



**ACTION  
PROGRAMME  
ON  
ESSENTIAL  
DRUGS**

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**Report of  
the Sixth Management  
Advisory Committee Meeting**

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Geneva  
22-23 March 1994



World Health Organization

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

Geneva, 22-23 March 1994

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## I. OPENING OF THE MEETING

1. The sixth meeting of the Management Advisory Committee (MAC) of the WHO Action Programme on Essential Drugs (DAP) took place in Geneva on 22 and 23 March 1994. The meeting was attended by representatives of Member States, UN agencies, and nongovernmental organizations. The participants are listed in Annex 1, the documents prepared for the meeting in Annex 2, and the agenda for the meeting is included as Annex 3.
2. The Chairperson, Dr John Primrose (Australia), opened the meeting and invited Dr Hiroshi Nakajima, Director-General, to address the meeting.
3. The Director-General welcomed participants to the meeting. He reported that the Programme's mandate and work are well accepted in all developing countries, and within developed countries too. They are particularly relevant to the current climate of economic stringency in developing country health systems. Increasing numbers of countries are thinking in terms of essential drugs, particularly in Central Asia, where economic changes have led to extreme shortages, and francophone Africa, affected by the devaluation of the CFA. These problems give added urgency to the need for rational drug procurement and use, an element of health sector reform that can be expected to result in improved population health status.
4. As a result of the global economic slump and the shift of some national economies that were previously centrally planned to a free market structure, health care services traditionally provided by the public sector are increasingly being taken over by the private sector. In some cases, these services are just no longer provided at all, he said. "In this new environment, it must be our duty and our responsibility to stand firm on the principle of health for all, that is equity in access to health care and drugs.
5. "We must remind policy makers, health authorities and economic advisers everywhere that access to essential drugs is a key element of health services", said Dr Nakajima. "We must also advocate that increased attention be given to regulations and quality control".
6. The Director-General pointed to other needs. Inappropriate use of drugs is a source of great concern everywhere, leading not only to wastage of resources but - as in the case of misuse of antibiotics - to serious long term individual and public health consequences.
7. "In many countries, access by prescribers and the general public to objective information about the appropriate use of medicines is non-existent, while commercial marketing practices continue to give cause for concern". He reminded participants of the importance of the WHO Ethical Criteria for Medicinal Drug Promotion and said that this issue was on the agenda of the Forty-seventh World Health Assembly to be held in May 1994.
8. Training of human resources must be a priority if the least developed countries are to be equipped with the capability of health planning, and implementation which many of them still lack. This is essential to enable them to establish and implement national drug policies, including regulatory measures and structures.
9. Dr Nakajima expressed his satisfaction with the achievements of the Action Programme to date, which had been made possible through the commitment of Member States and donors. He called for the continuation of the generous support to enable the Action Programme to maintain and strengthen its important technical support and leadership role.
10. The Director-General indicated that the Executive Board would conduct an indepth review of the Programme during its session in January 1995.

11. Dr Nakajima concluded by announcing the appointment of Mrs M. Helling-Borda as Director of the Action Programme. The appointment had been made after wide consultation, in which a number of excellent candidates had been identified. He indicated his future intention to strengthen the staff of the Programme with new recruits experienced in health sector reform.
  12. The Chairperson of the MAC congratulated Mrs Helling-Borda on behalf of the Committee and expressed its satisfaction with her appointment. He also thanked Dr F.S. Antezana, Assistant Director-General and previous Director of the Programme, for his contribution and leadership during his directorship.
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#### **Election of Officers**

13. Dr John Primrose, entering the second half of his two-year term as Chairperson, presided over the meeting. Ms Zhao Lili (China) was elected Rapporteur. Mrs M. Helling-Borda was Secretary of the meeting.
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#### **Adoption of the agenda**

14. The Committee reviewed the draft agenda, and adopted it with the following additions: implementation of WHO's Revised Drug Strategy: the rational use of drugs (as agenda item 8); Future Strategy: Action Programme on Essential Drugs (as agenda item 9). The agenda as adopted (document DAP/MAC(6)/94.2 Rev.1) is included as Annex 3.
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### **II. REPORT OF THE FIFTH MEETING OF THE MANAGEMENT ADVISORY COMMITTEE OF THE ACTION PROGRAMME ON ESSENTIAL DRUGS**

15. The Committee approved the report of the fifth meeting of the Management Advisory Committee, document DAP/MAC(5)/93.9, with the following amendment under Item I, Address of the Director-General:
  16. "The Director-General confirmed his support for the work of the Action Programme on Essential Drugs and assured the Management Advisory Committee that adequate resources would be provided to strengthen the Programme."
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### **III. REPORT OF THE BIENNIUM 1992-1993**

#### **Preliminary remarks by Director, DAP**

17. Mrs M. Helling-Borda, Director, DAP, first drew the attention of the Committee to the greatly increased documentation requested for the sixth meeting of the Management Advisory Committee. She illustrated this by pointing out that the MAC6 requirement was for seven substantive documents, compared with three the previous year. This represented a very heavy workload, she emphasized, not only for the DAP staff, who were relatively few in number compared with other similarly funded WHO technical programmes, but also WHO's translation unit which was constrained by severe regular budget cuts. She therefore proposed that future MAC meeting documentation be limited to: 1) the main technical, i.e. progress report; 2) the financial report for the period under review; 3) the proposed programme and budget for the coming biennium; 4) on alternate years, an outline of the DAP contribution to the WHO

Proposed Programme Budget for the subsequent biennium; 5) one technical theme or issue paper.

