

# Management Advisory Committee of the Action Programme on Essential Drugs

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## Report of the eleventh meeting

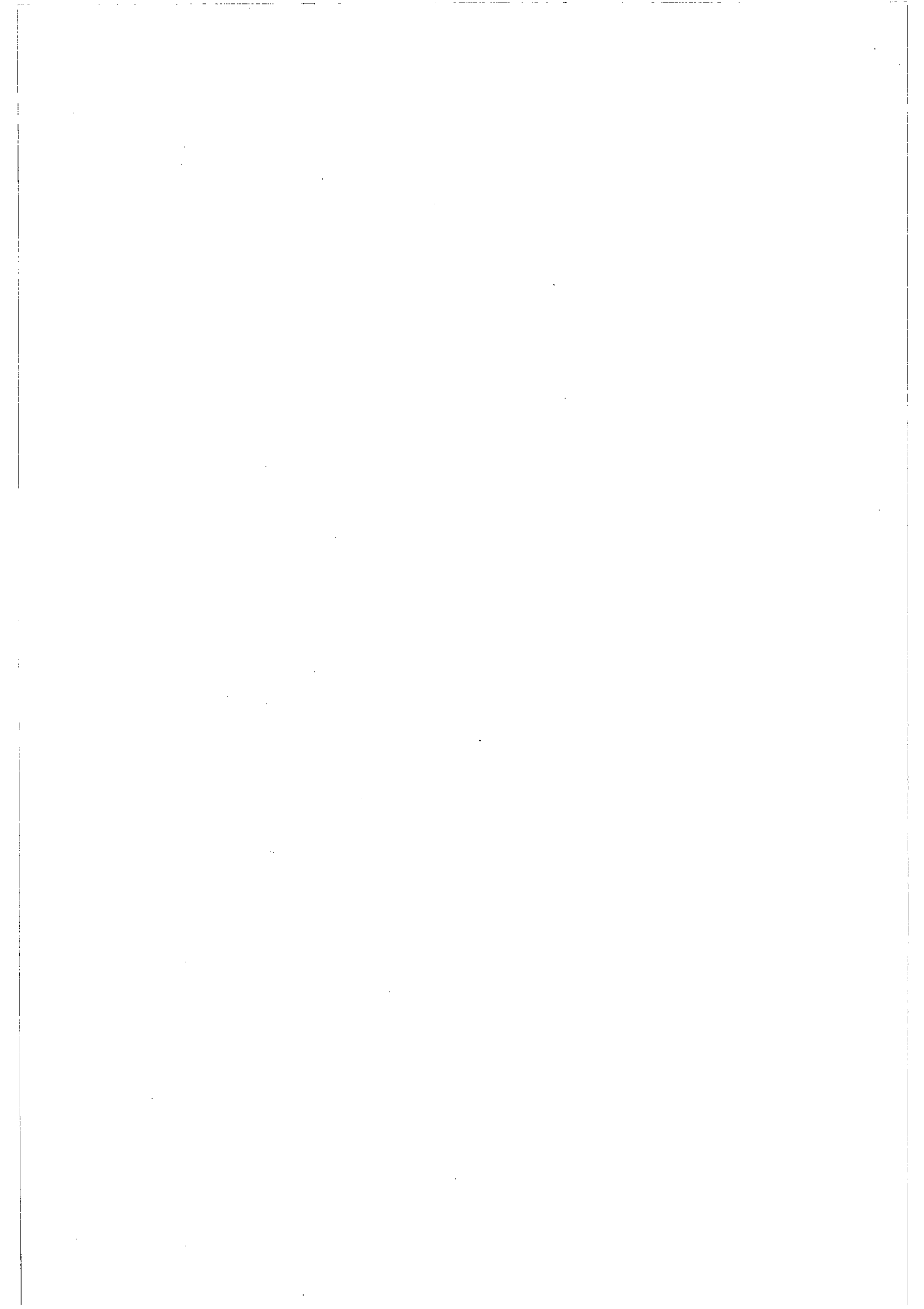
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Geneva  
17-18 March 1999



Department of Essential Drugs and Other Medicines  
Health Technology and Pharmaceuticals  
World Health Organization





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## CONTENTS

<b>CONCLUSIONS AND RECOMMENDATIONS .....</b>	<b>1</b>
MAC Chair .....	1
Report of MAC10 .....	1
EDM activities .....	1
Finances 1998 .....	2
Effective regulation of drugs: what can countries do?.....	2
EDM outlook and budget.....	3
<b>I. OPENING OF THE MEETING .....</b>	<b>4</b>
<b>II. ELECTION OF CHAIRPERSON AND RAPPORTEUR.....</b>	<b>6</b>
<b>III. ADOPTION OF THE AGENDA.....</b>	<b>6</b>
<b>IV. REPORT OF THE TENTH MEETING OF THE MANAGEMENT ADVISORY COMMITTEE.....</b>	<b>6</b>
<b>V. EDM ACTIVITIES 1998.....</b>	<b>6</b>
1998 Report .....	6
One WHO .....	7
Country support.....	7
Prioritization .....	7
Quality and safety of medicines.....	7
Traditional medicine .....	7
Training.....	7
Technical documents .....	8
Collaboration and Access.....	8
Electronic information.....	8
Essential drug lists .....	8
International trade issues .....	8
NGO statements .....	8
Response from the Secretariat.....	9
<b>VI. EDM FINANCES.....</b>	<b>10</b>
Interim financial report of the biennium 1998–1999: detailed financial statements and funding for the biennium 1998–1999 .....	10
Committee action and questions .....	11
Response from the Secretariat.....	12
<b>VII. THEME PAPER: EFFECTIVE REGULATION OF DRUGS: WHAT CAN COUNTRIES DO? .....</b>	<b>12</b>
Strengthening the paper: general comments.....	12
Specific points to be considered/inserted/highlighted .....	12
<b>VIII. EDM OUTLOOK AND BUDGET: 2000–2001 .....</b>	<b>15</b>
Committee action, comments and questions .....	16
Response from the Secretariat.....	16
<b>IX. CLOSURE OF THE EDM SESSION.....</b>	<b>17</b>
<b>ADDENDUM: DISCUSSION OF THE MIP CONCEPT.....</b>	<b>19</b>
Reports from other departments.....	20

**X. CLOSURE OF THE MIP ..... 20**  
**ANNEX 1: LIST OF PARTICIPANTS ..... 21**  
**ANNEX 2: LIST OF DOCUMENTS..... 28**  
**ANNEX 3: AGENDA..... 29**

## **REPORT OF THE ELEVENTH MEETING OF THE MANAGEMENT ADVISORY COMMITTEE OF THE ACTION PROGRAMME ON ESSENTIAL DRUGS**

**Geneva, 17–18 March 1999**

This report of the eleventh Management Advisory Committee of the former Action Programme on Essential Drugs covers the work of the Department of Essential Drugs and Other Medicines. These discussions took place during day one and part of day two of the Meeting of Interested Partners (MIP) of the cluster of Health Technology and Pharmaceuticals. The report is not a summary record. It contains an introduction by the Director-General, the conclusions and recommendations of the Management Advisory Committee and discussion highlights.

The report also contains the discussion and recommendations of a common agenda item on the MIP process and closing session remarks. Separate reports on the agenda items covering the Department of Vaccines and Other Biologicals and the Department of Blood Safety and Clinical Technology will be issued as a transition measure. In future years a fully integrated MIP report will be prepared.

