in the Criminal Justice Field" (Moscow, 9-10 November 2006);
- the feasibility study prepared for the CDPC on counterfeit medicines and pharmaceutical crime and the report on prioritised elements for a Council of Europe Convention on the protection of public health against pharmaceutical and healthcare product crime;
- the Convention on Cybercrime (ETS no 185).

Under the authority of the European Committee on Crime Problems (CDPC), and in relation with the implementation of Project 2004/DGI/199 (to be entitled 2008/DG-HL/1432 at a later date) "Monitoring the operation of conventions on co-operation in the criminal field" of the Programme of Activities, and bearing in mind the criteria developed in document CM(2006)101 final, the Group is instructed to:

prepare a report, in the light of indications given by the CDPC and document CDPC-BU (2007) 12, focusing on the key elements, which could be included in a possible international binding legal instrument to fight crime concerning counterfeit pharmaceutical products. This report:

- should deal first with the criminal law aspects of counterfeit medicines and other medical products including the means to prevent such crime and strengthening of international co-operation;
- should focus on conducts, which may jeopardise public health, and take account of existing

[1] http://www.coe.int/t/dc/press/News/20061107_fin_medicaments_en.asp

national legislation in this field;
- could indicate whether further provisions could be prepared to deal with specific issues concerning health care products;
- should take full account of other work being carried out at an international level, in particular by the European Union and the World Health Organisation.

5. Composition of the Committee:

5.A Members

The Group shall be composed of 11 specialists in the field of pharmaceutical crime and criminal law. The CDPC shall appoint one specialist who shall chair the Group. The Secretary General shall appoint the remaining specialists in consultation with the Chair of the CDPC. With this in mind, member states are invited to submit names of experts to the Secretary General, if they so wish.

The Council of Europe budget will bear the travel and subsistence expenses of the 11 above members of the Group.

5.B Participants

i. The Parliamentary Assembly may send (a) representative(s) to meetings of the Group, without the right to vote and at the charge of its administrative budget.

5.C Other participants

i. The European Commission may send (a) representative(s) to meetings of the Group, without the right to vote or defrayal of expenses.

ii. The following intergovernmental organisations may send (a) representative(s) to meetings of the Group, without the right to vote or defrayal of expenses:

- the World Health Organisation (WHO).

6. Working methods and structures:

The Group shall present its report at the next plenary meeting of the CDPC in 2008.

The Bureau of the CDPC will follow closely the progress made and, if appropriate, give further instructions concerning the work of the Group.

7. Duration:

These terms of reference will expire on 31 December 2008.

APPENDIX II

LIST OF PARTICIPANTS

MEMBERS OF THE GROUP / *MEMBRES DU GROUPE*

CHAIR, elected by the CDPC / PRESIDENT, élu par le CDPC :
M. Claude DEBRULLE (BELGIUM / BELGIQUE)

AUSTRIA / AUTRICHE
Mr Fritz ZEDER, Leiter der Abt. II.2 im Bundesministerium für Justiz, Head of Unit II.2 in the Federal Ministry of Justice

BELGIUM / BELGIQUE
Mr Roy VANCAUWENBERGHE, Inspector FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu

CROATIA / CROATIE
Ms Ksenija TURKOVIĆ, J.S.D., Professor of Criminal Law, Faculty of Law, University of Zagreb,

CYPRUS / CHYPRE
Ms Popi Nicolaidou KANARI, Acting Director, State General Laboratory

FRANCE
M. Jacques FRANQUET, Préfet honoraire, Vice-Président, Directeur de la Sureté et Sécurité Economique et Patrimoniale, Président de la cellule de coordination de la lutte anti contrefaçon du groupe Sanofi-Aventis

GERMANY / ALLEMAGNE
Mr Konstantin KELLER, Bundesministerium für Gesundheit, Federal Ministry of Health, Gruppe Internationale Arzneimittelfragen, Department for International Pharmaceutical Affairs

IRELAND / IRLANDE
Mr Hugo K. BONAR, Irish Medicines Board, Enforcement Manager

NETHERLANDS / PAYS BAS
M. Hendrick Jan de JONG, Institut de Recherches Int. Servier

RUSSIAN FEDERATION / FEDERATION DE RUSSIE
Mr Sergey V. GLAGOLEV, Managing specialist-expert, Dept of registration of drugs and active pharmaceutical ingredients, Federal Service for the Supervision in the Sphere of Public Health and Social Development (Roszdravnadzor)