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### **Report on DAP activities in 1992-1993**

18. Mrs Helling-Borda introduced the report on DAP activities for the biennium 1992-1993 (document DAP/MAC(6)/94.4). She drew the attention of new MAC members to the fact that the Action Programme on Essential Drugs is a central component of WHO's Revised Drug Strategy and acts as WHO's operational arm to assist in the development and implementation by Member States of their drug policies, in the supply of essential drugs of good quality at the lowest possible cost and in the development of training in the rational use of drugs. In May 1992 the Forty-fifth World Health Assembly had reaffirmed the continued validity of the essential drugs concept and the role of the Action Programme.
  19. The changing political and economic global situation had required new thinking and an indepth review of strategies and assessment of priorities. No ready-made solutions were available to design such new policies and many questions remained unanswered. Emphasis had to be placed on finding new and rapid solutions to the questions of how drugs were to be financed; how public health goals, including issues of equity, could be maintained in a changing mix of public and private sectors; and how national regulatory authorities could control an increasingly complex pharmaceutical sector, with particular respect to drug quality, safety and the provision of accurate information to prescribers and consumers.
  20. This new situation led the Programme and its collaborators to examine its future strategies and priorities resulting in a very useful Future Strategy paper. DAP also strengthened its collaboration with other WHO programmes and international and bilateral agencies in order to promote an integrated approach to drug supply and rational use at country level, within the framework of a national health policy.
  21. Country support remains the most important activity of the Action Programme. The final justification for all DAP work is to give support to Member States. Operational research, development work, information and advocacy all serve to improve or widen country support. During the biennium the Programme gave technical support to 80 countries. This support was closely coordinated with regional activities. DAP staff assisted most regional offices in preparing an overview of all regional and DAP-supported activities, as the basis for biennial work plans. This procedure ensures that DAP activities complement and are integrated with regional programmes at country level.
  22. The intensity of DAP's support varies between regions and countries. Programmatically for 1992-1993 it can be divided into three categories: the first refers to countries that receive substantial technical and/or financial support from DAP, covering most of the components of a national drug policy. The second category includes countries in which support is limited to one or two specific technical areas. The third category relates to countries that are in the process of developing a national drug policy and/or an essential drugs programme. Throughout the biennium special emphasis was given to the development or updating of national drug policies.
  23. Mrs Helling-Borda provided a brief situational analysis and summary of activities in each of the WHO regions.
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**Africa**

24. The African Region is characterized by stagnating economies, economic adjustment policies, reduced availability of public funds, a shift to privatization and increased health demands due to poverty, disease and population increase. Special emphasis was given to programme development in francophone and lusophone countries, as the proportion of countries without national drug policies is higher in this group than in anglophone countries.
  25. An important trend was the renewed support to a number of countries with longstanding essential drugs programmes to review their national drug policy, and to assist them in developing master plans for the pharmaceutical sector. In most cases these five-year plans were used by governments as the basis for requesting technical support and funding from donor agencies or the World Bank.
  26. Another trend was DAP assistance to countries and donor agencies in the development and implementation of large bilateral programmes, e.g. Ethiopia and Mozambique. In other countries, such as Uganda and Zimbabwe, DAP's main activity was to give selected technical support in the field of policy development, evaluation and programme planning. In a number of instances specialized technical support was also given to complement existing bilateral programmes.
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**The Americas**

27. The pharmaceutical situation in Latin America can be characterized by three trends. The first resulted from policies to open up the economy with little regard to public health considerations. Pharmaceuticals are increasingly being treated as ordinary commodities, and in some countries economic pressure has led to deregulation, liberalized prices, and automatic market approvals. However, there is also a trend towards promoting rational use through generic drugs, e.g. in Argentina, Brazil, Colombia, Ecuador and Venezuela. And thirdly, there is a trend towards subregional collaboration. For example, the five Andean countries are working to standardize their drug policies and essential drugs lists and to harmonize criteria for market approval. The Action Programme, in close collaboration with regional staff, has strongly supported activities aimed at furthering rational use and regionalization, for example through its sponsorship of annual meetings of Andean countries to review and coordinate progress in their essential drugs programmes and the 1992 regional conference in Venezuela on new approaches to drug financing.
  28. In addition, there are several very large DAP-supported country programmes in the region, such as in Bolivia, Colombia and Ecuador, which cover most components of a national drug policy.
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**Eastern Mediterranean**

29. The Eastern Mediterranean Region has countries in many different stages of development, ranging from some of the poorest in the world to very rich oil producing states. Country support in 1992-1993 ranged from emergency programmes to comprehensive programmes dealing with the basic issues of supply, quality assurance and rational prescribing. It also included highly technical consultancies on very specific subjects.
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**Europe**

30. DAP support in Europe is reported under item XII.
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**South-East Asia**

31. Most of the 11 countries in the South-East Asian Region have developed and are implementing national drug policies. Nevertheless, the inappropriate use of drugs remains a serious problem. In regional activities, an important milestone in 1993 was the DAP-supported regional meeting on rational drug use. DAP also gave extensive financial and technical support to a number of other regional meetings under the umbrella of ASEAN, and continued its technical support to the essential drugs programmes of countries in the Region.
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**Western Pacific**

32. Country situations in the Western Pacific Region reflect great disparities in economic power. For weaker economies, such as Cambodia and Laos, drug availability is hindered by inadequate technical, financial and human resources. In direct country support in this Region, DAP is mainly involved in programmes in the Philippines and Viet Nam, although some preliminary work has started in Cambodia and Laos.
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**Development work and operational research**

