



WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

**FIXED-DOSE COMBINATIONS FOR HIV/AIDS, TUBERCULOSIS AND  
MALARIA**

**Current status and future challenges from clinical, regulatory, intellectual  
property and production perspectives**  
*Salle A, WHO/HQ, Geneva 15-17 December 2003*

## Annotated agenda

### Monday 15 December

- 09h00-09h30    Opening session
- 09h30-13h00**    *Experiences with Fixed-dose Combinations*  
Objective    This session provides an overview of experiences with the use of FDC products for the treatment of TB, malaria and AIDS. The different papers and presentations highlight the issues related to selection, production, quality assurance, bioavailability and stability. The issues of field research on packaging and co-blistering will provide practical examples of attempts to address this delivery problem
- 09h30-10h00    Fixed-dose combinations for tuberculosis: lessons learned from a clinical, production and regulatory perspective (R. Panchagnula)  
Comments/Feedback  
*Bernard Fourie to comment*
- 10h00-10h30    Fixed-dose combinations for malaria: translating clinical recommendations to product supply (Peter Olumese and Andrea Bosman)  
Comments/Feedback  
*Clive Ondari to comment*
- 10h30-11h00    Discussions
- 11h00-11h30    *Coffee break*
- 11h30-12h00    Fixed-dose combinations for HIV/AIDS: the pros and cons of experiences to date (Sanjay Pujari)  
Comments/Feedback  
*Joep Lange to comment*

- 12h00-12h30 Analysis of the impact of introduction on Fixed-dose combinations on supply management and security when compared with separate dispensing and/or "co-blistering" (Jane Masiga)  
Comments/Feedback  
*Cécile Macé to comment on field experiences with FDCs and co-blistered products*
- 12h30-13h00 Discussion
- 13h00-14h00 *Lunch*
- 14h00-17h15 *Public Health Needs for Fixed-dose Combinations***  
Objective This session reviews the evidence available related to the value of FDC's in improving compliance and outcomes as well as the effect on the emergence of antimicrobial resistance.
- 14h00-14h30 Review of the evidence on better compliance and treatment outcomes with Fixed-dose combinations when compared with separate dispensing and/or "co-blistering" (Jennie Connor)  
Feedback/experience
- 14h30-15h00 Review of the evidence on effect of fixed-dose combinations on the development of clinical resistance when compared with separate dispensing and/or "co-blistering" (Warren Kaplan)  
*David Lee to comment on both papers*
- 15h00-15h30 Discussion
- 15h30-15h45 *Tea break*
- 15h45-16h15 Field research on packaging, co-blistering; and experiences with other combinations (Jane Kengeya Kayondo)  
*David Hoos to comment on the use of co-blistering for the MTCT+ program*
- 16h15-16h45 Comparison of the product cost of Fixed-dose combinations in comparison with separate dispensing and/or "co-blistering" (Robert Bwire)  
Comments/Feedback  
*Yolanda Tayler to comment on cost and FDC procurement issues*  
*Harvey Bale to comment on effect of tariffs and taxes on drug costs*
- 16h45-17h15 Discussion
- 18h00 *Reception/Cocktail*

## **Tuesday 16 December**

- 09h00-13h00 *Public Health Priorities***  
Objective These three presentations in the morning are designed to lay out the issues and experiences relating to the production, procurement, quality assurance and use of ARV FDCs.