### **CONCLUSIONS AND RECOMMENDATIONS**

#### **MAC Chair**

1. The Committee noted that the current MAC Chair, Dr David Nabarro, was now a WHO staff member and therefore had to be replaced. Ms Julia Cleves, UK, was elected Chair. The Committee decided that as the structure of future MAC/MIP meetings had still to be clarified, a country — the UK — rather than an individual would hold the chair for a further year, pending decisions on the structure and terms of reference of future meetings.

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#### **Report of MAC10**

2. The Committee adopted the report of MAC10, which it considered to be a clear and accurate reflection of the meeting. It welcomed the Secretariat's statement that early access to MIP documents would be facilitated in future through increasing use of the internet.

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#### **EDM activities**

3. The Committee commended the Department on the excellent work accomplished together with the transparent and accessible way in which it had been reported. The Committee recognized that the new cluster structure would facilitate interaction between EDM and the other departments in the cluster whose goals and work were closely related, and within WHO as a whole. It was particularly glad to see that a combined medicines department had been put in place since this would enable closer links between operational and normative work, thus strengthening country support capacity.
4. However, the Committee also observed that the overall relationship between HQ, regional and country offices remained unclear. This created problems for partner organizations and complicated channels of communication. It commended the intention of the Secretariat to create "one" organization, with fully shared objectives and transparent modes of work. It noted that the recent meeting of all WHO representatives was part of this new way of working.

5. The Committee also noted that the work involved in the restructure, combined with the number of posts that were vacant, had led to delay in implementation of some technical activities. It recognized an urgent need to fill these posts.
6. The Committee fully supported the assurance by the Director-General that new ways of working would be underpinned by a commitment to fundamental values based on WHO's responsibility to fight poverty and inequity and to strive for the goals of health for all.
7. The Committee further noted the Director-General's assurance that WHO would redirect funds from the lower to the higher priorities and that access to essential drugs was a priority area. However, the Committee highlighted that access to pharmaceuticals also had to be considered within the context of rational use of drugs, drug quality and drug safety.
8. The Committee was pleased to note that EDM activities were prioritised according to the methodology that been twice discussed and approved in previous meetings. It considered that the cluster as a whole could usefully benefit from the Department's experience in this area.
9. The Committee underlined a number of principles that should define EDM's work; these included the need for work to be "country-driven". Analysis of the underlying reasons for successes or failures was an important contribution to this work.
10. The Committee commended the wide range of technical documentation issued by EDM and the Department's success in disseminating information through a variety of low-cost or no-cost channels and partners, together with the Internet. It urged that materials be made available in as many languages as resources permitted.
11. The Committee recognized the importance of training and the "trickle down" impact of the courses which EDM regularly held with partner institutions. It emphasized that the key issues were institutional capacity building and cross-fertilization to spread knowledge gained.

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### **Finances 1998**

12. The Committee noted the implementation rate of 54% during 1998, which indicated that execution of the biennium budget was on target.
13. The Committee further noted that an additional US\$5.3 million of unspecified contributions would be needed to fund the remaining part of the 1998-1999 budget.
14. The Committee approved the interim financial report of the biennium 1998-1999.

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### **Effective regulation of drugs: what can countries do?**

15. The Committee considered the theme paper to be an excellent technical contribution to this area. It noted that the paper was a starting point to stimulate discussion and thinking, and with this perspective made a number of recommendations to strengthen the paper with a particular focus on increasing its value as a practical tool for countries.
16. The Committee also highlighted WHO's important role in supporting effective drug regulation. Activities should include: advocacy; information sharing; analysis of effective

strategies at different levels of development; development of a step-by-step approach that countries can use and build on; technical support; and capacity building.

### **EDM outlook and budget**

17. The Committee emphasized that extrabudgetary contributions were critical to WHO's operational and normative work in the pharmaceutical sector and called for continued support of this high priority area.
18. The Committee noted that while a strategic plan and approach would be developed by the end of the year for two biennia (2000–2003) a detailed budget would be developed for one biennium (2000–2001). This would present a core budget and unfunded priorities. The proposed budget of US\$28.8 million for the 2001–2002 biennium would be based on the 1997 WHO Essential Drugs Strategy and on constitutional and other mandates of the Department and WHO. EDM would build on and extend partnerships and collaborative arrangements in programme implementation.
19. The Committee further noted that the regular budget allocation to EDM would be “ring fenced” to cover core management and normative work, particularly that of the Quality and Safety of Medicines team.
20. The Committee welcomed clarification from the Secretariat that guidelines on collaboration between WHO and the private sector were under final review. It highlighted the urgent need for such guidelines to avoid conflict of interest.

## I. OPENING OF THE MEETING

21. The eleventh meeting of the Management Advisory Committee (MAC) of the former WHO Action Programme on Essential Drugs (DAP), now part of the Department of Essential Drugs and Other Medicines (EDM), took place in Geneva on 17 and 18 March 1999.<sup>1</sup> The meeting was held within the context of the first Meeting of Interested Partners of the Health Technology and Pharmaceuticals Cluster. The meeting was attended by representatives of Member States, UN agencies, nongovernmental organizations and the private sector. The participants are listed in Annex 1 and the documents prepared for the meeting in Annex 2.
22. Dr Michael Scholtz, Executive Director of the cluster, in a preliminary briefing, described how Health Technology and Pharmaceuticals was created by merging previous programmes and divisions into three departments: Essential Drugs and Other Medicines, Blood Safety and Clinical Technology, and Vaccines and Other Biologicals. Its mission was: "to maintain health, and reduce morbidity and mortality, through access to and optimal use of available and new health technology".
23. Dr Scholtz outlined plans for preventive and curative interventions to contribute to health sector development. The cluster would help in identifying needs, policy setting and capacity building. It would work to develop delivery systems, such as supply mechanisms and financing and delivery strategies. There would be a totally integrated approach with many cross-cluster activities, and specific action plans that would also be shared with agencies outside WHO.
24. The Executive Director described the components of Health Technology and Pharmaceuticals' budget for 1999. Many budgetary and personnel activities would be dealt with at cluster level by the new Management Support Unit, facilitating a speedier response in these areas. The aim throughout WHO was to reduce administration costs and increase efficiency through greater harmonization.
25. Dr Gro Harlem Brundtland, Director-General of WHO, then formally opened the meeting and welcomed participants. She confirmed that such meetings would continue, as they facilitated the type of dialogue and networking that were crucial for the Organization's success.
26. Referring to key aspects of WHO's change process, Dr Brundtland affirmed the Organization's fundamental responsibility to fight poverty and inequity, and to strive for the goals of health for all. This fully applied to the Organization's approach to drug and vaccination policies. WHO must have the independence and courage to speak out for the disadvantaged, to argue against unethical practice and to advocate the cost-effective use of resources. The Organization must be seen as a source of high-quality, evidence-based advice and a broker for better health, strengthening the technical and financial power of the health sector in Member States.
27. WHO had a new, more unified and strategic approach to working for and with countries — responding to their specific development needs, and working with the community to mobilize knowledge and experience. The Organization would become more focused in helping to obtain better and more equitable health outcomes; more effective in supporting health sector development; and more innovative in creating influential partnerships.

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<sup>1</sup> The Essential Drugs and Other Medicines Department (EDM) comprises the former Action Programme on Essential Drugs (DAP) and most components of the Division of Drug Management and Policies (DMP). The Department is situated within the Health Technology and Pharmaceuticals cluster.