33. Development work continued to play an important role. The main objectives are to strengthen human resources, and to provide effective tools for policy makers, managers, prescribers and other health workers to improve programme planning, implementation, monitoring and evaluation. The Programme uses three broad strategies: training at national and regional levels; the development of technical information on all aspects of drug policy and use, such as guidelines, methodologies, review of experience and training packages, to be adapted at country level; and global advocacy for the essential drugs concept and rational drug use.
34. Highlights of the work include the development of innovative training materials such as the *Guide to Good Prescribing*; a global evaluation of the operation and use of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce; an analysis of the economic aspects of drug supply and use; and a large number of regional and international training courses, seminars and meetings. Further development work priorities were identified through a systematic process of weighted evaluation by all DAP operational staff.
35. The Programme pursued a vigorous information and advocacy strategy through a wide range of publications, including more than 25 technical documents and four issues of the *Essential Drugs Monitor* in English, French and Spanish. DAP's Documentation Centre continued to expand and proved a valuable resource for individuals and institutions throughout the world.
36. In the field of operational research a systematic process of strategy review and priority setting took place during the biennium. A major trend had been an increase in operational research at the country level. Research subjects included drug financing, price monitoring, people's perception and use of drugs, the impact of national formularies and other interventions to promote rational prescribing and procurement practices. Standardized methodologies to investigate drug use in health facilities and the community were also developed. The

dissemination of research findings was greatly enhanced through the establishment of the new DAP Research Series.

37. At the global level a major project had been the development of indicators for monitoring national drug policies, which it was expected would be widely used by countries, WHO and others, and would facilitate the assessment and adjustment of policies and strategies. The Programme had also reinforced its links with universities and professional networks.
38. In discussing coordination and collaboration with other programmes, the Committee was informed of an example of "four-party" collaboration involving DAP, DMP, PSA and UNDCP (United Nations International Drug Control Programme). One recent activity under this umbrella had been a joint UNDCP-WHO Meeting which looked into problems associated with parallel drug markets in June 1993. The outcome of this meeting had been reported in detail in the Essential Drugs Monitor.
39. A representative from the Global Programme on AIDS (GPA) also updated the Committee on various collaborative activities with DAP, in particular work to access at an affordable cost drugs needed to treat opportunistic infections of ever growing number of AIDS patients.

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#### **Overall comments**

40. The Committee reaffirmed the important role of DAP, particularly with respect to pharmaceutical services in developing countries. It commended the work of the Programme and noted that outputs had exceeded targets. This was evidence of the effectiveness and motivation of DAP staff.
41. The Committee praised the excellent and comprehensive documentation that had been produced by DAP under difficult circumstances. It was pleased to see more qualitative information in the report and would welcome more analysis in future reports, using country experience as models. It would also welcome clarification about the process of prioritization in DAP's work.
42. The Committee requested that future documentation for MAC meetings be dispatched earlier in order to give members adequate time for full perusal.
43. The Committee welcomed the increased collaboration with other major agencies and WHO programmes and commended DAP on its information and advocacy work which made a critical contribution to its leadership and collaborative role. It was important that the World Health Assembly resolutions on the Action Programme and the Revised Drug Strategy, which articulated the critical importance of WHO's role in the pharmaceutical sector, be followed up. And regular reporting to the World Health Assembly on progress in the Action Programme and the Revised Drug Strategy was essential, the Committee emphasized.
44. Concern was expressed about the period which had elapsed before the appointment of a new Programme Director. It was considered that this had created uncertainty and a difficult situation for DAP. However, the Committee thanked the Director-General for his consultation with DAP "investors" regarding this appointment.
45. The Committee expressed its satisfaction with the development of DAP's operational research. Particular mention was made of the systematic inclusion of research into country programmes and the dissemination of findings through peer review journals and the DAP Research Series. The development of standardized research methodologies was also a valuable initiative, and the

collaboration with INRUD was a good example of capacity building. The Committee considered that research proposals should be peer reviewed.

46. A number of developing country members referred to the developments in the essential drugs programmes in their countries. The valuable support of DAP was acknowledged. The donors were thanked for making such support possible and the need for its continuation was emphasized. One developed country described how it had recently established an essential drugs list of 400 drugs, to be available free of charge, and was working on a revision of its national drug policy. The advocacy and information activities of WHO had substantially contributed to this work and its implementation.
47. The Committee welcomed the recognition in the biennium report and the working documents of the complexity of the health sector. Governments had to make difficult choices and these were inevitably politicized. There were no simple solutions. A key feature of health sector reform was a shift from systems and structures to outcomes and that included making informed choices, where possible, about health care and equity of access. In this context DAP had real strength with its focus on needs, access and a pragmatic approach. Access and equity were central in a global climate of structural adjustment and health centre services could not be measured only by cost-effectiveness.
48. The Committee welcomed the recognition in the biennium report of the importance of public education, and an integrated approach to issues of rational use. DAP should increase its involvement in community work such as awareness-raising concerning self-medication and illicit drugs.
49. Concern was expressed that there was no discussion in the report of the WHO Ethical Criteria for Medicinal Drug Promotion. Document EB 93/90 only invited the Executive Board to "note progress", but it was important to "monitor" as expressed in previous WHA resolutions on this subject<sup>1</sup>. The Committee believed that some of this work was a natural part of DAP's country support activities and that WHO should take the lead. The Ethical Criteria should be included in the indicators of national drug policy being developed by DAP.
50. The Committee raised the problem of coordination of drug supplies, particularly in the field in emergency situations. DAP could do more to guide donors and potential recipients in such situations to ensure that supplies matched needs.
51. Dr F. S. Antezana, Assistant Director-General, assured the Committee that access to essential drugs and issues of equity were of fundamental importance in WHO's work. These had been identified as core elements of primary health care by the Alma Ata Declaration. The Action Programme would continue to play its central role but as part of the WHO response to global change, DAP also, would need to adapt its strategy. This process was already underway and would be assisted by the DAP Future Strategy paper. The concern expressed about the Ethical Criteria and pharmaceutical issues in WHO was well taken. The Committee should be reassured that a full report would be made to the World Health Assembly. He affirmed that comments and proposals from the MAC regarding Programme policies and strategies were always welcome.
52. Mrs M. Helling-Borda, Director, DAP, thanked the Committee for its encouragement and support. She emphasized that the Programme welcomed and paid careful attention to MAC

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<sup>1</sup> Editorial footnote: The subsequent resolution WHA47.16 of the Forty-seventh World Health Assembly did in fact, inter alia, request WHO to give special attention to "monitoring the implementation of the WHO Ethical Criteria and collecting information on voluntary, self-regulatory national and international codes and guidelines that relate to the promotion of medicinal drugs, in consultation with all concerned parties;".

recommendations. Every effort would be made to provide MAC documentation earlier in future. She recognized the critical need for collaboration among agencies and programmes. This was already close but could be even stronger. DAP would take up the question of donor guidelines.