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- 09h00-09h30 Preferred fixed-dose combinations of ARVs for first line use in HIV/AIDS (Joseph Perriens/Marco Vitoria)  
Comments/Feedback
- 09h30-09h45 Clinical perspective from the field on dosing flexibility (Joep Lange)
- 09h45-10h00 Clients perspective on Fixed-dose combinations versus dosing flexibility
- 10h00-11h00 Discussion  
*Bernard Pécoul to comment*
- 11h00-11h30 *Coffee break*
- Objective This session will highlight the experiences faced in bringing FDC anti malarians to the stage of them being widely supported and promoted. The process which was used of undertaking clinical trials to demonstrate efficacy and additionality will be presented. The lessons learned about dealing with regulatory hurdles will be highlighted.
- 11h30-12h00 Additional fixed-dose combinations for malaria (Piero Olliaro and Robert Taylor)  
Comments/Feedback  
*Andrea Bosman and Tom Kanyok to comment*
- 12h00-13h00 Discussion
- 13h00-14h00 *Lunch*
- 14h00-17h00 *Intellectual Property Rights and Legal Options***
- Objective This session will address the legal and practical issues around patent barriers. The first paper and discussion will focus on the issues, the definitions and the options. The discussion will allow different perspectives to be expressed. The second part of this session will be an opportunity for members of industry to present the key results of the meeting held the previous Friday in Washington DC.
- 14h00-14h30 Legal options for overcoming patent barriers of fixed-dose combinations (Warren Kaplan)
- 14h30-15h00 Discussion led by Richard Wilder  
*Ellen 't Hoen and Cecilia Oh to comment*  
*Cynthia Cannady (WIPO) to comment*
- 15h00-15h45 Summary of Gates Foundation sponsored meeting on FDCs held in Washington DC December 12<sup>th</sup> 2003 Panel Presentation and Discussion
- 15h45-16h00 *Tea break*
- Objective These two sessions will focus on country experiences around the procurement of ARVs particularly FDC ARVs and also issues around TB FDCs. This will be done from the perspective of the major UN Pharmaceutical supplier and a major NGO responsible for both TB and AIDS treatment programmes.

16h00-16h15	Country level experience (Hanne Bak Pedersen)
16h15-16h30	MSF's experience in procuring ARVs. Lessons from the field (Bernard Pécoul)
16h30-17h00	Discussion

### Wednesday 17 December

**09h00-13h00** *Pharmaceutical Development and Quality Assurance and Regulatory Requirements*

Objective The sessions for the morning will all address the issues around formulation and registration and regulation of FDCs. The first presentation will outline the range of issues to be addressed in planning to produce an FDC product. The next session will report on practical experiences gained in producing FDCs from the perspective of a manufacturer. Issues around prequalification assessments will be presented by a regulator closely involved in this process. Thorny issues around when clinical trials are needed to validate FDCs and which comparators should be used for assessing bio availability will be addressed.

09h00-09h30 Development of Fixed-dose combinations; pharmaceutical considerations (Susan Walters)

09h30-09h50 Product formulation of Fixed-dose combinations; practical experiences (Vinod Arora)

09h50-10h30 Discussion

10h30-11h00 *Coffee break*

11h00-11h30 Assessment Experiences with fixed-dose combinations (ARVs and Tuberculosis) (János Pogány)

11h30-11h50 When are new clinical trials needed? (Leonard Sachs)

11h50-12h10 What comparator products should be used for bioequivalence? (Roger Williams)

12h10-13h00 Discussion  
*Jérôme Barré to comment*

13h00-14h00 *Lunch*

**14h00-17h00** *General Discussions*

Objective The afternoon session will be devoted to synthesizing what has been covered in the meeting, identifying areas of clear agreement, areas of dispute that could be investigated further and areas where further work is needed to clarify the issues. After the tea break a session will be held for WHO staff to agree on conclusions and recommendations for WHO actions.

- 14h00-15h30 Discussion by all participants  
Overview of main observations and recommendations for each of the main subject areas
- 15h30-16h00 *Tea break*
- 16h00-17h00 Conclusions and recommendations for WHO actions  
Note: This final session will be WHO staff members only.  
Identification of next steps (action points, research priorities, etc.) facilitated by Robert Ridley



## List of participants

Mr. Vinod Arora  
Ranbaxy Pharmaceuticals Inc.  
19, Nehru Place  
New Delhi  
India  
+91 11 26452666-72  
+91 11 26002076  
[vinod.arora@ranbaxy.com](mailto:vinod.arora@ranbaxy.com)

Dr Harvey E. Bale, Jr  
Director-General  
International Federation of  
Pharmaceutical  
Manufacturers Associations  
PO Box 758  
1211 Geneva 13  
022 338 32 00  
022 338 32 99  
[admin@ifpma.org](mailto:admin@ifpma.org)

Dr Jérôme Michel Barré  
Head of the Pharmacology and  
Toxicology Unit  
Centre Hospitalier Intercommunal  
Service de Pharmacologie  
40, avenue de Verdun  
94010 Créteil Cedex  
+33 1 45 17 53 80  
+33 1 45 17 53 72  
+33 1 45 17 53 89  
[Jerome.Barre@chicreteil.fr](mailto:Jerome.Barre@chicreteil.fr)