28. Recent management changes, including the introduction of the cluster concept and the amalgamation of programmes, would help to strengthen activities and impact. The Department of Essential Drugs and Other Medicines was one good example. By combining the previous Action Programme on Essential Drugs and most components of the Division of Drug Management and Policies, it brought together WHO's operational and normative work in the pharmaceuticals field. During the change process significant progress had still been made in technical areas, such as the consensus reached on the Revised Drug Strategy in October 1998.
29. Among the major global health problems facing WHO were lack of essential drugs and vaccines, irrational use of drugs, and poor quality. Yet essential drugs and vaccines were one of the most cost-effective elements in modern health care, with an enormous potential health impact. Immunization, for example, helped avoid over five million deaths in 1998. The Health Technology and Pharmaceuticals cluster was taking the lead in addressing three priority issues for WHO: eradication of polio, blood transfusion safety, and access to essential drugs.
30. The cluster was successfully liaising with others in WHO, such as the Roll Back Malaria Project and the Tobacco Free Initiative. New approaches to partnership included the roundtable process, which had started with meetings with public interest NGOs, the research-based pharmaceutical industry and the generics industry. All three roundtables involved a constructive exchange of views, which should lead to more effective future collaboration. Another successful collaborative initiative was a technical seminar on the pharmaceutical sector for World Bank and UNICEF staff, organized by Essential Drugs and Other Medicines with input from Vaccines and Other Biologicals. This would now be held annually.
31. WHO was also reaching out to link health issues with other policy areas, such as international trade agreements. Drugs and other health technology could not solely be treated as standard commodities. First, because they had great social value and also because those who consume and pay for them are not in a position to assess, try and choose from among the available technologies. Governments needed to install appropriate mechanisms to coordinate their action in the health and trade areas, to ensure that public health concerns were taken into account and the weaker part of society was protected. There would be greater collaboration between WHO and the World Trade Organization to increase understanding of issues related to world trade and health.
32. Dr Brundtland concluded by emphasizing her commitment to making WHO more focused in its work, through better coordination and clear priority setting. The Organization would redirect funds from the lower to the higher priorities, and from administrative to technical areas. It would work to develop new strategies for addressing the problems of access to drugs and vaccines. WHO would cooperate with all interested partners — governments, UN agencies, the private sector, NGOs and others — to find innovative approaches to bring prices down, to increase financial resources, and to improve the supply, selection and use of drugs, vaccines and other health technologies.
33. WHO counted on participants at the meeting to share experience and to guide the Organization in programme planning, and the Director-General thanked them for their sustained support.

## II. ELECTION OF CHAIRPERSON AND RAPPORTEUR

34. A new MAC chairperson was needed because the incumbent, Dr David Nabarro, UK, had joined the WHO staff. Ms Julia Cleves, UK, was elected as replacement chair. In a subsequent discussion on the second day, the Committee decided that the UK would hold the chair for a further year, pending decisions on the structure and terms of reference of future meetings.
35. Dr Conrado A. Gomez Velez, Colombia, was elected Rapporteur.
36. Dr Jonathan D. Quick, Director EDM, was Secretary of the meeting.
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## III. ADOPTION OF THE AGENDA

37. The Committee reviewed the draft agenda and adopted it without change. The agenda is included as Annex 3.
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## IV. REPORT OF THE TENTH MEETING OF THE MANAGEMENT ADVISORY COMMITTEE

38. The Committee adopted the report, commending its clarity and accuracy. Responding to one participant's query concerning delays in receipt of documents, the Secretariat explained that every effort was made to send out documentation well in advance. However, issues beyond the control of WHO, such as postal delays and non-dissemination of documents within ministries, sometimes led to participants having an unduly short time in which to review material. The Department hoped to minimize such inconvenience in the future by making MAC/MIP documents available on the Internet.
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## V. EDM ACTIVITIES 1998

39. The Director EDM, together with other Department staff members presented the Interim Report of the Biennium (WHO/HTP/EDM/MAC(11)/99.4) of the Action Programme on Essential Drugs, and activities of the broader department. Dr Enrique Fefer, of the WHO Regional Office for the Americas, provided a regional perspective and explained the complementarity and mutual reinforcement of HQ regional and country planning and activities. Dr Ranjit Chaudhury presented the programme on rational use of drugs in India. This was a unique example of WHO/EDM, state and NGO collaboration, which had started in Delhi and had now spread to 13 states covering a population of 580 million. Acting Team Coordinators of the Drug Action Programme; Policy, Access and Rational Use; Quality and Safety of Medicines; and Traditional Medicine presented an overview of activities of the unified Department and highlighted how this integration was strengthening normative and operational work.

### 1998 Report

40. The Committee commended the Programme on an excellent report and "down to earth" presentations. It noted the wide range of activities in priority areas that had been carried out despite the additional work necessarily involved in administrative and institutional change.

## **One WHO**

41. The Committee was pleased to note that the steadily increasing collaboration between the former DMP and DAP was now institutionalized through the programmes' integration into a common department. It was critically important that WHO should speak with one voice in the pharmaceutical area. One member commented that its embassy staff at the country level had stressed the need for greater clarity concerning roles and responsibilities at the different levels of the WHO structure: HQ, regional office, and office of the country representative.

## **Country support**

42. The Committee commended the reaffirmation in Dr Brundtland's speech of WHO's responsibilities and values, including the need to place greater emphasis on the needs of Member States that WHO is there to serve, and to fight poverty and inequity. The changes in WHO were positive. It was important that WHO should prioritize operational work because without impact at country level it had not done its work. However, political will at country level was essential and without this activities should not start. Recipient countries should be in the "driver's seat". Sometimes projects seemed overly ambitious and there were delays in execution, which was not to say that the fault necessarily lay with WHO. The real test was that activities and strategies should work at the country level, but problems clearly remained in implementing country-level activities and strategies. It would be interesting to know whether certain activities were more successful in some countries than others and, if so, why. It would also be helpful to analyse the difficult cases and identify connections. There were also still problems of interagency coordination.
43. The Committee asked for clarification about the extent to which activities were adapted to the local environment. Development agencies in general were facing problems with former strategic models. One particularly severe problem related to procurement issues, whose patterns often reflected donor pressures.

## **Prioritization**

44. The Committee suggested that the whole cluster could usefully share EDM's extensive experience in developing and using criteria to prioritize activities. The MAC had encouraged and contributed to this work, which was built on a sound basis of consultation. The key issues were flexibility in order to be able to respond to the needs of countries, transparency, responsibility and accountability.

## **Quality and safety of medicines**

45. The Committee echoed the importance of EDM's normative work. It enquired what progress had been made on the certification scheme for starting materials.

## **Traditional medicine**

46. The Committee asked for further information about WHO's commitment to traditional medicine.

## **Training**

47. The Committee expressed appreciation of the "trickle down" effect resulting from training activities of the Department — exemplified in the presentation from India — and considered this to be a useful model. It emphasized that the key issue was institutional capacity

building, not just that of individuals. Cross fertilization was needed to spread knowledge gained. The Committee also noted the success of EDM in stimulating subregional work, for example in Africa and Latin America; joining forces had brought added value to problem-solving and capacity building.

#### **Technical documents**

48. The Committee commented on the excellent and extensive documentation produced and urged that wherever possible it should be translated into additional languages.

#### **Collaboration and access**

49. The Committee welcomed the evident collaboration with other areas. The links with health systems development were very important, as was the need to go beyond the role of the ministry of health. Access to pharmaceuticals also needed to be seen in the context of quality of care, such as the rational use of drugs, respect for patients, and gender considerations. Privatization had grown rapidly. In many countries consumers bypassed the formal health care system and turned directly to drug vendors. Prescription drugs were frequently sold over the counter. More focused training in good pharmacy practice was needed.