53. She agreed that prioritization of countries to receive support had not been totally clear in the past but stated that there was greater clarification in the 1994-1995 programme of activities. Criteria included: government commitment; assessment of needs; likelihood of success; involvement of others; past record and availability of funds.
54. In response to issues raised concerning operational research, the Secretariat confirmed that monitoring of the WHO Ethical Criteria on Medicinal Drug Promotion was included in DAP's national drug policy indicators. However, more indicators would be needed at country level according to the socioeconomic level and other situational issues. With respect to review of research proposals and prioritization, the Technical Support Panel would be the most appropriate body. Drug use at the community level was tackled through DAP's IEC strategy at country level. The Programme worked at national and global levels with technical information and experience from each contributing to the development of global and national tools.

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#### IV. FINANCIAL REPORT OF 1992-1993

55. The Committee considered the financial report of the Programme, document DAP/MAC(6)/94.5. The report presented financial information for the biennium 1992-1993. Total resources available to the Programme amounted to US\$ 29.3 million. This figure included income received during the 1992-1993 biennium of US\$ 14.670 million and an opening balance at the start of the biennium of US\$ 14.669 million. Obligations (activities) incurred during the biennium amounted to US\$ 17.9 million leaving a closing balance at the end of the biennium of US\$ 11.4 million. It was noted that the Programme had sufficient funds to implement the plan and budget for the Programme for the biennium 1992-1993 approved at the fourth MAC in February 1992. Of the total income received during the biennium of US\$ 14.670 million, US\$ 12.4 million came from extrabudgetary contributions (85%) and US\$ 2.3 million from regular budget and other funds. The breakdown of extrabudgetary contributions between specified and unspecified amounts was approximately equal for 1992-1993.
  56. The Programme had strengthened its ties with donors. Donor visits were undertaken during the biennium and meetings were held with potential donors with the aim of expanding the donor base of the Programme. The financial contribution of all developed countries with which DAP had contact was now a priority so as to secure the Programme financially and enable it to meet future challenges. The Committee noted that DAP would continue to work to expand its donor base and to investigate all mechanisms through which resources could be made available.
  57. The Committee then considered the detailed financial statements which provided information on contributions by source, firm pledges, expenditures by Programme areas of work and expenditures by technical areas of intervention and on management activities, including staff costs. The financial report of the biennium 1992-1993 was adopted by the Committee which expressed its satisfaction with the clarity of presentation of the report.
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## V. PROPOSED PROGRAMME FOR THE BIENNIUM 1994-1995

### Proposed plan of activities

58. Director, DAP, introducing the programme (document DAP/MAC(6)/94.6), informed the Committee that it had been developed following the recommendations of the DAP Future Strategy document. She drew members' attention to the fact that the proposed programme included a description of the different types of DAP country support and support prioritization.
59. The Committee congratulated DAP on a clear paper which set out issues well and reflected the strategy paper. It welcomed the increased attention paid to the private sector, and highlighted the important role of local and regional production to create sustainable essential drugs supply.
60. A Russian edition of the Essential Drugs Monitor would be very useful in view of the pharmaceutical situation in the former Soviet Union and Newly Independent States stated one delegation and offered financial support for this development<sup>2</sup>.
61. Director, DAP told the Committee that local production was covered by some country support programmes and also under the DAP support to ASEAN with respect to GMP upgrading and reference standards. She agreed that a Russian edition of the Essential Drugs Monitor would be useful.

### Proposed budget for 1994-1995

62. Having considered the plan of activities for 1994-1995, the Committee then considered the budget, income and resources contained in document DAP/MAC(6)/94.6. As part of the budget presentation DAP explained the process of formulating the budget for 1994-1995. All of the Programme's activities were linked to projects and the total number of projects for 1994-1995 was 130. The Programme adopted a flexible and pragmatic approach to the establishment of project priorities and the allocation of scarce resources. This included an assessment of government commitment, needs, past performance, likelihood of success and the involvement of other agencies and availability of funds.
63. The budget for obligations for 1994-1995 was US\$ 19.8 million. This represented an increase of 10% over the actual obligations in 1992-1993 which were US\$ 17.9 million. The 1994-1995 budget was considered a zero growth budget after an allowance was made for inflation and cost increases. It was noted that the budget proposed to reduce the carry over balance, which at the start of the 1993-1994 biennium amounted to US\$ 11.4 million, down to US\$ 9.6 million at the beginning of 1996.
64. The Committee noted that the total income required for the biennium to fund the plan of activities was US\$ 17.969 million compared to US\$ 14.670 million received in 1992-1993. Unspecified funding required for 1994-1995 amounts to US\$ 8.5 million and this compared to US\$ 6.7 million received in 1992-1993. The Committee expressed its reservations about its ability to increase the unspecified funding to the level called for.
65. During the course of the Committee's discussion, a number of matters were considered in detail. The Committee expressed its concern that the regular budget income to the Programme appeared to be dropping. The Committee recalled its request at the fifth MAC in February 1993

<sup>2</sup> A Russian edition of the Essential Drugs Monitor is under preparation and will appear early in 1995.

that the Director-General be asked to give a higher priority to DAP within the Organization's regular budget provisions, which had also been supported in resolutions of the World Health Assembly. It pointed out that only two professional staff posts were now funded from the regular budget.