Dr Jaydip Bhaduri  
Lupin Limited  
Medical Director  
159, CST Road  
Kalina, Santacruz (E)  
Mumbai 400 098, India  
+91 22 56931001-10, Ext. 331  
+91 22 26526842 (direct)  
+91 22 26526755  
+91 22 26540484  
[jaydipbhaduri@lupinpharma.com](mailto:jaydipbhaduri@lupinpharma.com)

Dr Nubia Boechat  
Ministry of Health  
Oswaldo Cruz Foundation  
Institute of Drug Technology  
Far-Manguinhos  
Rua Sizenando Nabuco, 100  
21041-250 Manguinhos  
Rio de Janeiro  
Brazil  
+55 21 3977-2454/2455  
+55 21 2290-1297  
[boechat@far.fiocruz.br](mailto:boechat@far.fiocruz.br)

Mr Anthony F. Boni  
USAID/GH/HIDN/HSD  
Pharmaceutical Management Advisor  
Office of Health, Infectious Diseases and  
Nutrition  
Room 3.07-073, 3<sup>rd</sup> floor, RRB  
Washington, DC 20523-3700  
USA  
+1 202 712 4789  
+1 202 216 3702  
[aboni@usaid.gov](mailto:aboni@usaid.gov)

Dr Robert Bwire  
Berkenboog 24  
5386 GC Geffen  
The Netherlands  
+31 735320418  
+31 735320418  
[rbwire@planet.nl](mailto:rbwire@planet.nl)

Ms Cynthia Cannady  
Director  
World Intellectual Property  
Organization  
Intellectual Property Policy and New  
Technologies  
34, chemin des Colombettes  
Geneva  
[cynthia.cannady@wipo.int](mailto:cynthia.cannady@wipo.int)

Mr Andrew Clark  
Director of Medical Affairs  
Infectious Diseases and Immunology,  
Bristol Myers Squibb Company

[celias@path.org](mailto:celias@path.org)

Dr Jennie Connor  
Senior Lecturer, Epidemiology  
Section of Epidemiology and  
Biostatistics  
School of Population Health  
University of Auckland  
Private Bag 92019  
Auckland  
New Zealand  
+64 9 3737599 Ext. 84400  
+64 9 3737494  
[j.connor@auckland.ac.nz](mailto:j.connor@auckland.ac.nz)

Dr Bernard Fourie  
National TB Research Programme of the  
Medical Research Council (MRC)  
Programme Director  
1 Soutpansberg Road  
Private Bag X 385  
0001 Pretoria  
South Africa  
+27 12 325 5970  
[bernard.fourie@mrc.ac.za](mailto:bernard.fourie@mrc.ac.za)

Mr Robert Dintruff  
Abbott International  
Abbott Laboratories  
Dept 06MQ  
Building AP34-3  
Abbott Park, IL 60064-6189  
USA  
+1 847 938 7945  
+1 847 938 8497  
[rob.dintruff@abbott.com](mailto:rob.dintruff@abbott.com)

Ms Isabelle Girault  
Director, HIV/AIDS  
External Relations  
Global Government Affairs & Public  
Policy  
GlaxoSmithKline  
GSK Home CN10  
980 Great West Road  
Brentford  
Middlesex TW8 9GS  
United Kingdom  
+44 20 8047 5488  
+44 20 8047 6957  
[isabelle.s.girault@gsk.com](mailto:isabelle.s.girault@gsk.com)

Mr Jean-Pascal Ducret  
Director  
Sanofi-Synthelabo  
Impact Malaria  
82, avenue Raspail  
94255 Gentilly Cedex  
France  
+33 1 41 24 65 11  
+33 6 86 16 11 82  
+33 1 41 24 61 24  
[Jean-Pascal.Ducret@sanofi-synthelabo.com](mailto:Jean-Pascal.Ducret@sanofi-synthelabo.com)

Mr Michiel de Goeje  
IDA Foundation  
Pharmaceutical Advisor & GMP  
Compliance  
QA Department  
PO Box 37098  
1030 AB Amsterdam  
The Netherlands  
+31 20 4033051  
+31 20 4031854  
[mdgoeje@ida.nl](mailto:mdgoeje@ida.nl)

George Dunstan  
Merck & Co., Inc.  
One Merck Drive  
PO Box 100  
Whitehouse Station, NJ 08889-0100  
USA

Dr Jaideep A Gogtay  
Cipla Ltd  
Mumbai Central  
Mumbai 400 008  
India  
+91 309 5521  
+91 308 2891  
+91 414 9778 (res.)  
+91 412 4359 (res.)  
+91 22 23070013  
+91 22 307 0393  
+91 22 307 0385  
[jgogtay@cipla.com](mailto:jgogtay@cipla.com)

