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The quality of medicines in Europe

Report
Social, Health and Family Affairs Committee
Rapporteur: Mr Bernard MARQUET, Monaco, Alliance of Liberals and Democrats for Europe

Summary

The counterfeiting of medicines has developed into an industry that kills hundreds of thousands of people a year and can be associated with a form of organised crime.

Counterfeit medicines affect 10% of the world medicines market and the losses are estimated at about 500 billion euros a year.

The consequences of counterfeiting are genuine damage to public health, the economy and society as a whole.

The Assembly also notes that the phenomenon has increased with the sale of medicines through the Internet.

The Assembly therefore believes that it is necessary to make provision for an international legal instrument designed to introduce fresh legislation and establish specific offences and penalties for counterfeiting so that it is no longer considered a breach of trade rules but as a serious criminal offence.

The Assembly also recommends that states establish a comprehensive system for the traceability of medicines and set up, in conjunction with the European Directorate for the Quality of Medicines and Health Care, a training scheme for all those concerned.

A. Draft recommendation

1. The counterfeiting of medicines has developed into an industry that kills hundreds of thousands of people a year.
2. What was once confined to small-scale production is now an activity that can be associated with organised crime.
3. The counterfeiting of medicines is a scourge affecting 10% of the world medicines market, and its growth has been facilitated by globalisation and the expansion of trans-border trade, as well as the ease of use of modern technologies.
4. According to an OECD survey, the resulting losses amount to some 500 billion euros a year, with the sums concerned eluding national taxation systems. Counterfeit medicines therefore generate huge profits for counterfeiters, who are never arrested or prosecuted.
5. Counterfeiting affects not only medicines and generic medicines but also medical devices, cosmetics and veterinary products. It therefore represents a serious threat to the health of individuals and may lead to the failure of treatment, the worsening of diseases and may even sometimes be the cause of death. The Parliamentary Assembly underlines that the emergence of counterfeit medicines undermines the confidence both of individuals and of health professionals.
6. The Assembly notes that parallel trade has been growing rapidly during the last decade. Providing that proper checks, including traceability, are made by distributors, this type of trade maintains consumers' security.
7. The Assembly further notes that counterfeit medicines are beginning to appear in Europe as a result, in particular, of a lack or the inadequacy of regulations on quality control and distribution. Counterfeit medicines circulate illegally, bypass taxation systems and undermine the interests of consumers and of state and private industry budgets.
8. Moreover, the rules on the export of medicines vary from one country to the next, making any international controls or sanctions practically impossible.
9. As noted by the participants at the conference on "Europe against Counterfeit Medicines" held in Moscow on 22 and 23 October 2006, counterfeiting has been tackled mainly from the angle of industrial property rights rather than the protection of the rights of the individual. The participants also regretted the fact that there is no legal instrument on matters relating to crime in the pharmaceutical field.
10. The Assembly notes that this legal vacuum means that appropriate national authorities are either inexistent or weak, and therefore underlines the need to make provision for an international legal instrument establishing specific offences relating to counterfeiting so that counterfeiters can be arrested and prosecuted.
11. The Assembly is also concerned by the growth in sales of medicines over the Internet which could lead to uncontrolled trans-border trade in medical products that could be dangerous to public health and an absence of penalties for counterfeiters.
12. The Assembly therefore underlines the need to regulate Internet sales and establish real international co-ordination, in co-operation with the police, customs authorities, the judiciary and health professionals.
13. In the light of the above, there is an urgent need for states to take measures to protect the safety of patients in response to the increasing spread of counterfeit medicines.

14. The Assembly therefore recommends that the Committee of Ministers of the Council of Europe ask Council of Europe member states, non-member states and the Contracting Parties to the Convention on the Elaboration of a European Pharmacopoeia to make provision for an international legal instrument, in the form of a convention, designed to introduce new legislation including a new offence relating to pharmaceutical crime, to establish specific penalties for counterfeiting and impairing the quality of medicines and lay down rules governing jurisdiction allowing the interests of victims of pharmaceutical crime to be taken into account.

