TENTH MEETING

Friday, 22 January 2010, at 09:15

Chairman: Dr S. ZARAMBA (Uganda)

1. PROGRAMME AND BUDGET MATTERS: Item 5 of the Agenda

Eleventh General Programme of Work, 2006–2015: Item 5.1 of the Agenda (Documents EB126/3 and EB126/22)

Dr DAHL-REGIS (Bahamas), speaking in her capacity as Chairman of the Programme, Budget and Administration Committee, reported briefly on the Committee's discussion of the subitem as set forth in paragraphs 7 to 10 of document EB126/3. The Committee had suggested a further review of the indicators for use in monitoring and assessing implementation of the Eleventh General Programme of Work, 2006–2015, with the addition of new indicators where necessary, and had asked the Secretariat to provide details on how Member States would be involved in the assessment. The Committee had recommended that the Board should note the report contained in document EB126/22.

Mr TSESHKOVSKIY (adviser to Dr Starodubov, Russian Federation) requested clarification of paragraph 14 of the report.

In response, Dr JAMA (Assistant Director-General) explained that paragraph 14 reflected the conclusion reached, after review and internal discussion, that the Eleventh General Programme of Work remained relevant to the work of the Organization and, therefore, to the Medium-term strategic plan 2008–2013 and the Programme budget 2010–2011.

The Board took note of the report.

2. FINANCIAL MATTERS: Item 6 of the Agenda

Scale of assessments: Item 6.1 of the Agenda (Documents EB126/3 and EB126/23)

Dr DAHL-REGIS (Bahamas), speaking in her capacity as the Chairman of the Programme, Budget and Administration Committee, summarized the Committee's discussion of the subitem as set forth in paragraphs 18 and 19 of document EB126/3. The Committee had recommended that the Board should propose that the Sixty-third World Health Assembly adopt the proposed scale of assessments as contained in document EB126/23.

Ms RUIZ VARGAS (Mexico)[1] voiced concern over the increase in her country's assessed contribution under the proposed new scale. She emphasized that her Government was not opposed to supporting international organizations financially, but noted that the global financial crisis and the influenza pandemic had had a severe impact on the national economy. Recovery had been slow and

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

capacity to cover the country's contributions to all organizations had been severely compromised. Mexico would have considerable difficulties in contributing a greater amount to WHO, particularly as its assessed contribution to PAHO had also recently increased. She requested that countries whose assessed contributions were due to increase should be offered an adjusted payment schedule, as had been done in the past, that would mitigate the effect of those increases.

The DIRECTOR-GENERAL, noting comments made by some Committee members on the late distribution of the new scale of assessments, explained that WHO had not received notification of the adoption of the new scale in time to send the report to countries before the current session of the Board. However, the Secretariat would provide, as soon as possible, a comparison for individual countries between what they were paying currently in assessed contributions and what they would be paying under the new scale to be applied in 2011.

She recognized that some countries would be paying more than before and, inevitably, difficulties would arise in adhering to the proposed new scale. Although the scale itself could not be changed, the Secretariat was willing to discuss payment schedules with any Member State for which such problems arose, with a view to enabling all countries both to fulfil their obligations to the Organization and to maintain their voting rights. She appealed to those Member States due to contribute less under the proposed scale to continue paying, if possible, the same amount as before through a combination of assessed and voluntary contributions. Ideally, the latter would be in the form of core voluntary contributions.

The CHAIRMAN took it that the Board wished to recommend to the Sixty-third World Health Assembly that it should adopt the proposed scale of assessments as set out in document EB126/23.

It was so decided.

3. MANAGEMENT MATTERS: Item 7 of the Agenda

Safety and security of staff and premises and the Capital Master Plan: Item 7.1 of the Agenda (Documents EB126/3 and EB126/24)

Dr DAHL-REGIS (Bahamas), speaking in her capacity as the Chairman of the Programme, Budget and Administration Committee, reported briefly on the Committee's discussion of the item as set forth in paragraphs 20 to 23 of document EB126/3, noting that the Committee had requested further elaboration on financing options for capital expenditure and recurrent costs, including detailed assessments of possible mechanisms and their implications. There had been particular interest in the integration of the proposed mechanisms into the programme budget and the consequent impact on technical programme delivery. The Secretariat had agreed to provide those details in time for their consideration by the Sixty-third World Health Assembly.

Ms ROCHE (New Zealand) said that ensuring stable funding for staff safety and security improvements and for the Capital Master Plan should be a priority and be better reflected in future planning and budgeting. A financing mechanism should be developed that would give WHO the flexibility both to respond to urgent needs and to fund longer-term improvements.

Dr KÖKÉNY (Hungary), voicing concern at the deterioration of staff safety and security conditions in recent years, expressed strong support for the Director-General's proposal to establish a centralized trust fund, as described in document EB126/24.

Mr BRUCHEZ (Switzerland)[1] expressed support for the proposal to establish a specific fund to finance building maintenance and renovation, but stressed that such a fund must be sustainable and ensure regular, long-term provision of funds. He suggested that, for example, WHO should set aside, particularly for its headquarters, an annual allocation amounting to 1% of the fire insurance value of the building. Establishing a centralized trust fund and a sustainable financing mechanism would not, however, solve the problem of finding funding for urgent capital works. The Secretariat should estimate the amount needed for such works and seek an ad hoc funding solution.

