INTELLECTUAL PROPERTY, INNOVATION AND PUBLIC HEALTH AT WHO: A CHRONOLOGY

David G Legge
Posted 31 Aug 2013
Revised 10 Jan 2022

INTRODUCTION

Since 1994 (and the coming into force of the TRIPS (Trade Related Intellectual Property Rights) Agreement) there has been a dramatic strengthening of intellectual property (IP) protection with protection for product as well as process, increasing duration of protection and powerful new sanctions to encourage countries to adopt the new standards. (Scherer and Watal (2001) point out that many of today's developed countries excluded pharmaceutical products from patent protection until quite recently: Germany until 1968; Switzerland until 1977; Italy until 1978; Spain until 1992; Portugal until 1992; Norway until 1992; Finland until 1995, and Iceland until 1997.)

Also launched in 1994 was the NAFTA (North American Free Trade Agreement) which heralded a parallel drive, through the preferential trade agreements (PTA) pathway, for higher levels and wider scope of protection. Since the Cancun Ministerial Conference of the World Trade Organisation (and the deadlock in WTO negotiations) there has been a redoubling of effort into the negotiation of PTAs (such as the proposed Trans Pacific Partnership Agreement (TPPA), the US-EU Transatlantic Trade and Investment Partnership (TTIP), EU-India FTA) and tighter IP protection has been a constant feature of these.

Proponents for increasing IP protection, in particular the research based pharmaceutical manufacturers (RBPM) and their nation-state proxies, argue that it is necessary to support innovation.

Opponents to high levels of IP protection argue that:

- monopoly pricing (under patent protection) renders medicines unaffordable, especially for poor people and low and middle income country (L&MIC) governments; the abuse by RBPMs of their monopoly pricing power (for example with the prices for AIDS drugs determined on the basis of maximising revenues (as when revenue is maximised by higher prices for a smaller number of wealthier families) rather than ensuring access to treatment);
- that funding R&D on the basis of anticipated profit distorts investment in new medicines; manifest in lack of investment in diseases which mainly affect L&MICs and over investment in me-too modifications, disease-mongering therapeutics, and marginal end of life benefits; and
- that much of the profit garnered through monopoly pricing is misused in marketing with consequences in overuse, irrational use and antibiotic resistance.

The battle is being fought out in several different domains.

The RBPMs have sought to shore up their monopoly pricing powers by lobbying for higher levels of IP protection in PTAs and by attacking the use of generics, including through seizures in Europe, trade sanctions against countries using compulsory licensing and propaganda which conflates questions of IP with issues of quality, safety and efficacy. See SFC & QSE Chronology.

On the public health side there has been resistance to these strategies including defence of the use of generics and a drive to de-link R&D funding from sales revenues (and therefore IP protection), in particular through alternative ways of funding pharmaceuticals R&D.

These forces are engaging at different levels (global, regional, national), in different institutional settings (eg trade negotiation, public health conferences) and in different countries (eg USA, cf Thailand).

This note reviews decision making in and around the WHO with a focus on IP and innovation.

FROM TRIPS TO THE COMMISSION FOR IPRIPH

The TRIPS Agreement was adopted in 1994. This introduced longer periods of patent protection and required patents on product as well as process. Developing countries were given a 10 year grace period (to 2005) to bring their patent laws into conformity with TRIPS. TRIPS establishes certain principles which have to be reflected in patent law. There is some flexibility regarding details.

In 1997 a court case was brought by 30 international pharmaceutical companies, see CPT report (Consumer Project on Technology nd) against the government of South Africa alleging that its use of parallel importing was illegal in terms of South African legislation (as adopted to conform to TRIPS). At this time the RBPMs were selling a course of (branded) AIDS treatment in South Africa for $10,000 per year, while Cipla was selling such a course (generics) to MSF for $350 per year. Between 1998 and May 2001 the South African Treatment Action Campaign (Heywood 2009) generated national and international support for the South African government's position, demanding access to treatment and in 2001 the US government withdrew its political support for the drug companies (after ACTUP highlighted the issues in the context of the Al Gore presidential campaign). In May 2001 the drug companies withdrew their suit and agreed to pay the South African government's costs.