15. The Assembly also calls on Council of Europe member states, non-member states and the Contracting Parties to the Convention on the Elaboration of a European Pharmacopoeia:

15.1. to use the departments within the Organisation to collect and disseminate information;

15.2. to organise public information campaigns on the risks entailed in using counterfeit medicines, to encourage people to use legal distribution channels;

15.3. to promote interagency co-operation between the police, customs authorities, the judiciary, health professionals and other relevant medical bodies;

15.4. to draft legislation on medicines, including provisions prohibiting the manufacture, import and sale of counterfeit medicines, in order to regulate the manufacture and import of medicines and prevent counterfeit medicines from entering pharmaceutical distribution networks;

15.5. to introduce surveillance systems, in liaison with laboratories and distribution networks;

15.6. to establish a comprehensive system for the traceability of medicines, with the aim of producing a fully-fledged register of pharmaceutical products;

15.7. to set up a special system for monitoring and checking the quality of medicines dispatched for humanitarian purposes;

15.8. to set up, in conjunction with the European Directorate for the Quality of Medicines and Health Care, a training scheme for staff and professionals concerned so that they can take appropriate action to deal with crime in the pharmaceutical field;

15.9. to establish a system for checking the identity of online pharmacies.

16. The Assembly asks the Committee of Ministers to recommend to those states which have not already done so:

16.1. to sign and ratify the Convention on the Elaboration of a European Pharmacopoeia;

16.2. to sign and ratify the Convention on Cybercrime.

B Explanatory memorandum by Mr Bernard Marquet, Rapporteur

I. Introduction

1. Counterfeit medicines are responsible for hundreds of thousands of deaths every year. We are witnessing the emergence of a new concept, namely that of pharmaceutical crime, for what was once confined to small-scale production is now an activity that can be associated with organised crime.

2. At the conference in Moscow on 22 and 23 October 2006, the declaration of which is appended to this report, the experts stated that the counterfeiting of medicines was constantly on the rise. They also criticised the legal vacuum in this field and urged the authorities concerned to take rapid action to eradicate this form of crime.

3. First of all, it is important to establish the various factors that can impair the quality of medicines and to draw a clear distinction between generic medicines, European parallel imports that are legal, and counterfeit medicines.

4. By a medicine we mean any substance or compound presented as possessing curative or preventive properties in regard to human or animal diseases or any substance or compound that may be administered to humans or animals in order to establish a medical diagnosis or restore, correct or modify their organic functions. It should be borne in mind that medicines are composed of excipients and active ingredients.

5. A generic medicine is defined as having the same qualitative and quantitative composition in terms of the active ingredient and the same pharmaceutical form as a patented medicine that has passed into the public domain, and must undergo quality tests in order to obtain a product licence. Generic medicines are therefore not counterfeit medicines, as they are subject to the same safety and quality standards as original medicines.

6. Generic medicines are medicines sold under their customary scientific name or the internationally approved name of the active ingredient or ingredients, which must be accompanied by a brand or manufacturer's name.

7. The terms "parallel imports" or "parallel trade" are used in the European context to signify medicines purchased by a wholesaler/wholesale distributor from manufacturers in the European Economic Area and redistributed beyond national frontiers within the EEA without the consent of the intellectual property rights holder. Adaptations and changes to the packaging are authorised by the European Union in order to adapt such medicines to the national context. This means that once a product is on the market, it is perfectly legal to redistribute it to any other country in the European Economic Area, in accordance with the free movement of goods, as stipulated in the Union Treaty.

8. According to WHO, a counterfeit medicine is one that is deliberately and fraudulently mislabelled with respect to identity and/or source. Most such medicines do not meet the requisite quality standards and carry labels showing a false identity and/or origin. It must be stressed that generic products may also be counterfeit.