Sir LIAM DONALDSON (United Kingdom of Great Britain and Northern Ireland) pointed out that WHO was the only United Nations organization that did not have a programme budget allocation for safety and security. He noted the proposal for the establishment of a centralized trust fund to provide more sustainable funding but maintained that there should be discussion of other options before the matter was taken up by the Health Assembly. In particular, the possibility of providing funding directly from the regular budget rather than through a separately managed trust fund should be explored.

Ms BLACKWOOD (United States of America)[1] agreed that the regular budget should include allocations for safety and security expenditures, but stressed that such expenditures should be distributed evenly across all sources of funding. She looked forward to reviewing additional financing options at the Health Assembly.

Dr MOHAMED (Oman) acknowledged that the safety and security of the staff was extremely important but pointed out that the resources available through the regular budget were limited and that allocations to safety and security would reduce the funds available for technical cooperation programmes. He asked whether it would be possible to use some of the US$ 1600 million carried forward from previous financial periods, mentioned in paragraph 14 of document EB126/3.

Mr ALLO (adviser to Mr Houssin, France) agreed on the importance of the item and endorsed the comments made by the representative of Switzerland on the maintenance of WHO's buildings. The Secretariat should be requested to prepare a report for the Health Assembly outlining various possible options for mobilizing the necessary funding in the short and long term from both the regular budget and extrabudgetary resources. Consideration might also be given to amending the Financial Regulations to allow the Director-General more flexibility to take appropriate action in relation to safety and security expenditures.

Ms BILLINGS (alternate to Dr Dodds, Canada), voicing support for the Director-General's proposal to set up a centralized trust fund, said that that approach would not resolve all the immediate security concerns; however, there was an urgent need to begin the initial "catch-up" work, using a phased approach, and to set the stage for eventually dealing with such expenditures through the regular budgeting process. The Secretariat should continue to provide detailed information about the situation, and, as soon as possible, prepare estimates of the amounts that would be required from assessed and voluntary contributions.

Dr JAMA (Assistant Director-General) acknowledged the concern that WHO was not fully compliant with the United Nations Minimum Operational Security Standards, and that WHO staff members had lost their lives in the field as the security situation had deteriorated. There was clearly a need to enhance the protection of staff and premises. He confirmed that there was no regular budget allocation for security and safety, and detailed cost estimates had not yet been provided. The Secretariat was currently working on the estimates and they would be included, together with

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

additional options for sustainable security and safety financing mechanisms, in the report to the Health Assembly. The regular budget represented only around 20% of WHO's total budget, and there was therefore a need to look at the distribution of costs between the regular budget and voluntary resources, as had been noted. However, earmarking of many voluntary contributions reduced flexibility. The report to the Health Assembly would also include detailed information on the Capital Master Plan as a whole, including expenditures required for WHO's buildings in Geneva and the regions. He thanked the Government of Switzerland for its continued support as the host country for WHO headquarters and for the resources it had approved for perimeter protection.

The DIRECTOR-GENERAL, adding her thanks to the Swiss Government, noted that WHO was operating in about 150 countries, in some of which the exposure of staff members to risk was high. WHO was providing essential humanitarian assistance in critical situations, however, and she intended to maintain WHO's presence at country level, as she believed that to be the wish of Member States. Nevertheless, in her view, Member States must balance that wish with their duty, as the employers of WHO staff, to protect staff adequately and to cover the cost of that protection, bearing in mind that relocation or evacuation of staff in emergencies also entailed significant expense. There was an immediate shortfall in funding, which included a US$ 6 million increase in contributions to the United Nations Security Management System and in addition the costs of serious maintenance needed in WHO buildings. The Secretariat would continue to examine different options for establishing longer-term, sustainable and transparent financing mechanisms, and for separating capital costs from those for security and safety, and would report to the Health Assembly. The regular budget was limited and, if additional calls were made on it, there would have to be reductions in allocations to other activities.

The CHAIRMAN invited the Board to take note of the request by the Programme, Budget and Administration Committee that financing options for capital expenditure and recurrent costs should be further elaborated, to include detailed assessments of possible mechanisms and their respective implications, and that the information should be submitted to the Sixty-third World Health Assembly for consideration.

It was so decided.

Appointment of members of the Independent Expert Oversight Advisory Committee: Item 7.2 of the Agenda (Documents EB126/3 and EB126/25)

The CHAIRMAN recalled that, in resolution EB125.R1, the Board had requested the Director-General to propose candidates for membership of the new Independent Expert Oversight Advisory Committee. The Secretariat's report on that action was contained in document EB126/25.

Dr DAHL-REGIS (Bahamas), speaking in her capacity as the Chairman of the Programme, Budget and Administration Committee, said that the Committee had noted that the screening process had been thorough and that the selection had been strict. It had also noted an observation in respect of consideration of the geographical balance in that selection. The Committee had endorsed the Director-General's proposal to the Board for the selection of the five members of the new Committee.