During the controversy there was a policy debate around the legitimacy of using TRIPS flexibilities (such as compulsory licensing, parallel importation and price controls) versus other strategies for access including drug donations, differential pricing and philanthropy. In April 2001 Dr Brundtland co-hosted a workshop in Oslo on differential pricing as a solution to price barriers in low income countries (WHO, WTO et al. 2001); essentially seeking encourage a more charitable approach by the RBPMs.

However, in December 2001 the Ministerial Council of the WTO, meeting in Doha, adopted the Doha Declaration on the TRIPS Agreement and Public Health (WTO Ministerial Council 2001) which stated (para 4):

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The Ministerial Declaration from the meeting declared (para 6):

We recognize that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the level it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same

conditions prevail, or a disguised restriction on international trade, and are otherwise in accordance with the provisions of the WTO Agreements.(WTO Ministerial Council 2001).

The Commission on Macroeconomics and Health (Commission on Macroeconomics and Health 2001) was drawing to a close at the same time (actually reported in December 2001) but in June 2001 one of its Working Groups Scherer and Watal (2001) published a paper exploring the use of compulsory licenses, parallel imports, and price controls, for ensuring affordable access to patented medicines in developing countries. It also reviewed the role of corporate charity (drug donations by research-based pharmaceutical companies) and the role of aid through intergovernmental and nongovernmental organizations.

The debate over access and pricing, the TRIPS flexibilities and the Doha Statement found its way onto the WHA56 Agenda (May 2003) with Secretariat report, A56/17. The WHA adopted resolution WHA56.27 which urged member states (MSs), inter alia, to:

- 1(2)…adapt national legislation to enable the full use of TRIPS flexibilities;
- 1(3)…maintain efforts to operationalize paragraph 6 of the Doha Declaration (enabling compulsory licensing for export);
- 1(4)…encourage research on diseases that affect developing countries;
- and requested the DG inter alia to:
- 2(1)…promote technology transfer;
- 2(2)…establish an expert inquiry into IPRs, Innovation and Public Health;
- 2(3)…monitor and analyse trade agreements.

The Commission into IPRs, Innovation and Public Health was established at the end of Dr Brundtland's period as DG and reported at the same Assembly as Dr Lee died and so was inherited by Dr Chan. It was commissioned to:

- Summarize the existing evidence on the prevalence of diseases of public health importance with an emphasis on those that particularly affect poor people and their social and economic impact;
- Review the volume and distribution of existing research, development and innovation efforts directed at these diseases;
- Consider the importance and effectiveness of intellectual property regimes and other incentive and funding mechanisms in stimulating research and the creation of new medicines and other products against these diseases;
- Analyse proposals for improvements to the current incentive and funding regimes, including intellectual property rights, designed to stimulate the creation of new medicines and other products, and facilitate access to them;
- Produce concrete proposals for action by national and international stakeholders.

First meeting of the Commission took place on 5-6 April 2004 (see). It reported progress to WHA57 (May 2004, see report on progress in A57/18) and requested an extension of time to submit its final report to the Executive Board in January 2006 instead of 2005 as originally envisaged. This was granted. Further progress was reported to EB116 (May 2005, see EB116/10) and the Report of the Commission (Commission on Intellectual Property Rights Innovation and Public Health 2006) was submitted to EB117 (Jan 2006).

The Commission on IP, Innovation and Public Health drew upon a taxonomy of disease which had been developed by the Macroeconomics Commission. The three types of diseases were:

- Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and Haemophilus influenzae type b (Hib), and examples of noncommunicable diseases abound (e.g. diabetes, cardiovascular diseases, and tobacco-related illnesses). Many vaccines for Type I diseases have been developed in the past 20 years but have not been widely introduced into the poor countries because of cost.
- Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries.
- Type III diseases are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially based R&D in the rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans.

FROM THE IGWG TO THE GSPOA

The report was considered at WHA59 (May 2006) which (in Resolution A59.24, p32) appointed an intergovernmental working group (IGWG) "to draw up a global strategy and plan of action (GSPOA) in order to provide a framework based on the Commission's recommendations, with a focus on research and development relevant to diseases that disproportionately affect developing countries."

The first meeting of the IGWG on PHI&IP was held in Geneva 4-8 Dec 2006 (see report of this session). A progress report (A60/27) was considered by WHA60 (May 2007) and Resolution WHA60.30 (page 107) was adopted. The second session of the IGWG commenced in Nov 2006 (Lancet 2007) and a progress report (Document EB122/12) was considered by the EB in Jan 2008..