Dr Christopher J. Elias  
President  
Path (Programme for Appropriate  
Technology in Health)  
1455 NW Leary Way  
Seattle, WA 98107  
USA  
+1 206 285 3500  
+1 205 285 6619

Mr William F. Haddad  
Chairman/CEO  
Biogenics, Inc.  
Representing Cipla, Ltd (India)  
120 Manor Road  
Patterson, NY 12563  
USA

+1 845 278 8800

+1 845 878 3046

+1 347 693 3322

+1 845 878 8015

[wfhaddad@aol.com](mailto:wfhaddad@aol.com)

[biogenics@aol.com](mailto:biogenics@aol.com)

Mr Ton Hoek  
General Secretary  
Fédération internationale  
pharmaceutique  
Andries Bickerweg 5  
2517 JP The Hague  
PO Box 84200  
2508 AE The Hague  
The Netherlands  
+31 70 3021870  
+31 70 3021972 (direct)  
+31 620139954  
+31 70 3021999  
[hoek@fip.org](mailto:hoek@fip.org)

Dr David Hoos  
Assistant Professor of Clinical  
Epidemiology  
Mailman School of Public Health  
Columbia University  
722 West 168<sup>th</sup> Street - Room 707  
New York, NY 10032  
USA  
+1 212 342 0464  
+1 212 342 0412  
[dh39@columbia.edu](mailto:dh39@columbia.edu)

Mr Sandeep Juneja  
HIV Project Head  
Ranbaxy Laboratories Limited  
Devika Tower  
6, Nehru Place  
New Delhi - 110019  
India  
+91 11 26002120 (direct)  
+91 11 26452666-72 Extn. 2621  
+91 11 26002121  
[SANDEEP.JUNEJA@ranbaxy.com](mailto:SANDEEP.JUNEJA@ranbaxy.com)

Dr Valérie Lameyre  
Medical Manager  
Impact Malaria  
Sanofi-Synthelabo  
82, avenue Raspail  
94255 Gentilly Cedex  
France

+33 1 41 24 63 64

+33 6 74 44 78 08

+33 1 41 24 61 24

[valerie.lameyre@sanofi-synthelabo.com](mailto:valerie.lameyre@sanofi-synthelabo.com)

Dr Joep M.A. Lange  
Professor of Medicine  
Chief Scientific Adviser  
International Antiviral Therapy  
Evaluation Center (IATEC BV).  
Meibergdreef 99  
1105 AZ Amsterdam  
PO Box 22700  
1100 DE Amsterdam  
The Netherlands  
+31 20 566 75 37 (direct)  
+31 20 566 44 79  
+31 20 691 88 21  
[j.lange@amc.uva.nl](mailto:j.lange@amc.uva.nl)  
[jtongeren@amc.uva.nl](mailto:jtongeren@amc.uva.nl)

Dr David Lee  
Deputy Director  
Technical Strategy and Quality  
Center for Pharmaceutical Management  
Management Sciences for Health, Inc.  
4301 North Fairfax Drive, Suite 400  
Arlington, VA 22203-1627  
USA  
+1 703 524 6575  
+1 703 248 1612 (direct)  
+1 703 524 7898  
[dlee@msh.org](mailto:dlee@msh.org)

Ms Cécile Macé  
Pharmacist  
Médecins sans Frontières  
Access to Essential Medicines  
8, rue Saint-Sabin  
75544 Paris Cedex 11  
France  
+33 1 4021 2758  
+33 6 1404 5697  
+33 1 48066868  
[cmace@paris.msf.org](mailto:cmace@paris.msf.org)  
[cecilemace@hotmail.com](mailto:cecilemace@hotmail.com)

Mr Kevin Mak  
Holleykin  
Chongqing Holley Holding Co. Ltd  
12/F, Guangyu Building  
76 Jianxin North Road  
Jiangbei District  
Chongqing  
China 400020  
+86 23 67755788  
[kmak@china.com](mailto:kmak@china.com)

Dr Lynn Marks  
GlaxoSmithKline  
Philadelphia, PA  
USA  
+1 610 917 5011  
[Lynn.G.Marks@gsk.com](mailto:Lynn.G.Marks@gsk.com)