The DIRECTOR-GENERAL, expressing appreciation for the guidance on the item provided previously by Member States, recalled the terms of reference adopted for the new Committee (annexed to the report). The criteria for the composition of the Committee included, first and foremost, proven professional experience and competence, balanced representation of public- and private-sector experience, geographical and gender balance to the extent possible, and provision of services without payment. Of the 150 applicants received by the Secretariat, 140 responded to advertisements and 10 had been proposed by Member States; 17% were women and 21% were from developing countries. In the future, it was to be hoped that more women and candidates in developing countries would apply.

Candidates had been assessed internally in a robust and transparent process, which had been verified by an external independent company, since WHO did not have the requisite expertise to assess all aspects of the candidates' financial and risk management experience. That exercise had produced a list of 40 suitable candidates. It had proved a considerable challenge to select just five from the list. A relatively even gender balance had been achieved: two of the five proposed members were women. Every effort had been made also to achieve geographical balance, but it had been impossible to ensure representation of all six WHO regions because there were only five Committee positions. The Board might wish to consider increasing that number in the future with a view to achieving representation of all regions. Membership of the Committee would rotate and there would thus be a chance for candidates from currently under-represented countries and regions to be considered. She sought the Board's endorsement of the proposal, subject to which she would convene the first meeting of the Committee as soon as possible so that its work could begin before the forthcoming Health Assembly. The Committee would elect a chairman from among the five members.

Dr LUKITO (adviser to Dr Sedyaningsih, Indonesia) welcomed the proposal of a candidate from Thailand, a Member State of the South-East Asia Region, but expressed remaining concern about equitable geographical representation, as no candidate from the African or Eastern Mediterranean regions had been proposed. He understood the difficulties faced in making the selection but asked whether it was possible to include a member from at least one of those regions.

Sir Liam DONALDSON (United Kingdom of Great Britain and Northern Ireland) recognized the concerns regarding geographical balance, but favoured accepting the membership proposed, as the selection process described by the Director-General appeared to have been exhaustive, fair and strongly based on merit. With a view to achieving better geographical representation for the Committee in future, and indeed for other committees, it might be appropriate to identify, and endeavour to increase, the number of submissions of candidatures from under-represented regions.

The CHAIRMAN observed that the Board had approved a five-member composition of the Committee,[1] well aware that WHO had six regions. The intention had been that membership should be based not on political representation, but on competence.

Dr MOHAMED (Oman) said it was not clear to him whether the number of Committee members was to be increased in the next round or whether the figure of five was immutable. He observed that the proportion of candidates from developing countries equated to one in five members of the Committee.

The DIRECTOR-GENERAL encouraged the Board to agree to the five candidates proposed so that the Committee could begin its important work of ensuring that the Organization was run properly. As the process evolved, it would be up to Member States, in the light of operational experience, to provide the Secretariat with further instructions. In the meantime, the Secretariat had done its best to work within the boundaries established by the current terms of reference.

Dr DAHL-REGIS (Bahamas), speaking in her capacity as the Chairman of the Programme, Budget and Administration Committee, said that the membership of five could not currently be changed. The Committee's mandate was clear: to be an independent body to review and oversee the work of the Organization. The Programme, Budget and Administration Committee had discussed the matter at length, and a member speaking on behalf of the African Region had indicated that he was satisfied that the candidate selection process had been transparent.

[1] Resolution EB125.R1.

Dr REN Minghui (China)[1] acknowledged that the Secretariat had done its best to maintain a regional balance and that the candidates had been selected on the basis of their independence and personal competence. Nevertheless he expressed concern about the outcome of the selection process. It was to be hoped that in the future a better regional balance and developing country representation would be assured. He expressed his support for the current five candidates.

The CHAIRMAN said that in the absence of further comments he took it that the Board wished to appoint the candidates proposed by the Director-General as members of the Independent Expert Oversight Advisory Committee.

It was so decided.[2]

Method of work of the governing bodies: Item 7.3 of the Agenda (Documents EB126/3 and EB126/26)

Dr DAHL-REGIS (Bahamas), speaking in her capacity as the Chairman of the Programme, Budget and Administration Committee, summarized the Committee's discussion of the item as set forth in paragraphs 27 and 28 of document EB126/3. The Committee had recommended that the Board should provide guidance on the proposals contained in the report, and that it should adopt the draft resolution contained in document EB126/26.

Dr KÖKÉNY (Hungary) said that the effectiveness of the work of the governing bodies needed to be improved urgently. He agreed with the proposals of the Committee, but wished to make some more radical suggestions. Since it had proved difficult and at times counterproductive to include on the provisional agenda of the Health Assembly items that had not been examined by the Executive Board, a rule should be introduced allowing the inclusion of such items only if they were of the utmost urgency. Further, he questioned whether it was really necessary to re-examine at the Health Assembly topics that had been fully discussed and accepted by the Executive Board. Better use could perhaps be made of time and resources by selecting a few important and topical issues each year for full discussion by the Health Assembly, leaving the others for the Board to decide. The proposal was sensitive, but might be considered for the medium term.