The final report of the IGWG was presented to the WHA61 in May 2008, see Document A61/9. The chair of the IGWG reported on the proposed GSPA (report, p15 et seq) and a drafting committee was appointed to develop a resolution, to be chaired by Dr Viroj Tangcharoensathien. At the 11th meeting of committee A Dr Tangcharoensathien reported and tabled the draft resolution. There was a long debate over bracketed passages. In the end the Assembly adopted WHA61.21 (p31): … "the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property…". These 'agreed parts' included a commitment "to establish urgently a results-oriented and time-limited expert working group [EWG] to examine current financing and coordination of research and development".

Progress was reviewed at EB 124 in Jan 2009 under Item 4.13 (see EB124/16, EB124/16 Add.1, and EB124/16 Add.2). The Secretariat report outlined the Secretariat's response to Member States' requests in resolution WHA61.21, including proposals for the outstanding components of the plan of action, i.e. timeframes, progress indicators and estimated funding needs. It also describes the establishment of an Expert Working Group and a Quick Start Programme referred to in resolution WHA61.21.

The EWG, working on innovative approaches to financing and coordination, met for the first time in Jan 2009.

At WHA62 (May 2009) the GSPOA (Public health, innovation and intellectual property: global strategy and plan of action) was discussed (Item 12.8, Committee B meetings: B3, & B4, & B5). The documents were A62/16, A62/16 Add.1(time and money), A62/16 Add.2(performance indicators)

and A62/16 Add.3(stakeholders). A resolution submitted by Canada, Chile, Iran, Japan, Libya, Norway and Switzerland proposed acceptance of the stakeholders in Add3, the timeframes in Add1 and the progress indicators in Add2. There was a lot of debate over the removal of WHO from list of stakeholders with an interest in a global treaty for the funding of R&D.

The GSPA was finally agreed in Resolution WHA62.16 (see also Annex 4) in May 2009. See integrated version of finally agreed GSPA. It included eight elements:

- Element 1. Prioritizing research and development needs
- Element 2. Promoting research and development
- Element 3. Building and improving innovative capacity
- Element 4. Transfer of technology
- Element 5. Application and management of intellectual property to contribute to innovation and promote public health
- Element 6. Improving delivery and access
- Element 7. Promoting sustainable financing mechanisms
- Element 8. Establishing monitoring and reporting systems

COMPREHENSIVE EVALUATION AND OVERALL PROGRAMME REVIEW

Para 41 of the GSPOA stipulated a comprehensive evaluation was to be undertaken after four years. In addition, (in Clause 6 of WHA62.16 through which the Assembly adopted the GSPOA) the Assembly requested an overall programme review of the global strategy and plan of action in 2014, including recommendations on the way forward.

The evaluation of the GSPOA was discussed at EB133 (May 2013) informed by EB133/7. See official summary record of discussion (M4). At EB136 (Jan 2015) the Secretariat proposed (in EB136/31) a set of timelines for the evaluation and the EB adopted decision EB136(17), in which it decided, inter alia, to recommend to the Sixty-eighth World Health Assembly to extend the deadline for the overall programme review to 2018.

WHA68 (May 2015) reviewed this stream of discussion, informed by A68/35. A68/35 outlined a number of options for undertaking both the evaluation and the program review. The Assembly adopted WHA68.18 which committed to a staggered process with the evaluation preceding the program review.

In line with resolution WHA68.18, the Secretariat submitted to EB138 (Jan 2016) EB138/38 which provided an update on progress made in relation to the evaluation. An additional report (EB138/38 Add.1) reviewed the key points from the evaluator's inception report and comments from the ad hoc evaluation management group. Report of debate at EB138 here.

The EB140 in Jan 2017:

- reviewed the findings and recommendations of the comprehensive evaluation of the GSPOA;
- noted the Secretariat's proposals for the membership of the Expert Panel for the Overall Program Review and the proposed method of work of the Program Review Panel (including timelines); and
- in EB140(8) approved the proposed terms of reference for the overall programme review and requested the Secretariat to estimate the funding requirements and possible sources of funds for implementation of the Program Review Panel recommendations.