66. The Committee expressed the view that the proposed increase in the budget of 10% might be too high and that it might not be realistic to anticipate an income increase during 1994-1995. Finally, the Committee felt that caution was needed so as not to reduce the closing balance at the end of the biennium below a figure which would endanger the future stability of the Programme for the following biennium 1996-1997. In conclusion the Committee approved the Programme's plan and budget for 1994-1995. It was also agreed that the Programme plan and budget would be reviewed at the next MAC meeting and, if appropriate, revised taking into account the actual performance of the Programme during 1994 and the level of income received during the first half of the biennium.
  67. Director, DAP assured the MAC that implementation during 1994 would be based on income received and no actions would be taken to deplete the carry over balances below the figure of US\$ 9.6 million in the 1994-1995 plan and budget. A number of donor members confirmed their continuing financial support and some specific pledges were recorded.
  68. Dr F. S. Antezana, ADG, thanked donors for their support to the Programme - as expressed in their approval of the 1994-1995 plan and budget - and also for their consideration of the preliminary proposed programme and budget for 1996-1997.
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#### **VI. DAP'S OUTLINE FOR THE WHO PROPOSED PROGRAMME AND BUDGET FOR THE FINANCIAL PERIOD 1996-1997**

69. Director, DAP presented document DAP/MAC(6)/94.7, a draft outline for the preliminary proposed programme budget for 1996-1997. She pointed out that the document had not yet been formally approved within WHO. The preliminary proposed programme budget for 1996-1997 was US\$ 22.8 million. The regular budget contribution to this budget was US\$ 1.5 million (6%) and extrabudgetary funding was US\$ 21.2 million (94%). Country support continued to be the main area of activity with 63% of the total resources being allocated to this area of work.
  70. Dr F. S. Antezana, ADG, explained the budget reform process which was currently taking place as part of the preparation of the 1996-1997 budget for WHO. This included the more active role of the Executive Board in the allocation of resources over priority areas within the Organization.
  71. The Committee noted the document with thanks.
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#### **VII. IMPLEMENTATION OF WHO'S REVISED DRUG STRATEGY : THE RATIONAL USE OF DRUGS**

72. Director, DAP informed the Committee that this document had been written as an information document for the Executive Board in January. The Board had requested that it be presented to the World Health Assembly in May. An edited version of the document would therefore be presented to the Forty-seventh World Health Assembly<sup>3</sup>.

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<sup>3</sup> Document A47/8.

73. In response to a request for clarification about the status and form of the document, Dr F. S. Antezana, ADG, told the Committee that it would be presented to the WHA as a report from the Director-General on the Revised Drug Strategy, and as such would include not only a report on DAP activities but also on WHO's normative work in the pharmaceutical sector.
74. The Committee commended the background descriptive material in the document but felt that it could have been more specific on diagnostic elements and quantifiable outcome measures, such as the objective and comparative drug information mentioned as non-available. It would also have benefited from a more clearly presented action plan and it was hoped that this could be included in similar material in coming years.
75. The Committee expressed concern that despite resolutions requesting regular reports to the Assembly on the implementation of the Revised Drug Strategy and the work of the Action Programme, it had not originally been intended to present this report to the Assembly. The Committee considered that such regular reporting was essential to keep Member States informed of developments in this very important area and to maintain WHO's critical leadership role.
76. Under this agenda item two NGOs took the floor.
77. The representative of the International Pharmaceutical Federation described the positive collaboration of the Federation with DAP. He drew the Committee's attention to international guidelines developed by the Federation which set national standards for the promotion of health; the supply of medicines and medical devices; patient self-care, and improving prescribing and medicine use by pharmacists' activities. He also outlined a draft resolution on the role of the pharmacist to be presented to the Forty-seventh World Health Assembly<sup>4</sup>. He expressed the hope that this would lead to a closer and more concrete collaboration between the Federation and WHO.
78. The representative of the International Organization of Consumers' Unions and Health Action International confirmed their consistent support for the Revised Drug Strategy. Collaboration with the Action Programme was excellent and they welcomed their specific forthcoming cooperation with DAP in the area of public education. They were very pleased that a full report on the RDS would go to the World Health Assembly and considered that a strong resolution would help to remove any additional concerns. They considered that the recommendations of the WHO/CIOMS meeting on ethical criteria for medicinal drug promotion needed to be taken further with an action plan and a definition of DAP's role.

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### VIII. DAP FUTURE STRATEGY

79. The Committee commended the DAP Future Strategy document (WHO/DAP/94.4). It provided a clear strategy that would aid the development of the Programme's leadership role. However, the paper only presented a basic strategy which needed to be built on and operationalized. This would be an ongoing process.
80. In response to a query regarding the status of the document, Dr F. S. Antezana, ADG, explained that the document had been formally sent to the Director-General in February 1994. The Programme had taken the document into account in developing its future plans.

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<sup>4</sup> WHA47.12, Role of the pharmacist in support of the WHO Revised Drug Strategy.