9. Counterfeit medicines are now a worldwide scourge, which can be said to affect some 10% of the world medicines market, although it is difficult to obtain precise figures. According to certain studies, most of these medicines come from developing countries.

10. The characteristics of counterfeit medicines differ according to whether they come from industrialised or developing countries. In the case of industrialised countries, counterfeit medicines have three main features. The first is the quality of their outward appearance: the packaging is virtually indistinguishable from that of the genuine medicine.

11. The second is the fact that the marketing networks are international. The counterfeiters make use of countries that have little or no industrial property protection and have an efficient industry able to manufacture the raw materials. In addition, the medicines may be packaged in floating laboratories in ports outside the reach of Customs or in clandestine dispensaries. Furthermore, counterfeit medicines may be put on the legal market through wholesale distributors. In 1989, for instance, the United Kingdom was flooded with Zantac which, before it was seized, had travelled through part of Europe before eluding the vigilance of the health authorities. The raw material came from Singapore and Turkey, a Greek chemist had manufactured the copy and the stock had been sold to a Swiss company, which then convinced a Dutch distributor that it was offering a bargain. The Dutch distributor undertook, in good faith, to distribute the medicine in the Netherlands and Britain. The third feature is that counterfeit medicines are extremely profitable. The turnover in counterfeit medicines is reported to amount to €25 billion, which is 25 times more than that of heroin, and also undoubtedly much less of a risk from the standpoint of criminal sanctions for the counterfeiters.

12. In developing countries counterfeit medicines are very different in that they are of poor quality and affect public health. Moreover, in most of these countries, these medicines are to be found both in pharmacies and on market stalls.

13. Counterfeit medicines are difficult to detect because they manage to elude all checks and controls, taking advantage, in particular, of globalisation and the growth of trans-border trade. Furthermore, modern technologies make it easy to produce copies of packaging which are almost totally indistinguishable from the genuine article.

14. Counterfeit medicines are beginning to appear in Europe. This is the result in particular of a lack or deficiency of regulations and quality control, and the growing complexity of the movement of medicines, which makes it difficult to trace goods and operations. Many countries cannot therefore guarantee the safety and effectiveness of imported and locally produced medicines.

15. This is compounded by the fact that in most countries exported medicines are not covered by the same rules and checks as national products because exports most frequently transit through free trade areas.

16. There are other factors which influence the quality of medicines, such as the globalisation of trade, the boom in the sale of medicines via the Internet, restrictions on the distribution of medicines and the frantic search for cheaper products.

17. Finally, reference should be made to the counterfeiting of medical devices, cosmetics and veterinary products that can have an impact on public health. These products do not necessitate the same traceability requirements.

II. Impact of counterfeit medicines

18. The consequences of counterfeiting are genuine damage to public health, the economy and society as a whole.

i. Effects on public health

19. The distribution and sale of counterfeit medicines has very serious implications for health safety in general and the safety of patients in particular, as the fact that such medicines are beyond control means that it is often very difficult to know what they contain, and so their safety and therapeutic value cannot be guaranteed. Counterfeit medicines frequently contain dangerous excipients or excessively low or high doses or even no active ingredients at all or an incorrect active ingredient. The danger to health is largely due to the fact that the consumer cannot assess the risk attached to the product before consuming it.

20. The use of ineffective, poor-quality and harmful medicines may mean that treatment fails, the disease worsens, resistance to the medicines develops and, in some cases, death ensues. Ineffective medicines also have an impact on public health when, for example, antibiotics containing too low a dose are put on the market.

21. For the time being, it is difficult to know what the true impact is, mainly because of the clandestine nature of the problem, but it is noticeable that the increase in counterfeit medicines has led to a drop in patients' confidence in the health care system.