Ms BILLINGS (alternate to Dr Dodds, Canada) supported the Secretariat's efforts to foster more efficient and effective governance processes within WHO. Harmonization of the Board's Rules of Procedure with those of the Health Assembly and adherence to the good governance practices highlighted in the report would help to achieve that objective. The meeting of the Programme, Budget and Administration Committee the previous week had exemplified good chairmanship and effective and efficient management of the agenda. The inclusion of more strategic items on the provisional agenda of future meetings of that Committee might help to improve the effectiveness of Board meetings.

Dr MUÑOZ (Chile) supported the recommendations in the report but argued that they could be more strict. For example, the Organization might adopt the practice of the Human Rights Council and other organizations of not only closing the list of speakers on the first day but also of not allowing any more statements than could be accommodated within a pre-established period of time. It was simply not acceptable to delay the work of a body because there were still speakers left on the list after the time scheduled for discussion of an item had elapsed, particularly as the so-called "discussion" was often just an opportunity for heads of delegation to read out a prepared statement and have their photograph taken. Time should be limited even if that meant that some speakers could not take the

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

[2] Decision EB126(1).

floor. Another option would be to limit the number of delegates who could speak on behalf of country groups in any given year, for example, by allocating to each region a certain number of speaking slots according to the number of members for countries in that region on the Executive Board, it being understood that the designated countries would be obliged to speak not just on their own behalf, but on behalf of the group.

Dr WATT (alternate to Sir Liam Donaldson, United Kingdom of Great Britain and Northern Ireland) welcomed the report as an important starting point towards enhancing the efficiency of the work of the governing bodies and endorsed the suggestion made by the member for Canada.

Mr CHAWDHRY (adviser to Ms Sujatha Rao, India), supported by Dr TAKEI (adviser to Dr Omi, Japan), endorsed the statements by the members for Canada, Chile and the United Kingdom. More attention must be given to time management. The item under discussion repeatedly came up for debate, yet members failed to exercise the necessary self-discipline. A time cap should be considered for all agenda items. Member States should identify the priority items on which they wished to comment and refrain from making a statement on every item. If there was insufficient time for a Member State to speak on an item, it could ask another country to express its views. Ceremonial business such as the ratification of the appointment of Regional Directors should be considered to be carried by acclamation and not allowed to take up an entire half-day of meeting time as in the current session of the Board.

Ms ROCHE (New Zealand) endorsed the suggestion made by the member for Canada. As an outgoing member of the Board, she offered to share her views on ways of improving the methods of work of the governing bodies.

Mr SAMRI (Morocco)[1] cautioned against the introduction of speakers' lists with a requirement that Member States sign up in advance, a practice that had caused problems in other organizations. Moreover, the time allowed for a statement in most international organizations was five minutes. He said that he could not accept that a delegate could deliver a worthwhile statement in three minutes. Limiting the number of agenda items would be a more effective means of streamlining the governing bodies' work than limiting the speaking time and number of speakers.

Dr YOUNES (Office of Governing Bodies) said that it was clear that Board members wished to streamline the work of the governing bodies. Success in that endeavour would depend largely on Member States themselves, however. The Secretariat could not limit the number of agenda items or change the periodicity of reporting because reporting requirements were set by resolutions and generally extended over long periods. Hence agendas tended to become ever longer. The Board could assist the Secretariat by not adding supplementary agenda items except in cases of real urgency. The proposal that certain topics should be decided by the Board and not forwarded for consideration by the Assembly would certainly serve to enhance efficiency but was not a straightforward matter. The proposal relating to the list of speakers would apply to the general debate in plenary. Different rules clearly had to apply to the discussion of technical items in the committees. Noting the calls for further reflection and discussion, he said that the Secretariat would consult with Board members and others, also taking into account the experience of other agencies, before preparing a new report for consideration by the forthcoming Health Assembly.

Mr BURCI (Legal Counsel) said that he took comments made by members of the Board as endorsement of the proposals contained in the report. As had been observed, self-discipline was an important factor in agenda management. The debate on the methods of work of the governing bodies

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

recurred cyclically because of the dichotomy between Member States' wish to pursue their own policy aims through the governing bodies and the need to work as economically and efficiently as possible. The draft resolution contained in document EB126/26 offered the Board an opportunity to take concrete action right away, pending discussion of the topic at the forthcoming Health Assembly on the basis of a revised report that would take into account comments by Board members.

The CHAIRMAN stressed the need for self-discipline in discussing items on the Board's agenda. Speakers must make every effort to respect time limits and to make their arguments clearly and concisely, and he welcomed the approach taken by some regional groups to designate one member to speak on their behalf. The Board should be a forum for discussing and deciding on technical and policy issues, rather than for political debate.

The DIRECTOR-GENERAL emphasized that the role of the Secretariat was to implement the decisions and follow the guidance of Member States. The Secretariat could share with Member States its own experience and that of other organizations within the United Nations system in trying to establish efficient and effective methods of work for the Organization's governing bodies, but it fell to Member States to act on that information in order to render the Board's working methods more efficient. However, changes in the membership of the Board and political changes within Member States meant that decisions taken by members at one session might be reversed at a future session, thus restarting the cycle of rising frustration with the functioning of the governing bodies.