Ms Jane E.N. Masiga  
Head of Operations  
Mission for Essential Drugs & Supplies  
(MEDS)  
PO Box 78040  
Viwandani  
00507 Nairobi  
Kenya  
+254 20 551633  
+254 20 551642  
+254 20 551653  
+254 734 600310  
+254 722 202106  
+254 20 556632  
+254 20 556635  
[jmasiga@meds.or.ke](mailto:jmasiga@meds.or.ke)  
[sahibu@africaonline.co.ke](mailto:sahibu@africaonline.co.ke)

Dr John B. Morris  
Associate Director, CMC Project  
Global Pharmaceutical Research and  
Development  
Abbott Laboratories  
Dpt. R4R1, Bldg. R13-4  
1401 Sheridan Road  
North Chicago, IL 60064-6290  
USA  
+1 847 938 4996  
+1 847 935 8000  
[john.b.morris@abbott.com](mailto:john.b.morris@abbott.com)

Dr Eric Noehrenberg  
Director  
International Trade and Market Issues  
International Federation of  
Pharmaceutical Manufacturers  
Associations (IFPMA)  
30, rue de St-Jean  
PO Box 758  
1211 Geneva 13  
Switzerland  
+41 22 338 32 00  
+41 22 338 32 99  
[e.noehrenberg@ifpma.org](mailto:e.noehrenberg@ifpma.org)

Dr Ramesh Panchagnula  
National Institute of Pharmaceutical  
Education and Research (NIPER)  
Head of the Department of  
Pharmaceutics  
Sector 67  
S.A.S. Nagar - 160 062  
Punjab  
India  
+91 172 2214 682/685  
+91 9815901875  
+91 172 2214692  
[panchagnula@yahoo.com](mailto:panchagnula@yahoo.com)

Dr Atul K Patel  
Chief: Department of Infectious Diseases  
Sterling Hospital & ID Clinic  
Adit Medical Centre  
Navrangpura  
Ahmedabad-380 009  
Gujarat  
India  
+91 79 644 0816 (clinic)  
+91 79 685 0708 (residence)  
+91 79 644 0816  
[atulpatel@icenet.net](mailto:atulpatel@icenet.net)

Ms Mariclaire T Payawal  
Senior Director  
Global Access Program  
Bristol-Myers Squibb Company  
Corporate Policy  
PO Box 4000  
Princeton, NJ 08543  
USA  
+1 609 252 4469  
+1 609 456 8337  
+1 609 252 7356  
[mariclaire.payawal@bms.com](mailto:mariclaire.payawal@bms.com)

Mr Bernard Pécoul  
Médecins sans frontières  
78, rue de Lausanne  
PO Box 116  
1211 Geneva 21  
Switzerland  
+41 22 849 84 84  
022 849 8488  
[bernard.pecoul@geneva.msf.org](mailto:bernard.pecoul@geneva.msf.org)

Mrs Hanne Bak Pedersen  
UNICEF  
UNICEF Plads  
2100 Copenhagen OE  
Denmark  
+45 35 27 30 60  
+45 35 26 94 21  
[hpedersen@unicef.org](mailto:hpedersen@unicef.org)

Mr Greg Perry  
International Generic Producers  
Alliance (IGPA)  
PO Box 193  
B-1040 Brussels 4  
Belgium  
+32 2 736 8411  
+32 2 736 7438  
[gperry@egagenerics.com](mailto:gperry@egagenerics.com)

Mr Laurence Phillips  
Head of Customer Group HIV-  
Specialist/Virologist  
Boehringer Ingelheim GmbH  
55216 Ingelheim am Rhein  
Germany  
+49 6132 77 2081  
+49 6132 77 3829  
[laurence.phillips@ing.boehringer-  
ingelheim.com](mailto:laurence.phillips@ing.boehringer-<br/>ingelheim.com)

Dr János Pogány  
Consivers Consulting & Translation  
Group  
Sasadi út 140  
H-1112 Budapest  
Hungary  
+361 246 3341  
+361 246 3341  
[pogany@axelero.hu](mailto:pogany@axelero.hu)

Dr Sanjay Pujari  
Director HIV Unit  
Ruby Hall Clinic  
2, Jai Bhagirathi Apts.  
881/B, Sadashiv Peth  
Pune 411030  
India  
+91 9822058985  
[san1@medscape.com](mailto:san1@medscape.com)