22. The counterfeiting of medicines thus undermines the right to life, enshrined in Article 2 of the European Convention on Human Rights, and is contrary to the spirit of the revised European Social Charter, the signatories to which recognise the right to health protection.

ii. Effects on the economy

23. Counterfeit medicines can generate enormous profits for counterfeiters and are a major target for organised crime. As a result, they place a strain on national health budgets and reduce legal companies' incomes. According to a survey by OECD, the losses amount to some 500 billion euros a year. The counterfeit trade also eludes national taxation systems.

iii. Social effects

24. In countries where the population finds it difficult to obtain medicines, the situation is conducive to the spread of counterfeits and this in turn leads to unequal access to quality health care. 25% of medicines taken in poor countries are counterfeit or non-standard.

25. The medicines which are counterfeited the most are those used to treat potentially life-threatening illnesses such as malaria, tuberculosis and AIDS. In the case of Council of Europe member states, it is mainly lifestyle drugs and symptom-relieving medicines that are concerned.

III. Parallel trade

26. Parallel trade is a growing phenomenon and has increased in particular since the accession of the central and east European countries to the European Union and the opportunities to save on health expenditure, particularly for certain health insurance systems.

27. Parallel distributors purchase and resell original products from manufacturers, which means that, in theory, there is no change in the quality of the product. In actual fact, when checking newly arrived goods parallel importers often detect defective products.

28. Parallel traders must keep a precise record of shipments. Recent studies by the University of Denmark and an older one by the University of York suggest that parallel trade should lead to real financial benefits both for the state and for consumers.

IV. Internet sales

29. Counterfeiters are making increasing use of the Internet to sell their products and evade the numerous safeguards erected by governments and the pharmaceutical industry. Innumerable advertising messages in the form of spam daily clog the Internet.

30. There is very little supervision of Internet sales, particularly where it comes to quality control of medicines. It is also very difficult to co-ordinate internationally since the relevant legislation differs from country to country. For example, certain countries such as Germany authorise Internet sales, so long as they originate from a pharmacist.

31. It needs to be specified that Internet sales and parallel trade are very different concepts. Parallel traders are licensed wholesalers who are stocked by recognised and reliable suppliers. The Internet, in contrast, facilitates the illegal distribution of medicines, counterfeit or otherwise, to consumers. Some of the sites offer to provide medicines without medical prescription while these should not be distributed without it and such practices are not liable to sanctions of any sort. Moreover, supervisory authorities find it hard to oversee Internet sales since it is difficult to establish the physical location of intermediaries.

32. These purchases on Internet increase the risk of bad use, and could induce medical interactions sometimes dangerous to health. Moreover, neither the quality, nor the safety of conservation could be guaranteed.

33. Internet sales therefore represent a serious public health risk and an effective form of regulation is urgently needed.

V. Factors conducive to counterfeiting

34. Counterfeit products are not always manufactured in large establishments, and most counterfeiters work on a small scale, without making a large investment. Pharmaceutical counterfeiting is a very lucrative business because of the low production costs.

35. It must be recognised that at present there is no legal instrument on matters relating to crime in the pharmaceutical field, particularly in connection with the counterfeiting of medicines. This lack of legislation necessarily means that the appropriate national authorities are inexistent or weak, particularly as transactions involve numerous intermediaries who are nationals of different countries and ignore frontiers.

36. One factor conducive to the decline in the quality of medicines is that very often the controls on medicines intended for export are less strict than in the case of medicines intended for the domestic market.

37. An equally important factor is that, when medicines are expensive and there are differences in price between identical products, the customer tends to obtain supplies outside the normal system. Poverty is therefore one of the crucial factors in the production and consumption of products of inferior quality and counterfeits.

VI. Counter-measures

38. As a result of this and because of the lack of any effective pharmaceutical regulations and the increasing globalisation of trade in medicines, we are seeing a proliferation of harmful, ineffective, poor-quality and counterfeit medicines, both on domestic markets and on the international market.

39. In addition, as technologically sophisticated medicines are being introduced increasingly rapidly into import, export and distribution networks, including via the Internet, the safety, quality and effectiveness of counterfeit medicines are giving cause for concern.