SWEDEN / SUEDE
Ms Kerstin HJALMARSSON, Assessor Medical Products/Enforcement, Swedish Medical Agency

PERSONS ACCOMPANYING MEMBERS OF THE GROUP / *PERSONNES ACCOMPAGNANT LES MEMBRES DU GROUPE*

RUSSIAN FEDERATION / FEDERATION DE RUSSIE
M. Sergey DALECHIN, Conseiller adjoint au Représentant Permanent de Russie auprès du Conseil de l'Europe

SWEDEN / SUEDE
Ms Sara ÅSTRÖM, Lawyer, Legal Affairs, Medical Products Agency, Swedish Medical Agency

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PARLIAMENTARY ASSEMBLY – SOCIAL, HEALTH AND FAMILY AFFAIRS COMMITTEE/
ASSEMBLÉE PARLEMENTAIRE - COMMISSION DES QUESTIONS SOCIALES, DE LA SANTE ET DE LA FAMILLE

M. Bernard MARQUET, Conseiller, Conseil National de la Principauté de Monaco

Mme Agnès NOLLINGER, Secrétaire de la Commission des questions sociales, Assemblée Parlementaire, Conseil de l'Europe

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OTHER PARTICIPANTS / *AUTRES PARTICIPANTS*

EUROPEAN COMMUNITY / *COMMUNAUTÉ EUROPÉENNE*

EUROPEAN COMMISSION / *COMMISSION EUROPEENNE*
Mr Christian TOURNIE, National Seconded Expert, DG JLS – Justice, Freedom and Security, Organised Crime Unit

INTERNATIONAL INTERGOVERNMENTAL ORGANISATIONS /
ORGANISATIONS INTERNATIONALES INTERGOUVERNEMENTALES

WORLD HEALTH ORGANIZATION / *ORGANISATION MONDIALE DE LA SANTÉ*
Mr Valerio REGGI -, Coordinator, Medicines Regulatory Support, Department of Technical Cooperation for Essential Drugs and Traditional Medicine – *Apologised / Excusé*

SECRETARIAT OF THE COUNCIL OF EUROPE /
SECRETARIAT DU CONSEIL DE L'EUROPE

Directorate General of Human Rights and Legal Affairs / *Direction Générale des droits de l'Homme et des affaires juridiques (DG-HL)*

Law Reform Department / *Service des réformes législatives*

M. Carlo CHIAROMONTE, Head of the Criminal Law Division / Chef de la Division du droit pénal

M. David DOLIDZE, Administrator / Administrateur
Secretary to the PS-S-CP / Secrétaire au PC-S-CP

Mme Claire ROBINS, Assistant / Assistante

Mme Christiane WELTZER, Assistant / Assistante

Directorate General III – Social Cohesion / *Direction Générale III – Cohésion Sociale*
Partial Agreement in the Social and Public Health Field / *Accord partiel dans le domaine social et de la santé publique*

Ms Sabine WALSER, Administrative Officer / Administratrice
Deputy Secretary to the PC-S-CP / Secrétaire adjointe du PC-S-CP

INTERPRETERS / INTERPRETES

Mme Chloé CHENETIER
Mme Barbara GRUT
Mme Julia TANNER

APPENDIX III

AGENDA / *ORDRE DU JOUR*

1. Opening of the Meeting / *Ouverture de la réunion*

2. Adoption of the Agenda / *Adoption de l'ordre du jour*

Working documents / *Documents de travail :*

- Terms of Reference of the PC-S-CP / *Mandat spécifique du PC-S-CP*
- List of participants / *Liste des participants*
- Summary of the discussions of the CDPC concerning the PC-S-CP /
  Résumé des discussions du CDPC concernant le PC-S-CP *PC-S-CP (2007) 01*
- Reports of the first and the second meetings of the PC-S-CP / *Rapports des premiere et deuxieme réunions du PC-S-CP*
  06 – 07.11.2007 *PC-S-CP (2007) 03*
  17 – 19.12.2007 *PC-S-CP (2007) 04*
- *Summary meeting report / Rapport de réunion (16-18.01.2008)* *CDPC (2008) 07*

3. Discussion of the Draft Final Report in the light of the comments made by the members of the Group / *Discussion de Projet de Rapport Final à la lumière des commentaires des membres du Groupe*