See record of debate at EB140 in M11 , M12 & M17. (Highlights include the intervention by India, to the effect that the terms of reference for the Review should include operationalising the recommendations of the High Level Panel on Access to Medicines (not adopted); and by Brazil which was very critical of the capacity, conduct and report of the Evaluation. New Zealand doubted the need to continue the GSPOA which elicited a sharp ripost from South Africa.)

WHA70 (May 2017) reviewed the findings and recommendations of the Evaluation (see executive summary in Annex 1 of A70/21; the full report is here).

EB142 (Jan 2018) and WHA71 (May 2018) considered the final report of the overall programme review (here). In EB142/14 (and A71/13) the Director-General sets out the Priority Actions identified in the report.

The report presented recommendations on the way forward for the next stage of implementation of the Global Strategy and Plan of Action, with respect to the addition, enhancement and conclusion of relevant elements and actions. The Secretariat estimated that the cost of implementing all the recommendations of the Overall Programme Review across the four years 2019-22 as $31.5m for the full set of recommendations and $16.3m for the high priority actions. The proposed expenditure was not covered within existing resources.

The debate at EB142 was quite intense (see M7 and M10) particularly over the recommendations of the expert panel for the Overall Program Review of the GSPOA (summarised in EB142/14 Rev.1) and the draft decision proposed by the Secretariat to "to take forward the recommendations of the review panel" (EB142/14 Add.1).

The US and Switzerland proposed revising the draft decision in EB142/14 Add.1 (supported by Japan), but strongly opposed by many countries (Brazil, Thailand, the Netherlands, Libya, Algeria (on behalf of the member states of the African Region), Sri Lanka, Pakistan, Vietnam, Colombia, the Dominican Republic, Burundi, the United Republic of Tanzania, Benin), who argued that delays to adopting the decision "could be construed as serving to protect the interests of the pharmaceutical industry." Canada, France, Sweden and Italy proposed a drafting group restricted to 'minor' changes as a compromise.

While the drafting group reached a compromise, leaks from delegates participating in the drafting group (see "Member states clash as WHO mulls …") suggested that not everyone was happy with the revised decision, and that it was a pragmatic choice "so as not to risk losing the whole report altogether."

The revised decision (EB142(4)) distinguished between recommendations "emanating from the GPSOA" (which were to be implemented) and recommendations "not emanating from the GSPOA" (which were to be further discussed) and was adopted at WHA71 (2018) as (WHA71(9) including four components:

- Para (1) urges MSs to implement the recommendations of the Review Panel which are addressed to MS ('as appropriate', 'taking into account national context').
- Para (2) urges MSs to further discuss the 'recommendations not emanating from the GSPOA' but does not identify them. They are identified in footnote 1 on page 1 of EB146/15 as Recommendations 4, 27 & 28 from the Review Panel Report which are listed, in A71/13, as:
- 4. Member States to support the WHO Secretariat in promoting transparency in, and understanding of, the costs of research and development;
- 27. Member States to identify essential medicines that are at risk of being in short supply and mechanisms to avoid shortages, and disseminate related information accordingly; and

- 28. Member States to commit to dedicating at least 0.01% of their gross domestic product to basic and applied research relevant to the health needs of developing countries.
- Para (3) requests the Director-General to implement the recommendations addressed to the Secretariat, as prioritized by the Review Panel, in an Implementation Plan, consistent with the GSPOA.
- Para (4) requests a report on the implementation of the Decision.

EB146 (Jan 2020) reviewed progress on the implementation of WHA71(9) (at the request of Brazil; it was not on the original agenda). The Secretariat report (EB146/15) described what the Secretariat was doing but did not provide any information on paras (1) and (2) of Decision WHA71(9) which were addressed to MSs.

EB146 adopted decision EB146(10), in which the Board decided, inter alia, to reiterate to the Director-General the necessity of presenting an implementation plan consistent with the global strategy and plan of action on public health, innovation and intellectual property in conformity with paragraph 3 of decision WHA71(9) (2018).

