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NEGOTIATING THE INTERNATIONAL HEALTH REGULATIONS

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The SARS outbreak in 2003 gave a sense of urgency to the revision process of the International Health Regulations (IHR) and led to the realization that an international public health emergency not only affects human and animal health, but also economic life and countries' economic development.

It is against this background that the author of this paper, who chaired the negotiations to revise the International Health Regulations between October 2004 and May 2005, describes the process of these negotiations.

The paper outlines the organization of work, the issues at stake, the negotiating actors, as well as the challenges encountered within the negotiation process from the first session of the Open-ended Intergovernmental Working Group to the adoption of the text by consensus during the World Health Assembly in May 2005.

The author concludes by arguing that the IHR negotiations were unique in their common sense of purpose, in their technical yet political set-up, in re-affirming diplomacy as a unique profession, and in the support received from the WHO secretariat to enable the successful conclusion of the revision of the treaty.

Key Words

consensus decision, drafting process, global health diplomacy, health and foreign policy, health threats, intergovernmental working group, International Health Regulations, legally binding instrument, negotiation process, stakeholders in the negotiations.

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NEGOTIATING THE INTERNATIONAL HEALTH REGULATIONS

I have been asked to discuss my experience as chair of the negotiations on the revision of the International Health Regulations (IHR) and, based on this, to consider whether it is now possible to speak of public health diplomacy.

When approached in October 2004 to chair the process, I knew very little about the background to this issue. I very quickly learnt that, far from being a revision exercise, the outcome was intended to go far beyond the previous IHR.

As you know, the outcome was successful. This, I suggest, was due to unique factors which would be very difficult to replicate.

Background

In October 2004, discussions on the revision of the International Health Regulations had been ongoing for many years. The purpose of the original regulations was to monitor and control six major infectious diseases. However, since their adoption, new health threats had emerged, commerce and travel had increased exponentially and the regulations were no longer regarded as adequate to deal with current and future threats. It took the SARS outbreak in 2003 to impart a sense of urgency to the revision process. SARS provided a graphic illustration that an international public health emergency could affect not only human and animal health in countries at great distances apart, but it could also seriously impact on the economic life and develo-

[1] The paper was presented at the first high-level symposium on Global Health Diplomacy and Negotiating Health in the 21st Century: current issues and future challenges held on 22-23 March 2007, Geneva. The author is Irish diplomat and was Chairperson of the Intergovernmental Working Group negotiating the revision of the International Health Regulations.

pment of their economies. One SARS case in any city was enough to deal a major blow to its commerce as well as to its health.

In May 2003, the World Health Assembly (WHA) adopted Resolution 56.28, which established the Open-ended Intergovernmental Working Group (IGWG) to review and revise the International Health Regulations with a view to the adoption of the revised regulations at the 2005 meeting of the Health Assembly. It was an ambitious target.

At a time when multilateralism seemed to be going out of fashion, there was a political consensus that only a multilateral approach to dealing with an international public health scare could work. There was no sustainable counter-argument to the proposition that no matter how robust a country's public health surveillance and support system, it was dependent on the effectiveness of the systems in place in all other countries with which it had economic relations or person-to-person contacts.

While political will is an essential ingredient to secure a successful outcome to any negotiation, on its own it is not enough to ensure success. While all governments could agree on the objective, it remained to be seen if all could agree on the means by which it would be achieved.

An essential ingredient to meet the deadline for the conclusion of the negotiations – and it was by no means a foregone conclusion that the deadline could be met – was a good working basis on which to negotiate. This was provided by WHO itself. In January 2004, WHO produced a working paper which contained proposals for new International Health Regulations. Beginning in March 2004, a series of subregional and regional meetings considered this document. From this process, a revised working paper emerged, which was the foundation block on which to build future negotiations.

The pre-negotiation consultation process highlighted issues that would be at the heart of the subsequent discussions including scope, sovereignty, implementation issues, compatibility with other international agreements, and trade. It identified the need for balance between measures to protect against the spread of disease and the need to maintain the welfare of the economic system.

First meeting of the IGWG, 1–12 November 2004

The first session of the Intergovernmental Working Group was held on 1 November. A bureau was established, which comprised the various office-holders and the coordinators of the regional groups. The membership of the bureau was to vary over the three negotiating sessions in November, February and May. The bureau was to play a very useful role in determining the structure of the meetings. In particular, the regional coordinators – who continued as members of the bureau throughout the negotiations – played a key role in helping to meet the deadline set by the World Health Assembly.

{A word about regional groupings in WHO. The composition of regional groupings or coordinating mechanisms varies considerably between different UN entities. They are frequently criticized for lowering the level of ambition in negotiations, and are seen as the propagators of the lowest common denominator. In the case of WHO, they are truly regional entities. During the negotiations, some operated as coordinating mechanisms others as forums for exchanging views. Overall, they made a positive contribution to the IHR process.}

The organization of the work of the meeting presented some problems. In order to consider the range of topics to be covered, it was necessary to divide the work into three separate working groups, each with two co-chairs. However, in order to meet the concerns of smaller delegations, it was necessary to avoid parallel meetings. It was also necessary to provide time for regional group meetings. As a result, the amount of time available for negotiating was quite limited. In the second week, with the agreement of regional coordinators, some smaller, informal – albeit open-ended – groups carried out work on specific topics. This practice was to increase in subsequent sessions.