The CHAIRMAN suggested that orientation should be provided for all new Board members, so that they clearly understood how the Board's business was to be conducted. He invited the Board to consider the draft resolution contained in paragraph 24 of document EB126/26.

The resolution was adopted.[1]

4. STAFFING MATTERS: Item 8 of the Agenda (continued)

Appointment of the Internal Auditor: Item 8.3 of the Agenda (Document EB126/32)

The CHAIRMAN drew attention to the report, which contained an update on progress in appointing a new Director of the Office of Internal Oversight Services in the Secretariat. A copy of the curriculum vitae of the selected candidate had been provided to each Board member. Paragraph 112.2 of Rule XII (Internal Audit) of the Financial Rules required the Director-General to consult with the Board before appointing of the head of the Office and that he or she be technically qualified.

There being no comment, he took it that the Board wished to take note of the report and the appointment.

It was so agreed.

Human resources: annual report: Item 8.4 of the Agenda (Documents EB126/3, EB126/33, EB126/33 Add.1 and EB126/33 Add.1 Corr.1)

Dr DAHL-REGIS (Bahamas), speaking in her capacity as the Chairman of the Programme, Budget and Administration Committee, reported briefly on the Committee's discussion of the subitem as set forth in paragraph 29 of document EB126/3, noting that the Committee had emphasized the need for harmonization with developments in the United Nations common system and had endorsed

[1] Resolution EB126.R8.

efforts to identify talent and implement sustained performance management strategies. The Committee had recommended that the Board take note of the reports of the Secretariat contained in documents EB126/33 and EB126/33 Add.1.

Dr REITENBACH (adviser to Dr Seeba, Germany), commending the progress made in human resources management, said that a good, efficient and adaptable staff mobility scheme not only served the Organization's interests but was also important for career advancement and staff motivation. He welcomed the streamlining of recruitment, noting that the efficiency of any organization depended greatly on its ability to fill staffing gaps quickly. She also highlighted the importance of balanced geographical representation in all professional and, in particular, higher category posts across the Organization and expressed satisfaction at the steady narrowing of the gender gap.

Dr WATT (alternate to Sir Liam Donaldson, United Kingdom of Great Britain and Northern Ireland) expressed appreciation of the work of the new Director of the Department of Human Resources Management and encouraged the Secretariat to finalize work on a full human resources strategy. Endorsing the comments of the member for Germany, she drew particular attention to the issue of equal opportunity, in both recruitment and talent management, and the need for a robust performance management system.

The CHAIRMAN, praising the work of the new Director, Department of Human Resources Management, invited the Board to take note of the reports.

The Board took note of the report.

Confirmation of amendments to the Staff Regulations and Staff Rules: Item 8.5 of the Agenda (Documents EB126/3, EB126/39 and EB126/39 Add.1)

The CHAIRMAN invited the Board to consider the two draft resolutions set out in paragraph 10 of document EB126/39. The Programme, Budget and Administration Committee had recommended that the Board should adopt the two draft resolutions.[1]

The resolutions were adopted.[2]

Statement by the representative of the WHO staff associations: Item 8.6 of the Agenda (Document EB126/34)

Mr BAILEY (representative of the WHO staff associations), highlighting key issues from the statement contained in document EB126/34, drew attention to the need for maximum attention to staff safety and security, both at headquarters and in the field; the need for transparency and accountability; the possibility of a leave of absence for staff members running for elected office within the Organization in order to avoid potential conflicts of interest; the staff associations' wish for a third-party evaluation of the Global Management System; and the effect of the global financial crisis on WHO's work, with particular reference to the need for flexibility in managing human and financial resources, including staff mobility and rotation. He welcomed the constructive relationship between staff and managers within the Organization and reaffirmed the dedication of WHO staff members to working in and with Member States to improve the health of their populations.

[1] See document EB126/3.

[2] Resolutions EB126.R9 and EB126.R10.

The DIRECTOR-GENERAL, affirming that WHO's staff were its foremost asset, agreed that the constructive relationship between staff and managers was conducive to progress on staff matters and to the solution of difficult problems, such as the issue of staff security and safety. On the issue of staff rotation and mobility, it was necessary to strike an appropriate balance that took account of the specific nature of different posts; some simply did not lend themselves to rotation. She encouraged staff members to join the associations and thanked the representative for his support.

Mr SAMRI (Morocco)[1] commended the work of the Organization's staff and the sacrifices they made, particularly in emergency situations such as the aftermath of the recent earthquake in Haiti. Welcoming the generally positive relations between staff and management, he underscored the need to take the staff's safety and security concerns seriously.

The Board took note of the statement by the representative of the WHO staff associations.

Report of the International Civil Service Commission: Item 8.7 of the Agenda (Documents EB126/3, EB126/35 and EB126/INF.DOC./2)

The Board took note of the report.