#### **Electronic information**

50. The Committee commented on the growing availability and useful role of electronic sources of drug information, e.g. with respect to drug safety and counterfeits. On-line data were particularly helpful to Member States, which sometimes needed information urgently. Many professionals and students now had access to Internet. Transparency was needed. It was sometimes impossible for the drug regulatory authority in one Member State to get information about why a product had been withdrawn in another country.

#### **Essential drug lists**

51. The Committee emphasized that each country needed its own national essential drug list and that WHO should support work on such lists.

#### **International trade issues**

52. The Committee enquired what role WHO would play in international trade regulation related to pharmaceuticals. One committee member mentioned strong political and economic pressures placed on his country with respect to the parallel import of drugs.

#### **NGO statements**

##### **International Federation of Pharmaceutical Manufacturers Associations**

53. The IFPMA highlighted its concern about the volume of substandard and counterfeit pharmaceuticals on the market. In two studies in Asia one in 10 drugs dispensed was counterfeit. The industry had established a pharmaceuticals security institute to help combat the problem and hoped to continue its collaboration with WHO in this area.

### **Consumers International and Health Action International**

54. CI and HAI expressed their appreciation that WHO was reaching out to strengthen collaboration with civil society. The recent roundtable between WHO and public interest NGOs in the pharmaceutical sector had been a welcome and fruitful start to the process. However, this reaching out process included new corporate sponsorships. What progress had been made in developing guidelines to preclude conflict of interest in such partnerships? EDM had a great deal of knowledge to offer other departments regarding interaction with the pharmaceutical industry.

### **World Self-medication Industry**

55. WSMI emphasized that a medicine was a product plus appropriate information. To be defined as "appropriate" information must be usable, i.e. understood by its users and contributing to rational use. WSMI was currently working with an international group to develop principles of good information, including labels. There was evidence that many prescription drugs could be safely reclassified as OTC. In such cases they would automatically come with the required information for the user.

### **Response from the Secretariat**

56. The Committee was informed that the issue of collaboration between the three levels of WHO was being addressed. For the first time all the WHO country representatives had attended a meeting at HQ to discuss constraints on communication and how to work together effectively. Common objectives and budgets were being identified. A common agenda would help to create political will. WHO was committed to work with a range of partners, and not just with ministries of health.
57. With respect to health sector development the Department was participating in a cabinet project focusing on this area. EDM looked to the Health Systems cluster for collaboration and guidance. The Department was also collaborating with many other internal and external partners, including Roll Back Malaria, the Global Programme on AIDs, other UN agencies, NGOs, professional bodies and collaborating centres. The roundtable process was institutionalizing some of this external collaboration. And, of course, internally, integrated coordination took place regularly at the cabinet level.
58. EDM hoped to strengthen country support implementation. WHO recognized that if changes did not occur on the ground, work at central levels would have no impact. From a purely reporting viewpoint, money could always be spent to create high implementation percentages. However, WHO did not move faster than countries wished to move; it adjusted its pace to national absorption capacity and long-term development needs. Even the most realistic plans might need to be adjusted according to circumstances and new developments. Country support was tailored to specific needs, an example being essential drug lists, which were different in each country according to needs and resources.
59. EDM was working on access issues, examining their magnitude, their causes, evidence for interventions and what WHO specifically could do. It is proposed to have a meeting in 2000 when all these data could be integrated.
60. With reference to prioritization criteria, these existed at two levels. In each region there were programmes of support funded from the regular budget. At the HQ level, EDM had identified criteria for extrabudgetary-funded programmes: these include severity of need in the pharmaceutical sector; country category (least developed); chance of success (political

- will); demonstration value; and opportune timing. A formal evaluation would be made at the end of the biennium. With the resources available (human and financial) the Department had to set priorities and in document WHO/HTP/EDM/MAC(11)/99.7 unfunded priorities were described. It was simply not possible to do everything with the resources available. However, the rational use of drugs was a priority.
61. EDM had recently put relatively more resources into regional networking, collaborative centres and programmes.
62. The Department recognized the importance of translations in widening access to technical information and training materials. It had been successful in producing more translations of materials in the past year through a variety of strategies, which include authorizing commercial publications, and supporting low-cost local translations and editions by public interest NGOs. The *Guide to Good Prescribing*, now available in 15 different languages and editions, exemplified this approach. EDM hoped to continue this positive trend.
63. There was a strong association between the rational use of drugs and drug availability. Stock depletion led to irrational use. EDM would be placing more focus on procurement issues, particularly once the previously frozen post dealing with this area had been filled, which would be in August 1999.
64. Discussions had been held on the extension of the certification scheme to cover starting materials several months ago and it was agreed that they would build on good manufacturing practices. This work was currently on hold because only a very few countries inspected facilities where starting materials were manufactured. Some European Union work was also taking place in this area and this would be closely observed. Work was also taking place on a model certificate of analysis.
65. There was an increased focus on pharmacy practice reflected in recent reports on the role of the pharmacists, and two regional meetings on skills-based curriculum revision had been held in Africa and the Middle East with heads of the main schools of pharmacy. WHO was collaborating with the International Pharmaceutical Federation.
66. With reference to traditional medicine, the Department would be looking at priorities and would also include the regional advisers in this process. Some Regional Offices had strong programmes in this area.
67. (Due to lack of time questions concerning trade and pharmaceuticals were not addressed. However, the Committee should note that the Department is pursuing a programme of work in this area to support Member States. This work is consistent with the Director-General's statement at the October 1998 Ad Hoc Working Group on the Revised Drug Strategy that "WHO must ensure that health concerns are weighed appropriately when trade and health intersect. When trade agreements affect health, WHO must be involved from the beginning".)
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## VI. EDM FINANCES

### **Interim financial report of the biennium 1998-1999: detailed financial statements and funding for the biennium 1998-1999**

68. The Committee considered the Programme's interim financial report (WHO/HTP/EDM/MAC(11)/99.5). The report presented financial information on the

implementation of the 1998–1999 budget (US\$22 million), as approved at the tenth Management Advisory Committee meeting in March 1998 (Programme Plan and Budget for 1998–1999, DAP/MAC(10)/98.9). The Committee was reminded that policy and technical development represented 28% of this approved budget, country programme development 60%, and programme management 12%.

69. Expenditures (implementation) incurred during the first half of the biennium amounted to US\$11.9 million, representing an overall financial implementation rate of 54%. This rate indicated that execution of the budget was on target.
70. Expenditures for policy and technical development amounted to US\$2.4 million (39% implementation rate). This low implementation rate reflected the fact that some coordinators' posts were vacant, which had delayed execution of some projects.
71. Expenditures for country programme development amounted to US\$7.4 million (57% implementation rate).
72. Expenditures for programme management were US\$2 million (74% implementation rate). This high implementation rate was due primarily to the fact that staff costs were obligated in January 1998 for the whole of the biennium.
73. An analysis of the biennium budget by category of funds was presented. Expenditures against unspecified contributions amounted to US\$6.1 million (budgeted amount US\$12.7 million; 48% implementation rate) whilst those against specified contributions totalled US\$4.9 million (budgeted amount US\$7.4 million; 65% implementation rate). Expenditures against WHO regular budget allocation amounted to US\$897,000 (budgeted allocation US\$1.9 million; 47% implementation rate).
74. The summary interim financial statement for 1998–1999 was analysed. The opening balance at 1 January 1998 was US\$12.8 million, whilst the income (both voluntary contributions and WHO regular budget allocation) amounted to US\$9.5 million in 1999. A total of US\$22.3 million was therefore available for execution of the DAP 1998–1999 budget. Expenditures amounted to US\$11.9 million in 1998, leaving a closing balance at 31 December 1998 of US\$10.4 million. This balance was needed to continue implementation of the approved budget, and ensure that the Department had an adequate carry-over at the end of 1999 to start implementing the 2000–2001 plan.
75. An analysis was presented of the income required during 1999 to ensure full implementation of the approved 1998–1999 budget. The 1998 budgeted income was on target (US\$4.3 million in unspecified contributions, US\$3.8 million specified contributions; and US\$1.4 million WHO regular budget contribution, totalling US\$9.5 million). This sum represented 53% of the total budgeted income (US\$17.9 million) for the biennium. The attention of the Committee was drawn to the fact that at 15 February 1999, unspecified pledges recorded for this year amounted to US\$974,265. The Department would thus need an additional US\$5.3 million in unspecified contributions to fund the remaining part of its 1998–1999 budget.