81. The Committee adopted the paper and concluded that it would be a good basis for future strategic planning and operationalization.
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**IX. ISSUE PAPER ON DONOR CONTRIBUTIONS : SPECIFIED/UNSPECIFIED**

82. The issue paper, document DAP/MAC(6)/94.11, met the request of the fifth MAC for an issue paper on specified/unspecified contributions, drawing out all the consequences of a decision requiring, in principle, that 50% of donors' contributions be unspecified and indicating an optimal balance between the two types of contributions.
83. The Committee considered the paper and noted that with regard to contributions over the last four years, 1990-1993, 60% of extrabudgetary contributions from donor countries were unspecified and 40% were specified. When the extrabudgetary contributions from UN organizations and agencies (all specified) were added to the contributions from donor countries, unspecified contributions dropped to 53% with specified contributions amounting to 47%. Finally, when regular budget and other income were added, the split between unspecified and specified contributions over the last four years was 50% each. The important role that unspecified funds had played in the Programme's activities and accomplishments to date was stressed. In analysing the type of funds required for the next five years, due regard was given to the future strategy paper of the Programme and in particular to the new directions for DAP outlined in section 8 of that paper.
84. It was noted that the 1994-1995 plan and budget document had been prepared following the guidance of the future strategy paper which stated clearly how the Programme's resources were to be prioritized and which activities were to be funded from specified and unspecified funds. The 1994-1995 budget called for 50% of the total income to be unspecified.
85. After due consideration of the issue paper, the MAC agreed with the document's conclusion that 50% of the Programme's contributions should be unspecified for the foreseeable future so as to secure its global functions and prioritized activities, including prioritized country support activities.
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**X. ROLE OF THE PRIVATE SECTOR, INCLUDING IMPLICATIONS FOR FINANCING AND COORDINATING OF ACTIVITIES**

86. A number of developing countries described the difficulties they faced in rationalizing drug supply at a time of economic and political transition. Problems included reduced budgets, lack of human resources, unethical drug promotion, inadequate information for prescribers and consumers, predominance of commercial over health considerations by retail pharmacists and higher prices. Coping strategies included the promotion of generic drugs, development of objective drug information, linkages between public and private sectors and insurance schemes.
87. The Committee noted that the issue paper underlined that there was not one **right** solution. The blend of public/private involvement in drug supply was one that made the best use of resources while taking into full account issues of equity. The value of the paper would be increased by drawing on country experience and offering different options. It was also pointed out that privatization did not necessarily mean lower prices. One member reported that in Denmark, for instance, where drug supply was totally privatized, the drug prices were the highest in Europe. The Committee considered that the document was a start which needed to be taken further by a working group. Issues which needed future consideration in this context included the need for case studies to provide empirical data; an understanding of business finances in different

- contexts; and recognition that in most developing countries it was neither the prescriber nor a trained pharmacist who was the prime influence in drug consumption but vendors in drug shops; a different terminology was needed.
88. The Committee emphasized the importance of the public sector (the state) retaining its normative functions through a sound regulatory service. DAP had an important advocacy role to play in this regard.
  89. There was a market for locally produced generics and DAP should give guidelines on what could appropriately be produced. Solutions were needed for developing countries to find access to hard currency to buy raw materials. It was often easier for some developing countries to import rather than to manufacture finished dosage forms. The public sector also had much to learn from private product distribution and consideration should be given to using private systems which work well, such as those for soft drinks or beer.
  90. A number of NGOs took the floor contributing to the debate and described collaboration with the Action Programme.
  91. The representative of UNICEF described its fruitful collaboration with DAP at the country level and some joint global activities. Nevertheless, this collaboration could be strengthened. The dissolution of the former Soviet Union had created problems similar to many of those experienced by developing countries but had also created awareness of the need for international collaboration. Many governments saw delegation of responsibility to the private sector as a practical solution but a careful review of experience was needed to determine the impact of policies on the poor and on access. Deregulation in many cases had a negative impact and a transparent and competitive market did not always exist. A dialogue was needed with industry about how to make generic drugs available at affordable cost.
  92. The representative of the Christian Medical Commission expressed her organization's appreciation of its collaboration with DAP and the wish that this should continue. She emphasized that pharmaceuticals were a special product which could not be treated like other items of commerce but had to be controlled by the state. Inappropriate donations were a major problem and the private sector could be an entry area to tackling this. Better coordination was needed, as were DAP guidelines for donors. She specifically asked for problems of "drug dumping" to be placed on record and condemned. These included the supply of drugs which had no labels, inadequate information, were expired or which were not authorized for sale in the country of origin for reasons of safety.
  93. The representative of the International Federation of Red Cross and Red Crescent Societies said that DAP had one of the most important functions in the area of international health assistance. The IFRC was largely concerned with protracted emergencies often beyond government control. It encountered many problems with drug supply including inappropriate donations.
  94. The representative of the International Federation of Pharmaceutical Manufacturers Associations welcomed the discussion on the role of the private sector. It was clear that the roles of government and the private sector must be complementary, he said. In general the more advanced the economy the more the task of the government was to support and complement the activities of the private sector and the statement in the Proposed Programme Plan and Budget for 1994-1995 must be challenged for putting the cart before the horse. It was the responsibility of government to define guidelines and regulations for the operation of the private sector in the public interest but this regulation should not be unduly onerous nor provide a serious disincentive. The Federation had learned with interest that the Action Programme intended to

continue its work in this area and hoped that the IFPMA would be invited to be an active participant since it had an important contribution to make to the discussion.