40. So far, counterfeiting has been tackled mainly from the angle of industrial property rights, and medicines have been included solely in order to protect those who hold such rights, rather than to protect the rights of the public. The result is that many counterfeit medicines that do not violate property rights continue to circulate on the market, albeit illegally.

41. If the counterfeiting of medicines is to be consistently combated, it would seem necessary to pursue a multidisciplinary approach and make provision for an international legal instrument designed to establish specific offences and penalties for counterfeiting and impairing the quality of medicines. It is first necessary to establish a definition of pharmaceutical offences, so that counterfeiting is no longer considered as a breach of trade rules but as a serious criminal offence. Indeed, for want of deterrent legislation, counterfeiters have no fear of being arrested and prosecuted.

42. Such an instrument would oblige states to co-operate closely to ensure strict control of the quality of pharmaceutical ingredients and would also make it possible to protect people, in particular those in poor health, from the risks incurred from counterfeit medicines. This also means that states must take steps to set up a system to ensure the security of pharmaceutical distribution networks, organise a system for co-operation and the exchange of information among laboratories and arrange for special training schemes for public authorities, wholesalers, manufacturers and Customs officers.

VII. Recommendations

43. In the light of the foregoing, it would seem necessary for states to take steps to protect the safety of patients in response to the growing spread of counterfeit medicines.

44. The Assembly therefore recommends that Council of Europe member states, non-member states and the Contracting Parties to the European Pharmacopoeia take the following measures to combat pharmaceutical crime:

44.1. Organise public information campaigns on the risks entailed in using counterfeit medicines, to encourage people to use legal distribution channels;

44.2. Promote intersectoral co-operation between the police authorities, Customs, the judiciary and health professionals;

44.3. Draft legislation on medicines, including provisions prohibiting the manufacture, import and sale of counterfeit medicines, in order to regulate the manufacture and import of medicines and prevent counterfeits from entering pharmaceutical distribution networks;

44.4. Introduce surveillance systems, in liaison with laboratories and distribution networks;

44.5. Establish a comprehensive system for the traceability of medicines, with the ultimate aim of producing a fully-fledged register of pharmaceutical products;

44.6. Set up a special system for monitoring and checking the quality of medicines dispatched for humanitarian purposes;

44.7. Set up, in conjunction with the European Pharmacopoeia, a training scheme for professionals and personnel concerned so that they can take appropriate action to deal with crime in the pharmaceutical field;

44.8. Establish a system for checking the identity of online pharmacies;

45. The Assembly asks the Committee of Ministers of the Council of Europe to recommend that those states that have not already done so sign and ratify the Partial Agreement on the European Pharmacopoeia.

46. Bearing in mind the foregoing, the Assembly also recommends that the Committee of Ministers ask Council of Europe member states, non-member states and the Contracting Parties to the European Pharmacopoeia to make provision for an international legal instrument, in the form of a convention, designed to introduce a new offence and establish specific offences and penalties in connection with the counterfeiting and impairment of the quality of medicines.

Appendix

International Conference on Europe against Counterfeit Medicines Moscow, Russian Federation, 23-24 October 2006

Moscow Declaration

1. We, the participants of the International Conference, organised within the Programme of the Chairmanship of the Russian Federation in the Committee of Ministers of the Council Europe - the representatives of governmental institutions and agencies of the member states of the Council of Europe and of participating states of the Commonwealth of Independent States, of the Secretariat and the Parliamentary Assembly of the Council of Europe, as well as international and European organisations and institutions, key stakeholders from the essential pharmaceutical sectors, medical professionals, and representatives of professional and civil associations having met in Moscow, Russian Federation, on 23 – 24 October 2006, in order to:

- discuss pressing tasks in the fight against counterfeit medicines in European countries and on an international scale and the legal and organisational means and possibilities of opposing this phenomenon;
- reconfirm that the protection of human beings and their lives and health with all legal means including civil and criminal law shall be at the centre of attention of all member states of the Council of Europe and its future legal instrument in this area – a convention of the Council of Europe;
- bring forward a consensus among the civil society, the state and governmental, as well as private sectors of manufacturers and distributors of medicines with regard to practical measures to be taken with a view to optimising the protection of society and of the economy against the detrimental consequences of counterfeit medicines:
- consider the compensation of patients for damages resulting from counterfeit medication;
- encourage and advance the process of formulating under the aegis of the Council of Europe the appropriate international legal instrument (the Convention) on the co-operation in the field of the fight against counterfeit medicines, the production and distribution of which should be qualified as pharmaceutical crime;
- ensure co-ordination of the activities of the participants of this Conference in consistence with the conclusions of the Conference;

2. Considering that counterfeit medicines:

- represent a serious threat to everybody's health in Council of Europe member states and worldwide, while their production and distribution may constitute a prerequisite of violation of a human right to the maximum feasible degree of physical and mental health and the relevant human rights enshrined in the Universal Declaration of Human Rights and in the European Convention on the Protection of Human Rights and Fundamental Freedoms;
- are not subject to controls of quality, safety and efficacy as set out in the legislation in force in European states;
- are reported in an ever increasing number both in Europe and worldwide, in particular, in view of the trade via the Internet;
- have no internationally recognised harmonised legal definition and are not covered by unified international enforcement practice to fight against them;

- are in the illegal circulation and bypass the state tax system, infringe intellectual property legislation, and consequently harm the interest of consumers and state budgets and the budget of law abiding citizens and companies;
 - undermine the confidence which patients and healthcare professionals should have in safe medicines and other healthcare products;
 - are produced by counterfeiters who are criminals, often well-financed, well-equipped with the most recent technology and often belong to international organised and economic crime networks, which respect and observe neither laws nor state borders;
3. Call on the competent authorities, manufacturers, wholesalers, pharmacists and intergovernmental and non-governmental organisations for close co-operation in order to combat the threats posed by counterfeit medicines;
4. Reaffirm that the member states of the Council of Europe have a responsibility both to their populations and to other member states and to the world to strive for the promotion and respect of their obligations to defeat the counterfeiting of medicines and other pharmaceutical crime;
5. Express our concern with regard to the fact that there is no integrated European instrument, counteracting all aspects of international pharmaceutical crime, including the counterfeiting of medicines and other healthcare products, and encouraging public health protection and safety;
6. Taking into account the above, we are convinced that an international legal instrument – a Convention on combating pharmaceutical crime – should be developed without delay under the aegis of the Council of Europe and adopted, using international practical experience and knowledge in the field of law, economic regulation, public healthcare and the quality control of medicines;
7. Consider it advisable to cover the following issues within the international legal instrument (a convention) to be developed:
- legal definitions of key terms in the field of combating the counterfeiting of medicines and their distribution;
 - prevention of counterfeiting of pharmaceuticals *inter alia* using the measures included in paragraph 9 of the Declaration;
 - a protocol of state actions with regards to identified counterfeit pharmaceuticals and their distribution (confiscation, return to the country of origin and their destruction);
 - recognition that acts of counterfeiting medicines and distribution thereof as well as involvement in such acts are criminal acts and establishment by the participants of the Convention of respective punishments for these crimes, taking due account of their seriousness;
 - co-operation between healthcare authorities and law enforcement agencies of the member states of the Council of Europe;
 - development of mandatory systems of reporting on counterfeit medicines for all the parties to this Convention, *inter alia* via an intersectoral network of Single Points of Contact (SPOCs);
 - the links between such a Convention and other international legal instruments dealing with money laundering and financing of terrorism as well as cyber-crime;

8. Have due respect of the role and accomplishments of the Council of Europe in the field of consumer health protection, formulation of international standards in the field of public healthcare and quality control of medicines; appreciate highly the efforts of the European Directorate of the Quality of Medicines, the Partial Agreement in the Social and Public Health Field and the Council of Europe Directorate General I - Legal Affairs, which is contributing to formulating legal standards and international co-operation in the field of combating crime;

9. Invite all governments of the member states of the Council of Europe to provide the necessary means for the training of governmental officials in the field of combating pharmaceutical crime ensuring close collaboration with healthcare professionals and providers as well as wide dissemination of information to the general public about the threat to life, health and unpredictable consequences of using counterfeit medicines.