#### **Committee action and questions**

76. The Committee requested clarification on whether the balance remaining unobligated on 1 January 1999 (US\$10.4 million) took into account unliquidated obligations (financial commitments) from 1998.

77. The Committee enquired whether unspecified contributions received in 1998 totalled an amount lower than expected and budgeted.
78. The Committee adopted the interim financial report.

#### **Response from the Secretariat**

79. Prior years' commitments were deducted from the unobligated balance on 1 January 1999. This balance therefore represented funds available for obligation and programme implementation in 1999.
80. The approved budget for 1998–1999 against unspecified contributions amounted to US\$9.6 million. As US\$4.3 million had been received in 1998, US\$5.3 million was needed in 1999 to allow full implementation of the approved budget against unspecified contributions. As at 15 February 1999, WHO had recorded firm pledges for 1999 for a total of US\$974,265. It was therefore hoped that US\$4.3 million would soon be either pledged or contributed.

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### **VII. THEME PAPER: EFFECTIVE REGULATION OF DRUGS: WHAT CAN COUNTRIES DO?**

81. The Secretariat introduced the theme paper (WHO/HTP/EDM/MAC(11)/99.6), a topic chosen by the 1998 MAC meeting. Participants then split into three working groups to discuss the paper in detail and to identify what WHO can do. Working group reports are summarized below.

#### **Strengthening the paper: general comments**

82. Include step-by-step advice on building regulatory capacity and cover what are the most important questions countries need to ask if starting from zero.
83. Include advice such as “steal good ideas”; “adopt/adapt” and “don’t reinvent”; “learn from failures”; “be inspired by successes”. Within the approach the document should propose: the ICH guidelines process; seek help from successful “compatible” DRAs; consider arrangements to “adopt/be adopted”; fellowships/training at DRAs; access assessment/decisions of other DRAs; promote “south-south” collaboration.
84. In general, the document provides a “recipe for a perfect situation”; it needs to be more pragmatic about the realities facing developing countries.

#### **Specific points to be considered/inserted/highlighted**

85. Page 9 is incomplete and needs to cover OTC products and self-medication.
86. Figure 1 covers at the same time too much and too little. It is not very clear, and gives no indication of priorities and mention of partners.
87. Chapter 2
  - There is a need for quality products AND quality use.
  - The decision-maker in the case of prescription drugs is not the end-user or payer.

- Drug regulation is beneficial to all involved in the pharmaceutical sector: producers, wholesalers, dispensers, health professionals and the users.
  - Add “manufacturing and distribution” to “storage”.
  - Distinguish between independent drug information and promotion.
88. Chapter 3
- Liberalization and opening up the economy lead to a need for more regulation instead of deregulation.
89. Chapter 4.1
- Distinguish between independent information and promotion.
  - “Agencies” should be “Regulatory Authorities”.
  - Include discussion of self-assessment.
  - Cover who should be responsible for assessment.
90. Drug regulation financing
- Drug regulation is a state function: it cannot be privatized and it should be autonomous.
  - Consider in the context of health reform.
  - Fees are an appropriate funding mechanism but:
    - a regulatory agency should not be totally dependent on fees;
    - should support the regulatory process but should not be transferred to the government;
    - should not be a barrier to introduction of drugs to the market.
  - There should be a differential fee structure for essential vs. non-essential drugs.
  - Drug regulation should be separated from drug procurement.
91. Transparency and conflict of interest
- Involve consumers and public interest groups through participation in “shaping” public policy and drug regulation; control of drug promotion; some post-marketing activities.
  - Limited participation in case-by-case drug approval — could involve outside expert advisory groups with consumer participation; however, confidentiality of key information, such as on product formulation, would need to be maintained.
  - An appeals process, e.g. ombudsperson, is needed.

- A system of accountability of the regulator is required, such as monitoring and evaluation of the regulator or an external audit.

92. What WHO can do

- Needs to point out that WHO is not a supranational authority or a policeman.
- Give drug regulation and quality a high profile/priority and address the benefits to the whole sector (health professionals, industry), not just public health.
- Promote the development of national drug policies and implementation strategies as a package.
- Undertake advocacy to secure commitment of politicians to establishing an appropriate regulatory framework.
- Undertake research on “evidence-based regulation” at country level to find out what works and what does not.
- Distribute information and support/improve information networks.
- Recognize what is possible and what other countries have done.
- Seek simple techniques for drug testing.
- Assist countries in determining what they need within the context of their overall health strategies and their regulatory and resource capacity.
- Develop better indicators for assessing country situations focusing on: DRA capacity; implications/risk for patients; administrative setting.
- Develop a simple step-by-step approach.
- Describe options and their implications for quality, safety, efficacy, access and local production, and what consequences for users.
- Build capacity and know-how.
- Document good/bad examples.

93. The Committee commended the clear thinking and structure of the paper. It contained a good framework that should be made widely available. Participants had really appreciated the opportunity to work in groups and to discuss in some detail the important issues raised by the paper. There had been a general consensus that the state needed to be engaged not only in regulatory issues of quality and safety but also in resolving issues concerning market failure, imbalance of information and inequitable access.

94. The Secretariat thanked participants for the very useful input. The theme paper was not an end point but a starting point. Its intent had been to stimulate discussion and new ideas, not to give solutions. Solutions would vary according to different country situations.

95. EDM had a multi-country working group which was using a standard format to obtain evidence on success and failure. Development of a "how-to" manual based on this work was planned. However, this would not be a "cook book", giving standard solutions, but rather an ideas book presenting different options. The subject would be further discussed at the ICDRA in April 1999. The idea behind the framework diagram in figure 1 was to help people who were new to the terminology and whole concept of drug regulation. The diagram would be improved.
96. Advocacy was certainly needed. Many countries turned to WHO to request support for a quality assurance laboratory, but of course, that was only one piece of a complex puzzle.
97. South-south collaboration had been promoted in Africa, Latin America and Asia. One key strategy was to bring people together to pool resources and knowledge.