Mr Rudy van Puymbroeck  
The World Bank  
Procurement Policy and Service Group,  
OPCS VP  
Global HIV-AIDS Program, HDN  
1818 H Street N.W.  
Room G8-135 MSN G8-802  
Washington  
USA

Dr Françoise Renaud-Théry  
Care & Support Network Adviser,  
SIF/SMI, UNAIDS  
20, avenue Appia  
1211 Geneva 27  
Switzerland  
022 791 36 66  
022 791.41 87  
[theyf@unaids.org](mailto:theyf@unaids.org)

Dr Renee Ridzon  
Senior Program Officer  
Bill & Melinda Gates Foundation  
HIV, TB & Reproductive Health  
1551 Eastlake Avenue  
Seattle, Washington 98102  
USA  
+1 202 709 3383  
+1 202 709 3170  
[reneer@gatesfoundation.org](mailto:reneer@gatesfoundation.org)

Dr Lise Riopel  
Scientific Officer  
Medicines for Malaria Venture  
International Center Cointrin  
Block G, 3<sup>rd</sup> Floor  
Route de Pré-Bois 20  
PO Box 1826  
1215 Geneva 15  
Switzerland  
+41 22 799 4070  
+41 22 799 4061  
[riopell@mmv.org](mailto:riopell@mmv.org)

Dr Reeta Roy  
Divisional Vice President  
Global Citizenship and Policy  
Abbott Laboratories  
Dept. 0383  
Bldg. AP6D  
100 Abbott Park Road  
Abbott Park  
IL 60064-6048  
USA  
+1 847 936 0645  
+1 847 937 9555  
[reeta.roy@abbott.com](mailto:reeta.roy@abbott.com)

Dr Leonard Sacks  
Medical Officer  
U.S. Food and Drug Administration  
Division of Special Pathogens and  
Immunologic Drug Products  
5600 Fishers Lane, HFD 590  
Rockville MD 20857  
USA  
+1 301 827-2336  
+1 301 827 2475  
[Sacksl@CDER.FDA.GOV](mailto:Sacksl@CDER.FDA.GOV)

Dr Himadri Sen  
President  
Pharma Research & Regulatory Affairs  
Lupin Limited  
46A/47A, Nande Village  
Mulshi Taluka  
Pune 411 042  
India  
+91 20 512 6690  
+91 20 512 6451  
+91 20 512 6161/9  
+91 98230 20111  
+91 98230 38402  
[himadrisen@lupinpharma.com](mailto:himadrisen@lupinpharma.com)

Mr Dilip Shah  
Secretary General  
The Indian Pharmaceutical Alliance  
Vision Consulting Group  
201 Darvesh Chambers  
2473 P.D. Hinduja Road  
Khar, Mumbai 400 052  
India  
+91 2226 00 0632  
+91 2226 00 0633  
[dgshah@vision-india.com](mailto:dgshah@vision-india.com)

Mr Chang-Sik Shin  
Director  
R&D Department  
Shin Poong Pharm. Co. Ltd  
772, Yoksam-Dong, Kangnam-Ku  
Seoul  
Korea  
+82 2 553 0241-5  
+82 2 557 4372  
[shinpj@uriel.net](mailto:shinpj@uriel.net)

Dr Anthony So  
Associate Director, Health Equity  
The Rockefeller Foundation  
420 Fifth Avenue  
New York, NY 10018-2702  
USA  
+1 212 852 8340  
+1 212 852 8279  
[aso@rockfound.org](mailto:aso@rockfound.org)

Mr Robert Staley  
Principal Program Associate  
Management Sciences for Health  
Center for Pharmaceutical Management  
Management Sciences for Health, Inc.  
4301 North Fairfax Drive, Suite 400  
Arlington, Virginia 22203  
USA  
+1 703 524 6575  
+1 703 248 1602 (direct)  
+1 703 524 7898  
[rstaley@msh.org](mailto:rstaley@msh.org)

Mr David Stanton  
Global AIDS Coordinator Planning Task  
Force (S/GAC)  
Room 1004, Harry S Truman Building  
U.S. Department of State  
Washington, D.C. 20520  
USA  
+ 1 202 647 1145  
+1 202 647 5792  
[StantonDL@state.gov](mailto:StantonDL@state.gov)

Mr Joe Steele  
Vice President  
Commercial Development  
Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404  
USA  
+1 650 522 5740  
+1 650 504 5375  
+1 650 522 5696  
[jsteele@gilead.com](mailto:jsteele@gilead.com)