Reporting committee: Social, Health and Family Affairs Committee

Reference to committee: Doc. 10492, Reference No. 3070 of 25 April 2005

Draft recommendation unanimously adopted by the Committee on 22 February 2007

Members of the Committee: Mrs Lajla Pernaska (Chairperson), Mrs Christine McCafferty (1st Vice-Chair), Mr Cezar Florin Preda (2nd Vice Chair), **Mr Michael Hancock** (3rd Vice-Chair), Mr Farkhad Akhmedov, Mr Vicenç Alay Ferrer, **Mr Jorodd Asphjell**, Mr Miguel Barceló Pérez, Mr Andris Berzinš, **Mr Jaime Blanco**, Mrs Raisa Bohatyryova, Mrs Monika Brüning, Mrs Sanja Čeković, Mr Igor Chernyshenko, **Mr Dessislav Chukolov**, Mrs Minodora Cliveti, **Mr Imre Czinege**, Mrs Helen D'Amato, Mr Dirk Dees, Mr Stepan Demirchayan, Mr Karl Donabauer, Mr Ioannis Dragassakis, Mr Claude Evin, Mrs Daniela Filipiová, Mr Paul Flynn, Mrs Margrét Frimannsdóttir, Mrs Doris Frommelt, Mr Renato Galeazzi, Mr Jean-Marie Geveaux, Mr Stepan Glävan, Mr Marcel Glesener (alternate: **Mr Jean Huss**), Mrs Claude Greff, Mr Tony Gregory, **Mr Ali Riza Gülçiçek**, Mr Jean-Marie Happart, Mrs Olha Herasym'yuk, Mrs Sinikka Hurskainen, Mr Ali Huseynov, Mr Fazail Ibrahimli, Mr Mustafa Ilicali, Mrs Halide Incekara, Mr Denis Jacquat, Mrs Krinio Kanellopoulou, **Mr Marek Kawa**, Mr András Kelemen, Baroness Knight of Collingtree, Mr Slaven Letica, **Mr Jan Filip Libicki**, Mr Ewald Lindinger, Mr Gadzhy Makhachev, **Mr Bernard Marquet**, Mr Ruzhdi Matoshi, Mr Philippe Monfils, Mr Donato Mosella, Mrs Maia Nadiradzé, **Mrs Miroslava Němcová**, Mrs Carina Ohlsson, Mrs Vera Oskina, Mr Algirdas Palackis, **Mrs Marietta de Pourbaix-Lundin**, Mrs Adoración Quesada, Mr Walter Riester, **Mr Andrea Rigoni**, Mr Ricardo Rodrigues, Mrs Maria de Belém Roseira, Mr Alessandro Rossi, Mrs Marlene Rupprecht, Mr Fidas Sarikas, Mr Walter Schmied, Mr Gianpaolo Silvestri, Mr Hans Kristian Skibby, Mrs Darinka Stantcheva, Mrs Ewa Tomaszewka, Mr Oleg Tulea, Mr Alexander Ulrich, Mr Milan Urbáni, Mrs Ruth-Gaby Vermot-Mangold, Mr Aleksandar Vučić, Mr Victor Yanukovych (alternate: **Mr Ivan Popescu**), Mrs Barbara Žgajner-Tavš, ZZ, ZZ, ZZ.

N.B. The names of the members who took part in the meeting are printed in **bold**

Head of the Secretariat: Mr Géza Mezei

Secretaries to the Committee: Mrs Agnès Nollinger, Mrs Christine Meunier