In WHA73(11) the Assembly (in Nov 2020) silently endorsed EB146(10). WHA73 also considered WHO Reform, including how to manage resolutions whose mandate was due to expire. The Assembly adopted Decision WHA73(15) (on the recommendation of EB146(21)) which requested the DG to "include as substantive items on the agendas of meetings of the WHO governing bodies any global strategies or action plans that are scheduled to expire within one year in order to allow Member States to consider whether global strategies or action plans have fulfilled their mandates, should be extended and/or need to be adjusted."

EB148 reviewed a report from the Secretariat (EB148/10), responding to the request in WHA73(11) for an implementation plan for the 'prioritised recommendations of the Review Panel' in accordance with WHA68.18 (2015). This was considered again at WHA74 which adopted WHA74.6 ('Strengthening local production of medicines and other health technologies to improve access').

WHA74.6 urges a number of actions on member states and upon the DG. Importantly it requests the DG to continue to strengthen actions related to resolutions WHA61.21 (2008, adoption of the GSPOA), WHA66.22 (2013, follow up report of CEWG on F&C) and WHA67.20 (2014, regulatory system strengthening for medical products).

FROM EWG TO CEWG (FINANCING AND COORDINATION OF R&D)

The Expert Working Group on research and development financing met in December 2009 to discuss current financing and coordination of research and development, as well as proposals for new and innovative sources of funding.

EB126 (Jan 2010: agenda, report) reviewed progress on the global strategy and plan of action (Item 4.3). The Secretariat report (EB126/6) provided an account of progress in implementing the Global strategy and plan of action as required by resolutions WHA61.21 and WHA62.16.

The EB126 also received an extended Executive Summary of the EWG report (EB126/6 Add.1) just before the EB. The full report was not available because it had not been translated. There were criticisms of the EWG report: it had reconsidered issues which had been rejected by the Commission; it had not considered IP issues sufficiently. There were concerns regarding conflict of interest affecting big pharma members of the Group. There had been a letter from a member of the EWG to the EB which was regretted. There had been a leak (Mara 2009), apparently from a pharma representative, and a critical commentary in the Lancet on the leak alleging that big pharma was

exercising undue influence (Editorial 2010). See also the response of the chair of the EWG (Alleyne 2010) and by Jones (2010) of big pharma in Britain to the Lancet editorial. The EB decided to hold a web based consultation on the report once the EWG report had been released and then a one day consultative meeting before the PBAC in May.

The debate continued at WHA 63 May 2010 (agenda (Item 11.3), report). The documents were A63/6, A63/6 Add.1 and A63/6 Add.2 (the Chair's summary of the member state consultation on 13 May, 2010) and the EWG Report itself. Ecuador on behalf of UNASUR tabled a draft resolution with stringent criticisms of the EWG and calling for a new IGWG to be constituted to make progress "towards the development of innovative and sustainable financial mechanisms for research and development, in accordance with element 7 of the Global strategy on public health, innovation and intellectual property." The debate considered either a new IGWG or another EWG or nothing. A drafting committee was constituted which brought forth a draft which was adopted (as amended) as WHA63.28 which established a Consultative Expert Working Group to take forward the work of the EWG. The resolution urged MSs to support the CEWG and to propose names and support it; and requested the DG to share details of the proposals which had been considered by the EWG, the criteria it had used and the stakeholders who were interviewed or who had provided information. See Lancet commentary (Mullard 2010).

In Jan 2011 (agenda, report) EB128 considered the appointment of the Consultative Expert Working Group on Research and Development: Financing and Coordination (EB128/6). The Director-General proposed a composition of the Consultative Expert Working Group to the Board for approval, drawing on the roster of experts whose details had been submitted to the Director-General through the respective Regional Directors. There was an extended debate about the Swiss nominee Prof Herrling who not only worked for Novartis but who was a co-sponsor of one of the proposals which had been previously brought forward. Lots of concern was expressed. Membership adopted with commitments regarding conflict of interest.

EB129 (May 2011, following the WHA64, see agenda and report) considered the inception report of the Consultative Expert Working Group as Item 5.1. Document EB129/3 provided details about the work plan and inception report of the CEWG, in accordance with resolution WHA63.28 and as agreed during its first meeting. The inception report was noted without much discussion.