Mr Jeffrey Sturchio  
Vice President, External Affairs  
Europe, Middle East & Africa  
Human Health  
Merck & Co., Inc.  
One Merck Drive  
PO Box 100  
Whitehouse Station, NJ 08889-0100  
USA  
+1 908 423 3981  
+1 908 735 1704  
[jeffrey\\_sturchio@merck.com](mailto:jeffrey_sturchio@merck.com)

Ms Yolanda Tayler  
The World Bank  
Procurement Policy and Service Group,  
OPCS VP  
Global HIV-AIDS Program, HDN  
1818 H Street N.W.  
Room G8-135 MSN G8-802  
Washington  
USA  
+1 202 473 0810  
+1 202 522 3317/3235  
[Ytaylor@worldbank.org](mailto:Ytaylor@worldbank.org)

Ms Ellen F.M. t'Hoen  
Médecins sans frontières  
Access to Essential Medicines Campaign  
8, rue Saint-Sabin  
75544 Paris cedex 11  
France  
+33 1 4021 2836  
+33 6 22375871  
+33 1 40212962  
[ellen.t.hoen@paris.msf.org](mailto:ellen.t.hoen@paris.msf.org)

Mrs Trix Janet Tuin  
Pharmacist, Medical Export Group BV  
Manager Quality Assurance  
Papland 16  
PO Box 598  
4200 AN Gorinchem  
The Netherlands  
+31 183 356 130  
+31 183 356 131  
[tuin@meg.nl](mailto:tuin@meg.nl)

Ms Maria Vigneau  
Director, External Relations HIV/AIDS  
F. Hoffmann-La Roche Ltd  
Pharmaceuticals Division  
Pharma International  
Bldg 071/316  
4070 Basel  
Switzerland  
+41 61 688 92 91  
+41 79 506 99 41  
+41 61 688 27 78  
[maria.vigneau@roche.com](mailto:maria.vigneau@roche.com)

Dr Susan Walters  
Consultant  
10 Maria Place  
Lyons - ACT 2606  
Australia  
+61 2 6281 6948  
+61 2 6281 6948  
[susan.walters@netspeed.com.au](mailto:susan.walters@netspeed.com.au)

Mr Witold Wieniawski  
Polish Pharmaceutical Society  
Długa Street 16  
00-283 Warsaw  
Poland  
+48 22 842 09 31  
[wwieniaw@prc.neostrada.pl](mailto:wwieniaw@prc.neostrada.pl)

Mr Richard Wilder  
Consultant IPR  
Sidley, Austin, Brown & Wood  
1501 K Street, N.W.  
Washington, D.C. 20005  
USA  
+1 202 736 8017  
+1 202 736 8711  
[rwilder@sidley.com](mailto:rwilder@sidley.com)

Dr Roger L. Williams  
Executive Vice President and  
Chief Executive Officer  
The United States Pharmacopeia  
12601 Twinbrook Parkway  
Rockville, MD 20852-1790  
USA  
+1 301 816 8300  
+1 301 816 8299  
[rlw@usp.org](mailto:rlw@usp.org)

## WHO secretariat

Dr Jim Yong Kim  
Adviser to the Director-General  
x13910  
[kimj@who.int](mailto:kimj@who.int)

Dr Vladimir K. Lepakhin  
Assistant Director-General  
Health Technology and Pharmaceuticals  
(HTP)  
x14417  
[lepakhinv@who.int](mailto:lepakhinv@who.int)

Dr Jack Chow  
Assistant Director-General  
HIV/AIDS TB and Malaria  
x13800  
[chowj@who.int](mailto:chowj@who.int)

Dr Jonathan D. Quick  
Director  
Essential Drugs and Medicines Policy  
(EDM)  
x 14443/13834  
[quickj@who.int](mailto:quickj@who.int)

Dr H.V. Hogerzeil  
Coordinator  
Policy, Access and Rational Use,  
EDM/PAR  
x13528/14318  
[hogerzeilh@who.int](mailto:hogerzeilh@who.int)

Dr Lembit Rägo  
Coordinator  
Quality Assurance & Safety, EDM/QSM  
x14420/12657  
[ragol@who.int](mailto:ragol@who.int)

Mr Peter Graaff  
Policy, Access and Rational Use,  
EDM/PAR  
x14228  
[graaffp@who.int](mailto:graaffp@who.int)

Mr Rajesh Gupta  
Director General Office  
x13224  
[guptar@who.int](mailto:guptar@who.int)