5. TECHNICAL AND HEALTH MATTERS: Item 4 of the Agenda (continued)

Availability, safety and quality of blood products: Item 4.16 of the Agenda (Documents EB126/19, EB126/19 Add. 1 and EB126/19 Add.2)

The CHAIRMAN drew attention to the report contained in document EB126/19, to a draft resolution (which had been considered by the Board at its 125th session[2]) and its associated financial and administrative implications, contained in documents EB126/19 Add.1 and EB126/19 Add.2 respectively, and to an amended version of the draft resolution submitted by the member for Hungary on behalf of the European Union, which read:

> The Sixty-third World Health Assembly,
>
> Recalling resolution WHA58.13 on blood safety: proposal to establish World Blood Donor Day and preceding related resolutions since resolution WHA28.72 on utilization and supply of human blood and blood products, which urged Member States to promote the full implementation of well-organized, nationally coordinated and sustainable blood programmes with appropriate regulatory systems and to enact effective legislation governing the operation of blood services;
>
> **Recognizing that sufficiency in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply ~~based on voluntary, non-remunerated blood donation~~, are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population; [based on comments by Bangladesh, Japan, Nigeria, New Zealand and Republic of Moldova[2]]**

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

[2] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

Conscious that plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines[1] and of the need to facilitate access to these products by developing countries;

Concerned by the unequal access globally to blood products, ~~including~~ **particularly** plasma-derived medicinal products, leaving many patients in need of transfusion and with severe congenital and acquired disorders without adequate treatment;

Aware that a major factor limiting the global availability of plasma-derived medicinal products is an inadequate supply of plasma meeting internationally recognized standards for fractionation;

Bearing in mind that treatment using labile blood components is gradually being included in medical practice in developing countries and that thereby increased quantities of recovered plasma should become available for fractionation into plasma-derived medicinal products **to meet their needs**;

Concerned that in developing countries, blood components separation technology and fractionation capacity are lacking, and because of insufficient regulatory controls and failure to implement appropriate practices in blood establishments, plasma from developing countries is often unacceptable for contract fractionation, with considerable wastage of plasma as a result;

Convinced that assuring the suitability of plasma for fractionation requires the establishment of a nationally coordinated and sustainable plasma programme within a properly organized, legally established and regulated national blood programme;

Recognizing that the capacity to collect plasma is limited and would not suffice to produce enough essential medicines to cover global needs, it is essential that all countries have local capacity to collect plasma of acceptable quality and safety from voluntary and unpaid donations in order to meet their needs;

Convinced that fractionation should be set up as close to the source as possible, and that, where national plasma fractionation capacities are lacking, there should be an option for supply of fractionation capacity in other countries, it should be ensured that the supply of plasma derived medicinal products can be made available to meet local needs in the country of the plasma supplier;

Recognizing that access to information about strategies to ensure supplies of blood products sufficient to meet demand, effective mechanisms of regulatory oversight, ~~and~~ technologies to ensure the quality and safety of blood products, guidelines on the appropriate clinical use of blood products and the risks of transfusion have become more and more necessary;

Bearing in mind that voluntary and non-remunerated blood donations can contribute to high safety standards for blood and blood components and being aware that the safety of blood products depends on testing of all donated blood for transfusion-transmissible infections, and correct labelling, storage and transportation of ~~blood and~~ blood products;

Bearing in mind that patient blood management means that before surgery every reasonable measure should be taken to optimize the patient's own blood volume, to minimize the patient's blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia following the WHO's guide for optimal clinical use (three pillars of patient blood management);

Recognizing that excessive and unnecessary use of transfusions, and plasma derived medicinal products, unsafe transfusion practices and errors (particularly at the patient's

[1] The WHO Model List of Essential Medicines identifies individual medicines that together could provide safe and effective treatment for most communicable and noncommunicable diseases. This List includes plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide (http://www.who.int/medicines/publications/essentialmedicines/en/index.html).

bedside) seriously compromise patient safety; [based on comments by Bangladesh, Chile, Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

Concerned that unsafe and/or poor-quality blood products can render patients vulnerable to avoidable risk if the blood programmes are not subject to the level of control now exercised by experienced national or regional regulatory authorities;

Alarmed that patients in developing countries continue to be exposed to the risk of preventable transfusion-transmitted infections by blood-borne pathogens such as hepatitis B virus, hepatitis C virus and HIV;

~~Concerned~~ **Observing [Nigeria[1]]** that the increasing mobility of populations is contributing to increased risk of transmission of infectious diseases worldwide; **[deletion proposed by Brazil and Paraguay[1]]** [**deletion supported by EU**]

Noting the increasing movement across boundaries of blood products and blood safety related in vitro diagnostic devices, together with their rapid development and introduction into health-care systems of both developed and developing countries;

Recognizing the value of international biological reference materials (WHO International Standards) for the quality control of blood products and related in vitro diagnostic devices for detection of known and emerging blood-borne pathogens;

Convinced that traceability of all stages of the preparation of blood products, from the donor to the recipient and vice versa, is essential to identify risks, particularly the transmission of pathogens and transfusion reactions, and to monitor the efficacy of corrective measures aiming to minimize such risks;