Working documents */ Documents de travail :*

- **Draft Final Report /**
  Projet de Rapport Final *PC-S-CP (2008) FIN PROV*
- Comments on Draft Final Project from K. HJALMARSSON and J. FRANQUET
  Commentaires sur le projet de rapport final de K. HJALMARSSON et J. FRANQUET
  PC-S-CP (2008) 05
- **Comments of the PC-S-CP experts integrated into the Draft Final Report /** ***Commentaires des membres du PC-S-CP intégré dans le Projet de Rapport Final***
- **Expertise by B. GELLIE for the PC-S-CP** / ***Expertise par B. GELLIE pour le PC-S-CP***
  PC-S-CP (2008) 06
- Report by the PACE (Doc. 11227) / *Rapport de l'APCE (Doc. 11227)*
- Recommendation 1793 (2007) and the Reply by the Committee of Ministers / *Recommandation 1793 (2007) et la réponse du Comité des Ministres*
- PACE Recommendation 1794 (2007) and the Reply by the Committee of Ministers / *APCE Recommandation 1794 (2007) et la réponse du Comité des Ministres*
- Convention on Cybercrime, Budapest, 23.11.2001 / *Convention sur la cybercriminalité, Budapest, 23.11.2001*
- Prioritised elements for a Council of Europe convention on the protection of public health against pharmaceutical and healthcare product crime / *Eléments prioritaires pour une convention du Conseil de l'Europe sur la protection de la santé publique contre le crime pharmaceutique et le crime lié aux produits de santé* CDPC-BU (2007) 12

- Feasibility study for a Council of Europe convention on counterfeit medicines/pharmaceutical crime / *Etude de faisabilité d'une convention du Conseil de l'Europe sur la contrefaçon de médicaments et le crime pharmaceutique* CDPC-BU (2007) 01

- Model of a network of single points of contact (SPOCs) – English only

- Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use / *Directive 2004/27/CE du Parlement Européen et du Conseil du 31 mars 2004 modifiant la directive 2001/83/CE instituant un code communautaire relatif aux médicaments à usage humain*

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency / *Règlement (CE) N°726/2004 du Parlement Européen et du Conseil du 31 mars 2004 établissant des procédures communautaires pour l'autorisation et la surveillance en ce qui concerne les médicaments à usage humain et à usage vétérinaire, et instituant une Agence européenne des médicaments*

- Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights / *Règlement (CE) n° 1383/2003 du Conseil du 22 juillet 2003 concernant l'intervention des autorités douanières à l'égard de marchandises soupçonnées de porter atteinte à certains droits de propriété intellectuelle ainsi que les mesures à prendre à l'égard de marchandises portant atteinte à certains droits de propriété intellectuelle*

- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products / *Directive 2001/82/CE du Parlement européen et du Conseil du 6 novembre 2001 instituant un code communautaire relatif aux médicaments vétérinaires*

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices / *Directive 93/42/CEE du Conseil, du 14 juin 1993, relative aux dispositifs médicaux*

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices / *Directive 90/385/CEE du Conseil, du 20 juin 1990, concernant le rapprochement des législations des États membres relatives aux dispositifs médicaux implantables actifs*

- Terms of Reference for International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in the World Health Organisation (WHO) – English only

- Principles and Elements for National Legislation against Counterfeit Medical Products, approved by IMPACT (WHO) at the International Conference in Lisbon (10-11 December 2007) – English only

- Conclusions and Recommendations of the WHO International Conference on combating Counterfeit Medicines, Declaration of ROME, 18 Feb 2006 – English only

Approval of the draft Final Report / *Approbation de projet de Rapport Final.*

APPENDIX IV

Secretariat: Note for information

Patent-protected medicines on market in Europe

1. Data sources

1.1 Information Solutions for Pharmaceutical and Healthcare industries (IMS Health)

Information about size of different parts of the market ("never protected"/"no longer protected"/"protected"/ "on patent products"/"other-not classifiable") of the market in terms of volume made available by IMS, UK.

Note: The information was given by IMS exclusively for use in working documents in the frame of the scope of the activities carried out by the Council of Europe DG Human Rights and Legal Affairs.