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#### **VIII. EDM OUTLOOK AND BUDGET: 2000-2001**

98. The Director EDM and the budget officer from the HTP Management Support Unit presented the outlook and budget for 2000-2001.
99. The total combined budget of DAP, DMP and TRM had amounted to US\$24 million for the 1996-1997 biennium, and US\$27.1 million for the 1998-1999 biennium. In the period 1998-1999 EDM had a combined budget of US\$27.1 million (DAP 75%, DMP 22% and TRM 3%). The indicative budget for the period 2000-2001 was US\$28.8 million.
100. The Secretariat emphasized that extrabudgetary contributions were critical to WHO's operational and normative work in the pharmaceutical sector. In the period 1998-1999 voluntary contributions had represented 91% of the DAP budget, 42% of the DMP budget and 4% of the TRM budget. Voluntary contributions had amounted to approximately 80% of the total combined EDM budget.
101. EDM programme planning for the year 2000 and beyond,<sup>2</sup> including the proposed budget for 2000-2001, would be based on the 1997 WHO Essential Drugs Strategy, and on constitutional and other mandates of the Department. All partners would be consulted and involved in this planning process: the Management Advisory Committee, country programmes, regional advisers, UN and other international agencies, and also participants in the roundtable process.
102. EDM would build on partnerships and collaborative arrangements (such as with WHO collaborating centres, nongovernmental organizations, professional associations, and the private sector) for programme implementation. Regional and international networks would be either reinforced or established.
103. Whilst the strategic plan and approach would be developed for two biennia (2000-2003), a detailed budget would be developed for one biennium (2000-2001). This would present a core budget and unfunded priorities. The WHO regular budget allocation to EDM would be "ring fenced" to finance core management and normative work. Links with regional and country plans and budgets would be indicated. When developing this new budget, efficiencies would be sought, but not reductions in funding or activities. On the basis of this

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<sup>2</sup> The principle of a six-year strategic plan was mentioned by the Secretariat during this meeting. Since then, it has been agreed that the three HTP departments will develop a four-year strategic plan.

principle, and also taking into account the WHO programme budget for 2000–2001, an indicative core budget for 2000–2001 of US\$28.8 million was proposed. This consists of:

- US\$12.4 million for country and regional support (43%);
- US\$7.2 million for quality, safety and regulation (25%);
- US\$5.8 million for policy, access and rational use (20%);
- US\$0.9 million for traditional medicine (3%); and
- US\$2.6 million for programme management (9%).

104. The Secretariat proposed to have an approved four-year strategic plan, and two-year indicative budget by the end of 1999.

#### **Committee action, comments and questions**

105. The Committee congratulated the Department on a very lucid presentation.
106. The Committee expressed its satisfaction with the Director-General's clear statement that there would no change in WHO's role in the pharmaceutical sector, and that this would remain a high priority.
107. The Committee requested clarification on whether voluntary contributions that had been donated for DAP activities might in future be transferred to DMP (now QSM).
108. The Committee requested further information concerning the basis of the proposed 2000–2001 budget of US\$28.8 million.
109. The Committee enquired what proportion of activities operational research would represent in the new strategic plan and budget.
110. The Committee commented that considerable extrabudgetary resources were still required to fully fund the biennium budget. It enquired whether this was typical of the mid-biennial situation and how activities would be prioritized if sufficient funding was not received.
111. The Committee requested an update on WHO guidelines for collaboration with commercial enterprises. It emphasized that these guidelines were important to donors and to WHO's integrity in view of the Organization's critical dependence on extrabudgetary funds.
112. The Committee enquired about plans for future collaboration with the private sector.

#### **Response from the Secretariat**

113. All EDM income and expenditures would be tracked as before. Expenditures would be in line with the purpose indicated by donors when making a contribution. Activity and financial reports to be prepared for the 1998–1999 biennium would reflect the full picture for the new Department.
114. The 1999 World Health Assembly in May would decide whether the WHO programme budget for 2000–2001 would include an increase for inflation (zero nominal growth) or whether it would not (zero growth). The WHO regular budget allocation to EDM should be

US\$5.6 million. On the basis of the best estimate from the Secretariat, the difference of US\$23.2 million would be funded from expected voluntary contributions, both unspecified and specified. The total indicative budget of US\$28.8 million was calculated by the Secretariat on the basis of the total requirements for the core work.

115. In addition to that core budget, there would remain at least US\$2 million in unfunded priorities.
116. With respect to operational research, the 1998–1999 programme plan and budget detailed work in this area, including multicountry studies, smaller-scale studies and intervention studies. Strategic and operational research constituted over 25% of the US\$6.1 million 1998–1999 budget for policy and technical development work. It was anticipated that this level of research effort would continue in the future.
117. The financial situation at mid-biennium was normally at the current levels, as shown by the table for previous years. If, however, contrary to expectations there was a shortfall in the expected extrabudgetary funding, the Department would adjust activities at the country level using its prioritization indicators. In other areas activities such as technical publications and research projects, for which financial commitments had not yet been made, could be postponed.
118. Draft guidelines on collaboration with the private sector had been prepared and include issues related to conflict of interest. A WHO committee was reviewing these draft guidelines, and the review process also included consultation with the WHO Regional Offices.
119. Collaboration on access to essential drugs was a major topic of discussion in the roundtable process. To date, roundtable discussions had been held with public interest NGOs, the research-based pharmaceutical industry and the generics industry. This was intended to be a long-term process and there would be regular follow-up meetings.

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## **IX. CLOSURE OF THE EDM SESSION**

120. The EDM session closed at 10:30 a.m. on 18 March.



## ADDENDUM: DISCUSSION OF THE MIP CONCEPT

121. The meeting continued with a common cluster agenda item relating to the MIP concept.
122. This discussion was considered to be an excellent opportunity for crystallizing views on the role of MIPs, how they should be organized and what their principal areas of focus should be. As a contribution to the discussion, the Secretariat presented and distributed the results of a pre-meeting questionnaire. It was agreed that a follow-up questionnaire would also be sent to participants after the meeting. The results of this post-meeting questionnaire would be sent to participants by the end of June.
123. Participants supported the idea of holding partner meetings in Geneva. It was agreed that such meetings represented a major opportunity for bringing partners together, and could serve as a forum for information exchange and discussion of issues of mutual concern and interest. Participants considered interaction with key WHO staff to be a very important element of MIPs.
124. Questions were raised as to what type of participants should attend MIPs. Should the meetings be open to all partners and donors? Should every participant be able to make interventions? The importance of including participants from developing countries was stressed. It was also suggested that participation be broadened in order to improve dialogue.
125. Most participants considered MIPs to be preferable to individual department meetings, a useful means of streamlining and coordinating department meetings, and a good use of resources for both departments and participants. Some concern was expressed regarding the possibility that the MIPs of all clusters might be held in the same month each year. This would oblige donors to decide funding allocation at that time, even though this might not accord with their financial year. It was noted that the Executive Board had expressed great interest in evaluating this year's meetings. The Director-General's Office (DGO) would decide on the direction, timing and content of future meetings after the MIPs of the other clusters had been held (14-25 June) and an evaluation undertaken.
126. It was felt that the HTP MIP had been somewhat departmentalized, reflecting the fact that the new cluster had yet to become fully integrated. Some participants considered that future meetings should be divided into a technical session and a management session. Others preferred departmental presentations as these would allow participants to attend only those sessions of particular interest.
127. Some concern was raised concerning the possibility that the MIPs might discuss or decide on issues that — strictly speaking — were under the jurisdiction of the Governing Bodies. It was therefore proposed that terms of reference for future MIPs be prepared, stipulating their objectives, their content and who should participate in them. These terms of reference would be drafted once instructions had been received from DGO.
128. There was general consensus on the importance of knowing the dates of the MIPs well in advance. It was suggested that a calendar of WHO meetings be published early in the year.
129. The issue of earmarking funds was touched on. It was stated that earmarking was sometimes necessary for donors due to political and domestic constraints. A number of countries were likely to maintain earmarking.