Convinced that ~~the whole chain of processes in the production of plasma-derived medicinal products, i.e.~~ **good practices need to be implemented for** recruiting voluntary, non-remunerated healthy blood and plasma donors from low-risk donor populations~~,~~ **and** testing of all donated blood for transfusion-transmissible pathogens, **and that the whole chain of processes in the production of blood products, i.e.** correct processing, labelling, storage and transportation ~~of blood components and plasma-derived medicinal products~~ needs to be covered by **relevant,** reliable quality assurance procedures~~, compliant with good manufacturing practices~~;

Recognizing that stringent regulatory control is vital in assuring the quality and safety of blood products, as well as of related in vitro diagnostic devices, and that special effort is needed to strengthen globally the technical capacity of regulatory authorities to assure the appropriate control worldwide;

Recalling previous resolutions of the Health Assembly mentioning the vital need to strengthen blood establishments and ensure the quality, safety and efficacy of blood products.

1. URGES Member States:[2]

(1) to take all the necessary steps to establish, implement and support nationally coordinated, efficiently managed and sustainable blood and plasma programmes **according to the availability of resources**;

(2) to take all the necessary steps to update their national legislation on the collection, testing, processing, storage, transportation and use of blood products and operation of regulatory authorities to ensure that regulatory control in the area of quality and safety of blood products meets internationally recognized standards;

(3) to establish quality systems, **for the processing of whole blood and blood components,** good manufacturing practices **for the production of plasma-derived medicinal products** and appropriate regulatory control; ~~for the production of blood components and plasma derived medicinal products.~~

[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

[2] And regional economic integration organizations, where applicable.

(4) to build human resource capacity through the provision of initial and continuing training of staff to ensure quality of blood services and blood products; [based on comments by India and Republic of Moldova[1]]

(5) to enhance the quality of evaluation and regulatory actions in the area of blood products and associated medical devices, including in vitro diagnostic devices;

(6) to establish or strengthen systems for the safe and rational use of blood products and to provide training for all staff involved in clinical transfusion, to implement potential solutions in order to minimize transfusion errors and promote patient safety, ~~and~~ to promote the use of autologous transfusion and patient blood management; [based on comments by Bangladesh, China, Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

(7) to ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma-derived medicinal products, including transmissions of pathogens.

2. REQUESTS the Director-General:

(1) to guide Member States to meet internationally recognized standards in updating their **legislation, national standards [based on comments by Chile and New Zealand[1]]** and regulations for effective control of the quality and safety of blood products and associated medical devices, including in vitro diagnostics;

(2) to advise and build capacity in Member States on leadership and management of blood supply systems in order to strengthen national coordinated and sustainable blood and plasma programmes; [based on comments by Chile and New Zealand[1]]

(3) to extend the support offered to Member States for developing and strengthening their national regulatory authorities and control laboratories so as to increase their competence in the control of blood products and associated medical devices, including in vitro diagnostic devices, and fostering the creation of regional collaborative and regulatory networks where necessary and appropriate;

(4) to ensure sustainable development and provision of international biological reference materials (WHO International Standards) for use in the quality control and regulation of blood products and related in vitro diagnostic devices;

(5) to improve access by developing countries to international biological reference materials and to the scientific information obtained in their validation in order to assure the appropriate use of these materials;

(6) to develop, provide and disseminate guidance and technical support to strengthen national **coordinated** blood and plasma programmes and **introduction of blood component separation and plasma fractionation technology, to meet local needs, [based on comments by Bangladesh[1]**] and promote effective regulatory oversight of blood services and implementation of good manufacturing practices in plasma-fractionation programmes, under the responsibility of regulatory authorities;

(7) to provide guidance, training and support to Member States on safe and rational use of blood products, ~~and~~ to support the introduction of autologous transfusion~~, and~~ safe transfusion practices and patient blood management; [based on comments by Bangladesh, China, Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

(8) to encourage research into new technologies for producing safe and effective blood substitutes; [based on comments by Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

(9) to inform regularly, at least every four years, the Health Assembly, through the Executive Board, on actions taken by Member States and other partners.

Dr KÖKÉNY (Hungary), speaking on behalf of the European Union, said that the candidate countries Turkey, Croatia and The former Yugoslav Republic of Macedonia, the countries of the Stabilisation and Association Process and potential candidates Albania, Bosnia and Herzegovina, Montenegro and Serbia as well as Ukraine, the Republic of Moldova, Armenia and Georgia also aligned themselves with his statement. He recalled that in the 1980s the European Union had had to learn hard lessons from massive transmission of serious viral diseases through blood. Since then, amendments to legislation, enhanced regulatory controls and development of scientific guidance and good practices had yielded high levels of quality and safety in blood products. Similar measures should be adopted by all countries. In particular, it was essential for developing countries to have local capacity to collect sufficient plasma of acceptable quality and safety from voluntary donors.