1.2 Business Insights. Pharmaceutical Growth Opportunities in Brazil, Russia, India and China (BIRC); Revati Nehru (2006)

Information: Russia (2005)

1.3 European Generics Association (EGA)

EGA 2006 market review

Note: EGA data may serve as complementary background information to the data in 1.1 as the proportion of generics on the market depends from various factors:
e.g. size of innovative pharmaceutical industry,
reimbursement system and approaches,
attractiveness of market for a generic medicine from an out of patent medicine (e.g. pricing of off-patent original medicines, doctors' prescribing patterns),
historical/current patent protection legislation and status.

IMS (Data source 1.1)
Year to September 2007: Volume (SU[1]s)

Note: The information was given by IMS exclusively for use in working documents in the frame of the scope of the activities carried out by the Council of Europe DG Human Rights and Legal Affairs.

France Combined[2]	%
NEVER PROTECTED	42%
NO LONGER PROTECTED	32%
Other	3%
PROTECTED	22%
	100%

Germany Combined	
NEVER PROTECTED	62%
NO LONGER PROTECTED	21%
Other	2%
PROTECTED	15%
	100%

UK Combined	
NEVER PROTECTED	60%
NO LONGER PROTECTED	25%
Other	2%
PROTECTED	13%

Italy Combined	
NEVER PROTECTED	49%
NO LONGER PROTECTED	20%
Other	8%
PROTECTED	23%

Spain Combined	
NEVER PROTECTED	46%
NO LONGER PROTECTED	30%
Other	11%
PROTECTED	13%

Greece (Retail Only)	
NEVER PROTECTED	42%
NO LONGER PROTECTED	24%
Other	22%
PROTECTED	12%

Belgium Combined	
NEVER PROTECTED	40%
NO LONGER PROTECTED	38%
Other	2%
PROTECTED	20%

Netherland (Retail Only)	
NEVER PROTECTED	61%
NO LONGER PROTECTED	15%
Other	5%
PROTECTED	19%

Sweden Combined	
NEVER PROTECTED	53%
NO LONGER PROTECTED	23%
Other	10%
PROTECTED	13%

Austria Combined	
NEVER PROTECTED	42%
NO LONGER PROTECTED	34%
Other	10%
PROTECTED	14%

Portugal (Retail Only)	
NEVER PROTECTED	48%
NO LONGER PROTECTED	31%
Other	12%
PROTECTED	9%

Switzerland Combined	
NEVER PROTECTED	42%
NO LONGER PROTECTED	29%
Other	9%
PROTECTED	20%

Finland	
NEVER PROTECTED	53%
NO LONGER PROTECTED	27%
Other	4%
PROTECTED	16%

Denmark Combined	
NEVER PROTECTED	62%
NO LONGER PROTECTED	22%
Other	2%
PROTECTED	14%

Czech Combined	
NEVER PROTECTED	76%
NO LONGER PROTECTED	14%
Other	6%
PROTECTED	4%

Norway Combined	
NEVER PROTECTED	47%
NO LONGER PROTECTED	29%
Other	7%
PROTECTED	16%

Ireland (Retail Only)	
NEVER PROTECTED	49%
NO LONGER PROTECTED	31%
Other	3%
PROTECTED	17%

Russia (**Datasource 1.2.)**	
ORIGINAL BRANDED PRODUCTS	21,90%
LICENSED BRANDED PRODUCTS	5,40%
LOCAL GENERICS (BRANDED)	44,80%
UNBRANDED	9%
PATENT NOT APPLICABLE	18%

[1] Standard Units

[2] Combined = retail + hospital pharmacy

Data source 1.3

Market Share 2006

Country	Volume %	Value %
1 Italy	7,2	3,7
2 Portugal	9,7	15,2
3 Austria	12,3	10,7
4 Ireland	12,3	6,9
5 Belgium	12,7	8,7
6 Norway	18,6	9,7
7 Spain	28,6	13,7
8 France	31,1	14,7
9 Switzerland	34,6	16,5
10 Finland	36,3	13,5
11 Sweden	42,9	13,7
12 Turkey	50,7	32,8
13 Netherlands	53,4	23,2
14 Germany	56,4	22,8
15 United Kingdom	57,5	28,0
16 Slovenia	58,1	37,9
17 Denmark	68,8	38,5
18 Romania	71,4	31,0
19 Poland	76,7	60,0
20 Latvia	79,3	38,7
21 Czech republic	60,0	34,0
22 Hungary	44,0	29,0
23 Lithuania/Estonia	77,0	50,0

Sources: 1-20, EGA 2007 Market Review; 21-23, EGA 2006 Annual Conference