EB130 (Jan 2012) considered a progress report from the CEWG as Item 6.14 and informed by document EB130/23. (See EB agenda and report.) The report provided an account to the Board of the progress made by the CEWG in taking forward the work of the Expert Working Group on Research and Development Financing. The Board was invited to consider a summary of the outcome of the meetings held to date, and of the group's call for submission of proposals for research and development financing and coordination. Generally positive comments. India liked the proposed binding treaty on funding for R&D for diseases mainly affecting the developing countries.

The final report of the CEWG (A65/24 and A65/24 Corr.1) was presented to WHA65 in May 2012 (agenda Item 13.4 and see also report).

The CEWG report set the scene, reviewed all of the proposals which had been considered by the EWG, reviewed options for funds mobilisation and coordination, and ended up proposing a binding instrument for health research and development.

The Assembly had before it four resolutions. The resolutions from Kenya and UNASUR were directed to progressing the proposed binding convention on R&D funding. The resolutions from Switzerland and from Australia, Canada, Japan, Monaco and USA proposed further consideration without committing to the binding convention. An informal drafting group was set up to be chaired by India but a few minutes later (in the middle of a debate about infant nutrition) Argentina protested the lack of debate before setting up the drafting group and there was a general agreement to have a debate before the drafting group gets to work. After some debate further discussion was adjourned

from the 4th to the 11th meetings where a draft resolution (mandating an open ended MS meeting) was presented by Dr Viroj Tangcharoensathien which was adopted (WHA65.22) without substantive discussion.

The open ended Member State meeting to follow up the report of the CEWG was held 26-28 Nov, 2012, chaired by Dr Viroj Tangcharoensathien and subsequently reported to EB132 (Jan 2013) as EB132/21. (See agenda (Item 10.2) and records). EB132/21 comprised a brief report plus a draft resolution for adoption by the WHA which the EB was requested to convey to the WHA. There was a long discussion about whether the Board could or should reopen a resolution coming from the Open Ended Meeting of Member States on the follow up of the CEWG Report on R&D:F&C. Ecuador speaking on behalf of UNASUR wanted to reopen the draft resolution forwarded from the OE Meeting of MS. USA disagreed. Deals had been done. Legal counsel and DG commented. The EB did not reopen the report from the OEMS Meeting.

The report from the Open Ended Meeting of Member States (Nov 2012) was duly reported to the WHA66 (May 2013) under Item 17.2 (Doc A66/23). See debate at B4, B5 and the B6.

Dr Viroj Tangcharoensathien from Thailand reported:

"The outcome of the meeting held in November 2012 – the draft resolution contained in the Appendix to document A66/23 – provided for a complex, stepwise process of implementation and reporting thereon. Two reports would be drafted in time for the Sixty-seventh World Health Assembly, one on the review of existing coordination mechanisms, as proposed in subparagraph 4(5) of the draft resolution, and the other on the evaluation of existing mechanisms for contributions to health R&D, as proposed in subparagraph 4(6). A further report would be prepared for the Sixty-eighth World Health Assembly on the implementation of health research and development demonstration projects, as proposed in subparagraph 4(4). Another open-ended meeting of Member States would be held prior to the Sixty-ninth World Health Assembly and would report to that Health Assembly on its findings."

There was a long debate touching on many of the issues. The USA put forward a draft decision and an informal drafting group was constituted to consider. In the Sixth Meeting of Committee B the Draft Resolution in A66/23 was approved (as WHA66.22) and the draft decision (based on the US draft as amended, see pp2-3 of B6) was adopted as WHA66(12).

The binding treaty was shelved for the time being. The action points in WHA66.22 included:

- work on norms and standards for classifying R&D,
- the observatory,
- the demonstration projects, and
- the review and evaluation of existing mechanisms.

The Decision (see WHA66(12)) mandated a technical consultative meeting (part technical, part MSs) to be held by end 2013 and reported to EB134 in Jan 2014.

Demonstration Projects

Following WHA66 (May 2013) calls for demonstration project proposals were issued and 22 were shortlisted for consideration by a technical consultative meeting of experts in early Dec 2013 which identified 7+1 proposals that were seen to have the potential to be demonstration projects.

EB134 (Jan 2014) considered EB134/26 and adopted decision EB134(5), identifying next steps – examination of the additional information and convening of stakeholder meetings. The decision also requested the Secretariat to identify indicators to measure success in this process.

In March 2014 four projects were identified as being ready for implementation.