The aim of the amended draft resolution proposed by the European Union was two-fold: to emphasize continuing support for existing or emerging national blood systems with regard to supply, testing, processing, rational clinical use and patient blood management, and to advocate strongly local plasma collection and, when possible, local fractionation capacity. To those ends, the resolution encouraged Member States to amend their relevant legislation, strengthen regulatory oversight and enhance the capacity of their control authorities, and called on the Secretariat to support Member States by providing technical cooperation to enable them to meet international quality and safety standards for blood products and to strengthen their national regulatory authorities and control laboratories.

Dr AL HAJ HUSSEIN (alternate to Dr Said, Syrian Arab Republic), speaking on behalf of the Member States of the Eastern Mediterranean Region, observed that many of those countries suffered from a lack of blood supplies and blood products and from difficulties with blood safety. The Millennium Development Goals relating to reduction of child and maternal mortality and to control of HIV/AIDS and malaria could not be attained without improving the availability, safety and quality of blood products. That would require adoption of sound policies and appropriate strategies and the creation of the necessary framework within which they could be applied. A workshop had been held in Tehran during 2008 to seek ways of achieving those objectives. The workshop had focused on the establishment of new regulatory authorities, or the enhancement of existing ones, to take responsibility for monitoring the safety and quality of blood products. The countries of the Region looked forward to receiving support from the Secretariat in their efforts to improve their blood systems.

Mr PRASAD (alternate to Ms Sujatha Rao, India) said that amendments to legislation, enhanced regulatory control and scientific guidance, personnel training and technology transfer were needed in order to build capacity to produce sufficient supplies of safe blood products. WHO should take steps to ensure efficient use of plasma and should issue guidelines on proper synergy among the stages of blood collection, component separation, plasma preparation and production of therapeutic blood products. It should also give consideration to coordinating and facilitating technology transfer, training in and implementation of good manufacturing practices, and support for the establishment of plasma fractionation centres in developing countries. The Organization might also issue uniform guidelines on testing of plasma for bloodborne viruses and set harmonized safety and potency standards. It should establish a network of collaborating centres to facilitate and strengthen research and development activities and ensure availability of rare blood group antigens and antisera, and should promote cooperation between regulatory authorities with regard to compliance with good manufacturing practices and encourage the establishment of haemovigilance systems.

Dr DOS RAMOS (Sao Tomé and Principe), speaking on behalf of the Member States of the African Region, said that the challenges facing them with respect to availability, quality and safety of blood products included weak implementation of national transfusion policies, lack of human and financial resources, high demand for blood, high prevalence of bloodborne infections and heavy

reliance on paid family donors. With WHO's guidance, 45 countries of the Region had drawn up national blood transfusion policies and several had established a legal framework to support such policies. However, support was needed to speed up their implementation, which remained slow.

Through innovative strategies, such as the formation of clubs of young blood donors, voluntary unpaid donation had increased, but only 20 countries had reached the target of obtaining at least 80% of blood from voluntary unpaid donors. Screening of donated blood had improved significantly over the years, and currently 98% of transfused blood was tested for HIV, 96% for markers of hepatitis B virus infection and 84% for hepatitis C markers. Nevertheless, the risk of infection through blood transfusion remained higher in Africa than elsewhere. Forty-one countries had drawn up guidelines on the appropriate clinical use of blood, but countries needed support in order to provide training on their application. The countries of the Region also needed support in strengthening the infrastructure of their blood transfusion services and in implementing good manufacturing practices.

Dr LUKITO (adviser to Dr Sedyaningsih, Indonesia) expressed support for WHO's strategy for blood safety, which promoted the establishment of nationally coordinated blood transfusion services and emphasized collection of blood only from voluntary unpaid donors and high-quality screening and processing of blood and its rational use. The Indonesian National Blood Transfusion Council was working to implement WHO's strategy and to ensure that ethical principles were respected, both for donors and for recipients. The Secretariat should continue to support Member States in policy and programme development and capacity-building in order to improve the availability, safety and quality of blood products. He strongly supported the draft resolution.

Dr TAKAI (adviser to Dr Omi, Japan) commended the Organization's efforts and achievements in blood safety and expressed support for the resolution. He proposed two amendments: the word "sufficiency" in the second preambular paragraph should be replaced by "achieving self-sufficiency", and the phrase "with the aim of achieving self-sufficiency" should be added after "according to the availability of resources" at the end of paragraph 1(1). He encouraged the Secretariat to provide further technical support to Member States to strengthen their national blood and plasma programmes.

Ms ROCHE (New Zealand) proposed four amendments. At the end of the twenty-first preambular paragraph, which began "Convinced that good practices need to be implemented", the phrase "reliable quality systems based on the principles of good manufacturing practice" should be added. Secondly, the term "donor management" might be included in that paragraph, as a broad concept to include selection and counselling processes. In paragraph 1(2), she proposed the wording "to take all necessary steps to update their national legislation on donor assessment and deferral, collection, processing, storage, transportation and use of blood products, and operation of regulatory authorities to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards". In paragraph 1(6), she proposed that "the use of autologous transfusion" should be replaced by "availability of transfusion alternatives including, where appropriate, autologous transfusion". If that change were accepted, a similar one would also need to be made to paragraph 1(7).

The meeting rose at 12:30.