130. It was suggested that a more consistent approach to reporting on progress and achievements be attempted. It was also suggested that a standardized cycle of reporting be agreed upon with major partners and donors.<sup>3</sup>

#### **Reports from other departments**

131. The meeting continued with reviews of the work of the Department of Vaccines and Biologicals and the Department of Blood Safety and Clinical Technology. Separate reports of these discussions are being issued.
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#### **X. CLOSURE OF THE MIP**

132. The Executive Director, HTP, made the closing remarks. He noted that more information had been presented for EDM and V&B than for BCT. This was because the departments were currently at different stages in their evolution; however, they would grow together.
133. Dr Scholtz stressed the importance of the MIP for the cluster's strategic direction setting. The timing of the MIP — earlier rather than later — was deliberate. Although this earlier timing entailed the risk of the cluster not yet being able to present itself as fully integrated, the cluster had been able to gather valuable input which would help it to prepare its long-term vision and strategy. Moreover, WHO itself was still at a transitional stage and still in the process of establishing synergies.
134. The Executive Director went on to say that it was likely that next year's HTP MIP would focus on specific issues (rather than on individual departments) for discussion with partners.
135. He concluded by thanking donors for their support to the cluster and hoped that this expression of confidence in the work of WHO would be maintained and even strengthened.

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<sup>3</sup> The Resource Mobilization Department is considering this issue, including whether WHO financial reporting to donors should take the form of a single report. Decisions on reporting will be taken later this year.

## ANNEX 1: LIST OF PARTICIPANTS

### MEMBERS

#### Australia

Mr Kerry Kutch, Counsellor, Permanent Mission of Australia to the United Nations Office and other International Organizations at Geneva

#### Bangladesh

Professor Syed Modassar Ali, Director, NIO/Chairman, BMRC, Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh

#### Barbados

Mrs Maryam Hinds, Director, Drug Service, Ministry of Health and the Environment

#### Belgium

Dr Jacques Laruelle, Chargé de Programmes au Service des Nations Unies, Belgian Administration for Cooperation Development

Ms Sonja Gerlo, Permanent Mission of Belgium to the United Nations Office and the Specialized Agencies at Geneva

#### Benin

Mr Adrissou Abdoulaye, Directeur des Pharmacies et des Laboratoires, Ministère des Affaires Etrangères et de la Coopération

#### Botswana

Mr S.L. Ramothlwa, Ministry of Health

#### Canada

Ms Patricia Lemay, Acting Director, Bureau of Policy and Coordination, Therapeutic Products Programme, Health Canada

#### Colombia

Dr Conrado Adolfo Gomez Velez, Ministerio de Salud

#### Denmark

Mr Peter Hertel Rasmussen, Minister-Counsellor, DANIDA, Royal Danish Ministry of Foreign Affairs

Dr Pia Rockhold, Technical Advisor, DANIDA, Royal Danish Ministry of Foreign Affairs

#### Finland

Dr Hanna Nohynek, Research Physician, KTL National Public Health Institute, Department of Vaccines

Ms Hanna Rinkineva-Heikkilä, Counsellor, Permanent Mission of Finland to the United Nations Office and other International Organizations at Geneva

#### France

Mr Philippe Bouscharain, Pharmacien, Ministère des Affaires Etrangères, Direction Générale de la Coopération Internationale et du Développement

Mme Rosine Deniau, Agence du Médicament, Mission des Affaires Européennes et Internationales

Dr Frédéric Fleurette, Directeur des Etudes et de l'Information pharmaco-économique, Agence du Médicament, Mission des Affaires Européennes et Internationales

#### Germany

Dr Ingeborg Geisler, Development, Production, Licensing and Quality Control of Pharmaceuticals, Federal Ministry for Health

Dr Klaus Hornetz, Senior Health and Population Adviser, Kreditanstalt für Wiederaufbau

Dr Eltje Aderhold, First Secretary, Permanent Mission of Germany to the United Nations Office and other International Organizations at Geneva

**Islamic Republic of Iran**

Dr Abdolmajid Cheraghali, Director, Iran Drug Selection Committee, Department of Deputy Minister for Food and Drugs, Ministry of Health and Medical Education

**Israel**

Ms Magister Batya Haran, Head, Pharmaceutical Division, Department of International Relations, Ministry of Health

Mr Gary Koren, Counsellor, Permanent Mission of Israel to the United Nations Office and other International Organizations at Geneva

**Italy**

Dr Pasqualino Procacci, Ministry of Foreign Affairs, Directorate General for Development Cooperation

**Japan**

Mr Hisashi Ito, Chief, International Affairs Division, Minister's Secretariat, Ministry of Health and Welfare

Mr Shigeki Tsuda, Deputy Director, International Affairs Division, Minister's Secretariat

Ms Kazuko Kurata, Section Chief, International Organizations, International Affairs Division, Minister's Secretariat, Ministry of Health and Welfare

Mr Akito Yokomaku, Second Secretary, Permanent Mission of Japan to the International Organizations at Geneva

**Luxembourg**

Dr Victor Arend, Centre Hospitalier, Luxembourg

**Mexico**

Ing. Alberto Gomez, Ministry of Health

Dr José Ignacio Santos, Director, National Immunization Council of Mexico (CONAVA)

**Mongolia**

Mrs Ch. Munkhdelger, Drug Policy Officer, Ministry of Health and Social Welfare

**Myanmar**

Dr U. Min Swe, Project Manager, Myanmar Essential Drugs Project, Ministry of Health of the Union of Myanmar, International Health Division

Permanent Mission of the Union of Myanmar to the United Nations Office and other International Organizations at Geneva

**The Netherlands**

Dr John A. Lisman, Senior Staff Member, Department for Pharmaceutical Affairs, Ministry of Health, Welfare and Sport

Dr Martijn ten Ham, Senior Adviser, International Affairs, Department for Pharmaceutical Affairs, Ministry of Health, Welfare and Sport

Ms José Hansen, Inspector for Pharmaceutical Care, Ministry of Health, Welfare and Sport

Mr Jacob Waslander, First Secretary, Permanent Mission of the Kingdom of the Netherlands to the United Nations Office and other International Organizations at Geneva

**Norway**

Ms Marit Andrew, Director, Norwegian Board of Health

Ms Ellen Hoiness Flotve, Senior Executive Officer, Royal Ministry of Foreign Affairs

Ms Margrethe Sunde, Adviser, Norwegian Board of Health

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**Portugal**

Dr José António Aranda Da Silva, Instituto Nacional da Farmácia e do Medicamento (INFARMED)

**Russian Federation**

Dr A. Pavlov, Counsellor, Permanent Mission of the Russian Federation to the United Nations Office at Geneva and other International Organizations in Geneva

**South Africa**

Dr Desmond Johns, Permanent Mission of the Republic of South Africa to the United Nations Office at Geneva and other International Organizations in Geneva

**Spain**

Dr Alfonso Rodriguez Alvarez, Ministry of Health

**Sweden**

Dr Torkel Falkenberg, Sida Consultant, IHCAR, Karolinska Institute

Dr Inger Näsman, Medical Products Agency

Dr Anders Nordström, Deputy Head of Health Division, Swedish International Development Cooperation Agency (Sida)

**Tunisia**

Dr Ali M'Henni, Director, Quality Control Laboratory, Pasteur Institute

**Turkey**

Ms Sevgi Öksüz, Director, General Directorate of Pharmaceuticals, Ministry of Health

**United Arab Emirates**

Dr Maryam Kaldary, Director of the Pharmaceutical and Medicine Control Department, Ministry of Health