95. Director, DAP, responding to the debate, concluded that there was a need for further study in this area.
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#### **XI. SELECTION OF THEME FOR DETAILED DISCUSSION AT MAC7**

96. The Committee considered a number of potential themes proposed in paper DAP/MAC(5)/93.6 which covered: generic prescription and use; coordination and collaboration in national drug policy development; financing; human resources development; education and training; role and integration of drugs and vaccines in the health services and self-medication; the role of drugs and vaccines in the health services; financing; generic prescription and use; privatization and self-medication. Additional themes proposed by members included drugs for HIV, and drug research and development.
97. After some debate the Committee voted to adopt the theme of "coordination and collaboration in national drug policy development, including the role of indicators" for detailed discussion at its next meeting.
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#### **XII. ISSUE PAPER ON ASSISTANCE TO EASTERN EUROPE AND THE REPUBLICS OF THE FORMER SOVIET UNION**

98. The Committee considered the issue paper Assistance to Eastern Europe and the Republics of the former Soviet Union, DAP/MAC(6)/94.10. The paper was prepared at the request of the MAC in consideration of the prospect that the donor community might wish to provide additional funding for increased levels of activities in the countries of Central and Eastern Europe (CCEE) as well as the New Independent States (NIS), which encompass a number of the republics of the former Soviet Union.
99. The MAC was informed that the CCEE and NIS are in political and economic transition affecting all government sectors. Lack of adequate resources for the public sector, including health, is a major constraint. The provision of health care is handicapped by lack of drugs. Although many of the CCEE had a long tradition of local drug production only a narrow spectrum of drugs has been produced in any one country. With the cessation of functioning of a centralized drug supply system, the NIS faced a situation in which drug production and distribution had to be restructured.
100. Although most CCEE and NIS face basically similar problems, there are differences in focus and importance, as well as in levels of economic development and the degree of autonomy that existed in the former socioeconomic system. Thus areas of support must be tailored to each individual environment. However, the problems facing these countries have a strong resemblance to those experienced in developing countries in other parts of the world and can be summarized as follows:

- resources for health care including drugs are limited and are decreasing;
- need for clearly defined drug policies impedes the development of efficient drug supply systems;

- need for a drug regulatory and enforcement system responding to present needs may create problems of drug safety and efficacy;
  - need for prescribing policies or consensus treatment guidelines at a time when new drugs are being marketed, and prescribers have little information about them;
  - need for up-to-date drug information for prescribers, dispensers and consumers;
  - outmoded education and lack of training in modern therapeutics.
101. DAP considered that this situation highlighted the importance of focusing on the development of an appropriate framework for a comprehensive national drug policy.
102. The Committee was informed of current technical support activities by WHO's European Regional Office programme EUROHEALTH. The World Bank, the CEE and other agencies were also working in this area. DAP had received requests for direct assistance from these Member States and also from EURO. Its response had been primarily to provide technical assistance by means of assessment missions, without additional financial implications, but also the provision of extensive documentation on development of national drug policy, legislation and other areas related to drug supply systems.
103. The approach and experience of the Action Programme have proved valuable in a number of countries where problems are comparable to those faced in CCEE and NIS. While the EUROHEALTH programme can provide limited support in response to requests from the CCEE, there are greater difficulties in supporting the NIS as the problems in general are more severe. Jointly DAP and the EURO Programme for Pharmaceuticals could offer technical assistance to a wider range of countries in the region.
104. In the following debate the Committee expressed its agreement with the situation analysis presented by the paper and the urgency of the problems faced. DAP's experience and mandate qualified it to play an important role, particularly with respect to technical issues and policy development. At present there appeared to be a problem of donor coordination and here again, DAP could play a crucial role.

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### **XIII. DATE AND PLACE OF THE NEXT MEETING OF THE MANAGEMENT ADVISORY COMMITTEE OF THE ACTION PROGRAMME ON ESSENTIAL DRUGS**

105. The Committee decided that its next meeting (MAC7) would be held in Geneva on 21 and 22 March 1995.

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### **XIV. ANY OTHER BUSINESS**

106. The Committee enquired about the status of the terms of reference of the Technical Support Panel, its financial implications and structure
107. Director, DAP stated that the name had been changed to Technical Support Panel to indicate the flexibility of the group and to make it less formal. The Panel's terms of reference had formed part of the documentation provided to the Committee (DAP/94.7). The Technical Support

Panel would be flexible and not fixed and could include members of the Expert Advisory Panel on Drug Policies and Management, which was in the process of being expanded.

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## **XV. CONCLUSIONS AND RECOMMENDATIONS**

108. The following conclusions and recommendations were adopted by the Committee.
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### **Fifth Management Advisory Committee meeting**

109. The Committee adopted the report of the fifth Management Advisory Committee meeting.
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### **Implementation of the Programme in the biennium 1992-1993**

110. The Committee expressed its satisfaction with the progress made by DAP during the biennium and praised the commitment and work of the Programme's staff.
111. The Committee complimented the Programme on the excellent documentation of its activities during the 1992-1993 biennium. It particularly appreciated the response of the Programme in its reporting to the request by the fifth MAC for more qualitative information. While recognizing the volume of work involved in document preparation, the Committee requested that future MAC documents be dispatched earlier to members in order to provide adequate time for their careful consideration.
112. The Committee approved the programme report and the financial report of the biennium 1992-1993.
113. The Committee noted with satisfaction the support for the Programme expressed by the Director-General in his opening address, but was concerned that despite WHA resolutions requesting that the Programme be strengthened, this had not been reflected in the regular budget allocation to DAP, which in fact had decreased. The Committee considered that DAP had a critically important role in the international pharmaceutical sector through its conceptual leadership and operational support to countries. This role should be reflected in its regular budget funding.
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### **Proposed 1994-1995 Programme Plan and Budget**

114. The Committee approved the proposed programme plan and zero growth budget for 1994-1995, in the amount of US\$ 19.8 million, and expressed its appreciation of the clarity of the document. It was agreed that the Programme Plan and Budget would need to be reviewed, and if appropriate revised, at the seventh MAC meeting.
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### **Proposed 1996-1997 Programme Plan and Budget**

115. The Committee reviewed the Programme Plan and Budget for 1996-1997 and noted that this was only a preliminary proposal, prepared under WHO's new budgetary planning system, which had not yet been fully reviewed or finalized.
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**Revised Drug Strategy: Report on the Action Programme on Essential Drugs - Information Document to the Executive Board**