WHA67 (May 2014) reviewed two Secretariat reports on action underway by way of follow up of the CEWG. A67/27 presented a revised version of EB134/26 dealing with the Observatory; options for coordination of R&D; and options for funding and management of funds. A67/28 (a revised version of EB134/27) dealt with the selection of demonstration projects. WHA67 adopted decision WHA67(15), which asks, among other things, the Secretariat to "expedite the process" of the other four projects (that were not selected).

EB136 (Jan 2015) reviewed report EB136/30, on the possibility of using the Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development, and EB136/30 Add.1, detailing progress made in implementing the selected health research and development demonstration projects.

WHA68 (May 2015) reviewed two reports: A68/34 dealing with the proposed funding mechanism; and A68/34 Add.1 which reported on progress made in implementing the selected health research and development demonstration projects.

Document A68/34 proposed the Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development. The report described how such a fund might be established and managed, as well as its relationship with the R&D Observatory and the future coordination mechanism.

The Secretariat's report was noted (B5).

The Observatory

In resolution WHA66.22 the Assembly requested the Director-General to establish a global R&D observatory and to review existing mechanisms which could be used to coordinate R&D under the CEWG process.

The Assembly (May 2014) considered the report A67/27 which inter alia reported on the work done to date in relation to the Observatory. It reported that the Secretariat has started the process of establishing the Global Health Research and Development Observatory. It proposed the establishment of a global research and development advisory body and the institutionalization of an annual research and development stakeholder conference.

The objectives of the Global Observatory are described in document A67/27. Further information is available at http://www.who.int/phi/implementation/phi_rd_observatory/en/.

Document A68/34 discusses how the the relations between the Funding Mechanism, the Observatory, the Coordination Group and TDR are seen by the Secretariat.

At the end of the debate at WHA68 the Secretariat noted that the Observatory was expected to be launched in Jan 2016. See call for publications.

See presentation on progress on the global observatory presented at OE MSM in May 2016

The Demo Projects

The emergence of the demonstration projects, from the original adoption of the Global Strategy and Plan of Action to the discussions at EB136 is noted in A68/34 Add.1 but the paper focuses on the more recent re-evaluation of one merged project and three resubmitted projects.

See presentation on demo projects prepared for OE MSM.

More in A/RDMCF/2.

FUNDING MOBILISATION, HOSTING AND COORDINATION

Resolution A66.22 commissioned further exploration of pooled funding and funding coordination.

A67/27 discussed 'Managed coordination' of R&D activities and their funding. It argued that the creation of any new funding mechanism would introduce strong, managed coordination of the research that a new fund would support. The priorities supported under such a financing mechanism would be those identified through the global advisory committee and could be endorsed at the annual stakeholder conference.

In Decision A67(15) the Assembly asked the Secretariat to explore this proposal in more detail and to report, through EB136 to WHA68 in May 2015 on the outcomes of this exploration.

A range of possible hosts for the pooled funding had been considered in EB134/26 (Jan 2014) and the EB was advised that TDR had rated highly on most criteria. In early May 2014 WHO hosted a meeting of the proponents of the four projects selected in the initial round of demonstration projects (A67/28 Add.1). At this meeting TDR tabled a proposal (9 May 2014) outlining how it might take on the role of manager of the pooled funds (see also TDR news release 9 May). While the TDR proposal was not included in the papers published by the Secretariat for WHA67 it was clearly under consideration with several speakers referring to it in debate and its endorsement in A67(15) above.

The Joint Coordination Board (JCB), the top governing body of the Special Programme for Research and Training in Tropical Diseases (TDR) held its annual meeting in Geneva from 23 June 2014 to 25 June 2014. In its media note (26 June, 2014), TDR recorded the support of the JCB for taking on this role.

The TDR option was further discussed at EB136 (report of debate) and there was general support plus some specific suggestions which were incorporated into A68/34 which was noted.

More in A/RDMCF/2.

See presentations prepared for the OEMSM in May 2016 on: financing and coordination.

In resolution WHA66.22 (2013), as part of the follow up of the report of the Consultative Expert Working Group, the Director-General was requested, inter alia, to convene an open-ended meeting of Member States prior to the Sixty-ninth World Health Assembly in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development.