Dr Warren Kaplan (Rapporteur)  
Policy, Access and Rational Use,  
EDM/PAR  
x12436  
[kaplanw@who.int](mailto:kaplanw@who.int)

Dr Richard Laing (Secretary)  
Policy, Access and Rational Use,  
EDM/PAR  
x14533  
[laingr@who.int](mailto:laingr@who.int)

Ms Cecilia Oh  
Drug Action Programme, EDM/DAP  
x11547  
[ohc@who.int](mailto:ohc@who.int)

Dr Clive Ondari  
Policy, Access and Rational Use,  
EDM/PAR  
x13676/12902  
[ondaric@who.int](mailto:ondaric@who.int)

Mr Adriaan van Zyl  
Quality Assurance & Safety, EDM/QSM  
x13598/13527  
[vanzyla@who.int](mailto:vanzyla@who.int)

Dr Sabine Kopp  
Quality Assurance & Safety, EDM/QSM  
13636/13642  
[kopps@who.int](mailto:kopps@who.int)

Dr Pascale Vanbel  
Quality Assurance & Safety, EDM/QSM  
x13669/13642  
[vanbelp@who.int](mailto:vanbelp@who.int)

Mr Olivier Gross  
Quality Assurance & Safety, EDM/QSM  
x14805  
[grosso@who.int](mailto:grosso@who.int)

Ms Ivana Tasevska  
Quality Assurance & Safety, EDM/QSM  
x13717  
[tasevskai@who.int](mailto:tasevskai@who.int)

## Other WHO sections

Dr Virginia Arnold  
Stop TB  
x12399  
[arnoldv@who.int](mailto:arnoldv@who.int)

Dr Mohammed Akhtar  
Stop TB  
x11895  
[akhtar@who.int](mailto:akhtar@who.int)  
Dr Yevgeny Goryakin  
Stop TB  
x11278  
[goryakiny@who.int](mailto:goryakiny@who.int)

Dr Ernesto Jaramillo  
Stop TB  
x13034/14650  
[jaramilloe@who.int](mailto:jaramilloe@who.int)

Dr Fabienne Jouberton  
Stop TB  
x11881  
[jouberton@who.int](mailto:jouberton@who.int)

Dr Thomas Kanyok (Rapporteur)  
UNDP/World Bank/WHO Special  
Programme for Research and Training  
in Tropical Diseases  
x13684  
[kanyokt@who.int](mailto:kanyokt@who.int)

Dr Kayondo J.F. Kengeya  
UNDP/World Bank/WHO Special  
Programme for Research and Training  
in Tropical Diseases  
x13737  
[kengeyakayondo@who.int](mailto:kengeyakayondo@who.int)

Dr Robert H. Matiru  
Stop TB  
x13971  
[matirur@who.int](mailto:matirur@who.int)

Dr Stéphanie Meredith  
IMD/BLT  
x12070  
Dr Peter Olumese  
Roll Back Malaria  
x14424  
[olumesep@who.int](mailto:olumesep@who.int)

Dr Philip C. Onyebujoh  
UNDP/World Bank/WHO Special  
Programme for Research and Training  
in Tropical Diseases  
x14478  
[onyebujohp@who.in](mailto:onyebujohp@who.in)

Dr Joseph Perriens  
Director, HIV/CRE  
x14456/13477  
[perriensj@who.int](mailto:perriensj@who.int)

Dr Robert G. Ridley  
Coordinator  
Product Research and Development  
x13767/13778  
[ridleyr@who.int](mailto:ridleyr@who.int)

Dr Allan Schapira  
Roll Back Malaria  
x11864/13419  
[schapiraa@who.int](mailto:schapiraa@who.int)

Dr Kenji Tamura  
HIV/CRE  
x11641  
[tamurak@who.int](mailto:tamurak@who.int)

Dr Walter R.J. Taylor  
Product Research and Development,  
TDR/PRD  
x13853  
[taylorw@who.int](mailto:taylorw@who.int)

Dr Paulo Teixeira  
Director, HIV/AIDS  
x14642  
[teixeirap@who.int](mailto:teixeirap@who.int)

Dr Marco Vitoria  
HIV/CRE  
x11949  
[vitoriam@who.int](mailto:vitoriam@who.int)

Dr Hugo Vrakking  
Stop TB  
x14267  
[vrakkingh@who.int](mailto:vrakkingh@who.int)