116. The Committee noted that this document, with minor editorial modifications, would be presented to the World Health Assembly, and would form the major part of a combined report from the Director-General on the Revised Drug Strategy. The Committee expressed concern that despite resolutions requesting regular reports to the Assembly on the implementation of the Revised Drug Strategy and the work of the Action Programme, it had not originally been intended to present this report to the Assembly. The Committee considered that such regular reporting was essential to keep Member States informed of developments in this very important area and to maintain WHO's critical leadership role.
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**DAP Future Strategy document**

117. The Committee thanked the Chairman of MAC and the staff of DAP for their preparation of this very important document, which would provide a useful basis of future activities. The Committee emphasized that the broad strategies outlined in the document would need to be elaborated in more detail during implementation by the Programme and noted that the programme plan for the biennium already represented initial steps in this direction. It emphasized that the operationalization of the strategy document should not be regarded as static but as a continuous process.
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**Donor contributions**

118. The Committee thanked the Programme for the issue paper on donor contributions which had helped to clarify many of the issues raised at the last MAC, especially the proportion of specified and unspecified funds. It noted with satisfaction that DAP planned to make every effort to broaden its donor base.
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**Role of the private sector**

119. The Committee welcomed the contribution of the issue paper prepared by the Programme to the discussion of the role of the private sector. It emphasized that this was a very complex issue, which was influenced by the characteristics of particular countries and which warranted further consideration. The Committee proposed that a multidisciplinary working group could assist DAP to take the matter further and, in particular, to prepare and review case studies of national experience. The Committee emphasized the complementarity of the public and private sector, and the centrality of issues of access and equity in the interests of public health. It stressed the need for a continued regulatory and monitoring role for government, in all aspects of pharmaceutical production, distribution, marketing and use. DAP and other organizations had an important supporting role to play in this area.
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**Selection of theme for detailed discussion at MAC7**

120. The Committee requested that the issue of coordination and collaboration in national drug policy development, and the role of performance indicators, be the subject of the theme paper for discussion during MAC7.
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**Assistance to Eastern Europe and the Republics of the former Soviet Union**

121. The Committee welcomed the contribution of the issue paper prepared by the Programme to the discussion of assistance to Eastern Europe and the Republics of the former Soviet Union. It considered that the issues surrounding this had been well covered in the paper which provided guidance for future assistance in this area. The Committee concluded that DAP's global mandate qualified it to play an important role in assistance to CCEE and NIS, particularly with respect to technical issues and policy development.
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**Representatives from:**

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Division of Diarrhoeal and Acute Respiratory Disease Control \*

Division of Information System Management \*

Global Programme on Vaccines \*

Office of Publications \*

Programme for the Prevention of Blindness \*

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\* Unable to attend

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**List of Documents**


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<b>Reference</b>	<b>Title</b>	<b>Agenda item</b>
DAP/MAC(5)/93.9	Report of the fifth meeting of the Management Advisory Committee	Item 4
DAP/MAC(6)/94.1	Provisional list of documents	-
DAP/MAC(6)/94.2, Rev.1	Draft agenda	Item 3
DAP/MAC(6)/94.3	Provisional list of participants	-
DAP/MAC(6)/94.4	Report of the Biennium 1992-1993	Item 5
DAP/MAC(6)/94.5	Financial Report of the Biennium 1992-1993	Item 5.2
DAP/MAC(6)/94.6	Proposed Programme Plan and Budget for 1994-1995	Item 6
DAP/MAC(6)/94.7	A draft outline for the preliminary proposed programme budget for 1996-1997	Item 7
DAP/MAC(6)/94.8	The Developing Role of the Private Sector in Health Care and Provision of Drugs	Item 11
DAP/MAC(6)/94.9	Themes for further detailed discussions during meetings of the Management Advisory Committee	Item 12
DAP/MAC(6)/94.10	Issue paper on assistance to Eastern Europe and the Republics of the Former Soviet Union	Item 13
DAP/MAC(6)/94.11	Issue paper on donor contributions: specified/unspecified	Item 10
WHO/DAP/94.4	DAP Future Strategy	Item 9
(unnumbered)	Implementation of WHO's Revised Drug Strategy	Item 8

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 Agenda
 

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	Reference documents
1. Opening of the meeting	-
2. Election of Rapporteur	-
3. Adoption of draft agenda	DAP/MAC(6)/94.2, Rev.1
4. Report of the fifth meeting of the Management Advisory Committee	DAP/MAC(5)/93.9
5. Report of the biennium 1992-1993	DAP/MAC(6)/94.4
5.1 Report on DAP activities in 1992-1993	DAP/MAC(6)/94.4
5.2 Financial report of 1992-1993	DAP/MAC(6)/94.5
6. Proposed programme for the biennium 1994-1995	DAP/MAC(6)/94.6
6.1 Proposed plan of activities for 1994-1995	DAP/MAC(6)/94.6
6.2 Proposed budget for 1994-1995	DAP/MAC(6)/94.6
7. DAP's outline for the WHO proposed programme budget for the financial period 1996-1997	DAP/MAC(6)/94.7
8. Implementation of WHO's Revised Drug Strategy: the rational use of drugs	(unnumbered)
9. Future Strategy: Action Programme on Essential Drugs	WHO/DAP/94.4
10. Issue paper on donor contributions: specified/unspecified	DAP/MAC(6)/94.11
11. Theme for detailed discussion during MAC6: role of the private sector, including implications for financing and coordinating of activities	DAP/MAC(6)/94.8
12. Selection of theme for detailed discussion at MAC7	DAP/MAC(6)/94.9
13. Issue paper on implications for assistance to Eastern European countries	DAP/MAC(6)/94.10
14. Management Advisory Committee	-
14.1 Date and place for the next meeting	-
15. Other matters, as relevant	-

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