During the EB138 (Jan 2016) discussion of this item (at PSR11(4)) there were expressions of support for the various elements of the program but regret at how far behind the financial commitments were against the estimated needs.

At WHA69 (May 2016) the outcomes of the open ended meeting in Geneva 2-4 May were reported in A69/40. A69/40 included a report from the secretariat summarising progress in relation to the various elements of the CEWG workstream (Appendix 2), and a richly conflicted draft [decision / resolution] on the follow up to the report of the CEWG.

The Secretariat's Progress Report to the OEMeeting of MS (A/RDMCF/2) reviewed the elements of the CEWG workstream and summarised progress with respect to the Observatory, the demonstration projects, funding provision, financing mechanisms, coordination of R&D, the R&D Blueprint for action to prevent epidemics, and R&D for new antibiotics.

Appendix 3 to A69/40 included a draft [decision / resolution] from the OE Meeting which remained highly contested.

See also the Lancet assessment (7 May) that delinkage models are gaining ground while 'countries mull over incentives for developing antibiotics'.

WHA69 adopted Resolution WHA69.23 urging implementation of the strategic work plan adopted in WHA66.22.

The Secretariat report (A70/22), prepared in response to requests made by the Health Assembly in resolution WHA69.23 (2016), proposes:

- terms of reference and a costed workplan of the Global Observatory on Health Research and Development (Annex 1 in A70/22); and
- goals and an operational plan for a voluntary pooled fund to support research and development (Annex 2 in A70/22; see also TDR report).

Responding to further requests in A69.23, A70/22 also

- reports on the approval by EB140 of the terms of reference for the Expert Committee on Health Research and Development (as set out in EB140/22);
- provides an update on the development of the Global Observatory on Health Research and Development;
- reviews the six demonstration projects and their funding status (in paras 10-11);
- sketches out the roles and inter-relationships of the Global Observatory, the Expert Committee and the Scientific Working Group (in paras 12-15);
- reviews the funding so far secured for the demonstration projects and the global observatory (facing a $US71m shortfall); and
- (in para 19) acknowledges the need for policy coherence across the principles agreed to regarding R&D under the follow up of the CEWG; the Research and Development Blueprint to foster research and development preparedness for infectious diseases with epidemic potential, and the Global Antibiotic Research and Development Partnership, a joint venture by WHO and the Drugs for Neglected Diseases initiative.

Clause 2(12) of WHA69.23 also proposes that the DG requests WHA70 to 'consider convening another open-ended meeting of Member States in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development, taking into account relevant analyses and reports'. Clearly the Secretary General's High Level Panel on Access to Medicines is a relevant analysis and report. This may be why the request in OP2(12) of WHA69.23 is not mentioned in A70/22. However, it may be raised in debate.

WHA70 noted the report.

COMMENT

While the immediate issues at stake in the TAC of 1997-2001 were price and parallel importation it was evident that the funding of innovation was a critical part of the issue (see for example, Scherer and Watal 2001, section 5).

The establishment of the Commission on IP, Innovation and PH in 2003 reflected a determination among WHO member states to build on the Doha Statement and to explore alternative approaches to innovation and the logic of monopoly pricing.

From the Commission (2003-06) to the IGWG (2006-08) to the EWG (2009-10) to the CEWG (2011-12) to the OEMS Meeting (November 2012) to the observatory and demonstration projects, this has been a tortuous affair. Led by Brazil, India and Thailand the case for delinking pharmaceutical R&D from IP protection and monopoly pricing has been largely supported by Latin America, Africa and Asia. The opposition, led by the US and Europe, has taken the form of continued re-examination of old proposals, continued assertion that other mechanisms to boost investment in drugs could be

explored. It is interesting that the only country which is already investing the benchmark figure in innovation is the US, so a binding treaty would require increased investment from all other countries.

It is clear that monopoly pricing is not an effective way of funding of innovation to meet the needs of developing countries and the case for delinking and a binding agreement is strong; see Velásquez (2012). However, it is clear that delinking for drugs of relevance to developing countries would establish a precedent that could be extended to other pharmaceuticals and the RBPMs and their host countries are strongly opposed.

FURTHER LINKS

Tracker links to EB and WHA discussions of GSPOA and CEWG

See also the web pages for:

- the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property
- the Open-ended Meetings of Member States on Follow up of CEWG on R&D

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