**United Kingdom of Great Britain and Northern Ireland**

Ms Julia Cleves, Department for International Development

Dr Neil Squires, Department for International Development

Dr Wendy Thorne, Department of Health, International Branch

**United States of America**

Dr Robert Clay, US Agency for International Development

Dr Elaine C. Esber, Associate Director, Food and Drug Administration

Dr Ruth Frischer, US Agency for International Development

Dr Roger L. Williams, Deputy Center Director, Office of Pharmaceutical Science, Food and Drug Administration

**World Bank**

Dr Ramesh Govindaraj

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**REPRESENTATIVES OF OTHER UNITED NATIONS OFFICES**

**United Nations Children's Fund (UNICEF)**

Mrs Hanne Bak Pedersen, Senior Technical Officer, UNICEF Supply Division

**United Nations Industrial Development Organization (UNIDO)**

Ms Elizabeth Metz, Liaison Officer

**United Nations Population Fund (UNFPA)**

Mr Patrick Friel, Senior Logistics Adviser

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**REPRESENTATIVES OF INTERGOVERNMENTAL ORGANIZATIONS**

**Commonwealth Secretariat**

Dr Clement Chela, Chief Programme Officer, Health Department, Commonwealth Secretariat

**Organization of African Unity (OAU)**

Mr Venant Wege Nzomwita, Assistant Permanent Observer, Permanent Delegation of the Organization of African Unity in Geneva

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**REPRESENTATIVES OF NONGOVERNMENTAL ORGANIZATIONS**

**Aga Khan Foundation**

Dr John Tomaro, Director, Health Programmes

**The Delhi Society for the Promotion of Rational Use of Drugs**

Professor Ranjit Roy Chaudhury

**Consumers International**

Mr Bas van der Heide

**International Federation of Pharmaceutical Manufacturers Associations**

Dr Harvey E. Bale, Jr., Director General

Mr Jean-François Gaulis, Director of Public Affairs

Mr Alain Aumonier, Public and Pharmaceutical Affairs, Hoechst Marion Roussel

Dr Patricia Carlevaro, Head of International Aid Unit, Pasteur Mérieux Connaught

Dr Odette Morin Carpentier, Manager, Pharmaceutical and Biological Affairs

**International Federation of Red Cross and Red Crescent Societies**

Ms Birgitte Stalder-Olsen, Officer, Logistics Service

**International Pharmaceutical Federation**

Mr A.J.M. Hoek, General Secretary

**International Plasma Products Industry Association**

Mr Jan M. Bult, Executive Director

**Mérieux Foundation**

Dr Betty Dodet, Scientific Director

Dr Gilles Landrivon, Director

**National Institute for Biological Standards and Control**

Dr Geoffrey Schild, Director

**Oxfam**

Ms Philippa Saunders, Project Manager, Essential Drugs Project

**World Council of Churches**

Mr Manoj Kurian, Executive Secretary

**World Self-medication Industry**

Dr Jerome A. Reinstein, Director General

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**OTHER ORGANIZATIONS**

**Centers for Disease Control and Prevention**

Mr Robert A. Keegan

## **PRIVATE SECTOR REPRESENTATIVES**

### **Pasteur Mérieux Connaught**

Dr Shawn Gilchrist, Medical Consultant, International Public Health Affairs (IPHA)

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## **WORLD HEALTH ORGANIZATION**

Dr Gro Harlem Brundtland, Director-General

### **Secretariat/Health Technology and Pharmaceuticals**

Ms Fabienne Adam, Dr Guitelle Baghdadi, Dr Raffaella Balocco-Mattavelli, Ms Pascale Boulet, Ms Kari Bremer, Dr Edelisa Carandang, Ms Renia Coghlan, Ms Charlotte Danielsen, Dr Mark Demesmaeker, Ms Patricia Downes, Dr Jean Emmanuel, Ms Daphne A. Fresle, Dr Robin Gray, Dr Vincent Habiyambere, Ms Joan Hawe, Mr Jörg Hetzke, Dr Hans V. Hogerzeil, Ms Kathleen Hurst, Dr Juhana Idänpään-Heikkilä, Dr Kazuko Kimura, Dr Sabine Kopp-Kubel, Mr Jean-Pierre Lafaille, Dr Bjorn Melgaard, Mrs Marie-Thérèse Panayotti, Dr Jonathan D. Quick, Dr Valerio Reggi, Dr Françoise Renaud-Théry, Ms Jacqueline Sawyer, Ms Monique Schmid, Dr Michael Scholtz, Dr Germán Velasquez, Mr Kidane Woldeyesus, Mr Eshetu Wondemagegnehu, Mr Jun Yoshida, Mr Tokuo Yoshida, Dr Xiaorui Zhang.

### **Regional staff**

Dr Enrique Fefer, Regional Adviser, Regional Office for the Americas/Pan American Health Organization

Mr Peter Graaf, Regional Adviser for Essential Drugs, WHO Regional Office for the Eastern Mediterranean Region

Mr Kees de Joncheere, Regional Adviser for Pharmaceuticals, WHO Regional Office for Europe

Dr Iman Mochny, Regional Adviser, EPI, WHO Regional Office for South-East Asia

Dr Ciro de Quadros, Special Adviser to the Director-General at WHO and Director, Programme on Vaccines & Immunization (SVI), Regional Office for the Americas/Pan American Health Organization

### **Representatives of other clusters**

Dr Hans Troedsson, Health Systems and Community Health

Mr J. Akre, Sustainable Development and Healthy Environments

Mr James Cheyne, External Relations and Governing Bodies

Dr David Heymann, Communicable Diseases

Dr Ala Alwan, Noncommunicable diseases



## ANNEX 2: LIST OF DOCUMENTS

Reference	Reference document
DAP/MAC(9)/98.10	<i>Report of the Tenth Management Advisory Committee Meeting</i>
WHO/HTP/EDM/MAC(11)/99.1	<i>List of documents</i>
WHO/HTP/EDM/MAC(11)/99.2	<i>Agenda</i>
<p>(There was no WHO/HTP/EDM/MAC(11)/99.3 document. This would have been the list of participants. But this year a document relating to the whole cluster was provided.)</p>	
WHO/HTP/EDM/MAC(11)/99.4	<i>Interim report of the biennium 1998–1999</i>
WHO/HTP/EDM/MAC(11)/99.5	<i>Interim financial report of the biennium 1998–1999</i>
WHO/HTP/EDM/MAC(11)/99.6	<i>Effective drug regulation: what can countries do?</i>
WHO/HTP/EDM/MAC(11)/99.7	<i>Supplementary financial information</i>



## ANNEX 3: AGENDA

Item	Reference document
1. Opening of the meeting	—
2. Election of chairperson Election of rapporteur	— —
3. Adoption of draft agenda	WHO/HTP/EDM/MAC(11)/99.2
4. Report of the Tenth Meeting of the Management Advisory Committee	DAP/MAC(9)/98.10
5. EDM activities: 1998–1999	WHO/HTP/EDM/MAC(11)/99.4
6. EDM finances: 1998–1999	WHO/HTP/EDM/MAC(11)/99.5
7. Theme for detailed discussion during MAC11: <i>Effective drug regulation: what can countries do?</i>	WHO/HTP/EDM/MAC(11)/99.6
8. EDM outlook and budget: 2000–2001	WHO/HTP/EDM/MAC(11)/99.7

Please note that this is only an excerpt from the MIP agenda and relates only to meeting elements relating to the Department of Essential Drugs and Other Medicines.









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