My ambition during this first session was to ensure:

→ a first reading of the text to identify problems
→ a second reading to seek to reconcile differences and move towards consensus
→ an outcome document that might serve as the basis for further work

The first objective was achieved, the second partially achieved and, as far as the third objective is concerned, I had been too sanguine.

Progress in the different negotiating groups varied, which, in part, reflected the relative difficulties of the issues under consideration. On 12 November, the outcome of the deliberations in the three subgroups was circulated in a single document, which was a compilation of drafts prepared by the six co-chairs. In places, the text suggested that the IGWG was close to agreement; in other places, the text was littered with square brackets which signified unagreed language (or text).

Unfortunately, it was not possible to get agreement to use me, as chair, to bring forward a new text as the basis for the second session of the IGWG. I was very reluctant to do so as I felt that on some issues positions were still far apart, that a new text could hinder rather than advance the process and, most importantly, that the request for a chair's text did not enjoy consensus support. My pessimism proved unfounded.

The outstanding issues included the following:

→ The issue of balance between the sovereign prerogatives of prospective States Parties, the role of the WHO Secretariat, and balance between effective, science-based measures that would protect public health without placing unnecessary restrictions on international traffic.

→ The issue of scope and how to define and determine the existence of a 'public health emergency of international concern' (PHEIC). The core issue was to ensure that the IHR applied to naturally and non-naturally occurring outbreaks of disease likely to lead to a PHEIC. This raised the question of the role of the IHR with regard to the deliberate release of chemical, biological and radionuclear agents and the problems arising from shortcomings in arms control agreements, in particular the Biological and Toxin Weapons Convention (BTWC).

→ Sovereignty – to be effective, the IHR had to give to an international entity that was reasonably free from political interference the key role in determining a public health emergency. That entity had to be the Director-General of WHO. This was not immediately acceptable to all delegations, although there was no realistic alternative. Given the economic and other consequences that would flow from the exercise of such authority, governments were understandably concerned that there should be adequate consultative mechanisms in place to ensure that this authority was exercised with prudence, and after having taken the broadest possible advice.

→ Federal and confederal States had particular issues around the designation of a single focal point and other implementation measures which reflected the diffusion of responsibilities for health within their domestic jurisdictions. It seemed that each such State was unique in its structure, and yet a formula would have to be found that would cover all.

→ Human rights – given the very wide powers to quarantine travellers, insist on medical examinations etc., there was support across the board for the inclusion of a strong reference to the need for the IHR to take account of broader human rights issues in their implementation; the issue here was at what point to include an appropriate reference and how it would be formulated.

→ Implementation issues – core capacity requirements were of particular concern to developing countries. On the one hand, the regulations would not be specifying the financial and other support that governments would receive to meet their obligations under the IHR

while, on the other hand, developing countries were reluctant to assume obligations that they could not meet for financial reasons.

→ Some States wished to be in a position to introduce additional measures that went beyond the requirements of the IHR. Others saw this as a means by which the IHR would be undermined and the precautionary principle used in a manner that would needlessly hinder travel and commerce.

→ Other difficult issues related to the entry into force of provisions, reservations, universality and the application of the IHR to diplomats and armed forces.

As you can see, many of the outstanding issues were not health-specific. Some others were unique to this one negotiation.

Process

I would like to turn to the process itself and consider some of the lessons to be drawn from it.

→ While the first negotiating session had helped build consensus around the overall approach and had gone beyond that in a number of areas, it had proved to be quite slow. The pace needed to be speeded up if the May 2005 deadline was to be met. Establishing subsidiary bodies had helped to deal with a large area of work, but it had also meant that overall control of the negotiations was difficult.

→ Whatever organizational approach was adopted, it was clear that to command support and credibility it had to be open-ended.

→ It was notable that key negotiators frequently did not know their interlocutors. Delegations would come to me to discuss difficulties when they might have been better advised to seek out those negotiating partners with a different perspective.

→ Some of the larger delegations had experts covering many different areas of government. These experts needed to obtain a broader picture of their own government's overall objectives and of the process itself if they were to engage effectively in it. In such cases, the role of the Geneva-based diplomatic missions in ensuring an overall coherent approach in national delegations was to prove important.

→ It was obvious that other intergovernmental organizations saw themselves as important stakeholders in the proceedings, and their views would be important in ensuring coherence in the final outcome.

→ The presence as observers of other intergovernmental organizations illustrated the fact that some of the more difficult issues related to areas outside the health sector, including international trade and arms control. It was important that the IGWG be aware of these issues, but not to allow them to overly influence or determine the course of the negotiations.

→ There were political issues on the fringes of the negotiations which were seldom, if ever, referred to by name but which were ever-present. Delegations had to be clear about their prime objective. Was it to pursue issues which could not be advanced and that had implications far beyond the scope of the IHR, or was it to deal pragmatically with likely threats to health?

Intersessional period

As I mentioned earlier, it was not possible get agreement to use the outcome of the November meeting as the basis for the second negotiating session. In response to requests for a chair's text in late November, I convened a small drafting group comprising the WHO officials most closely involved in the negotiations. We met frequently over the coming weeks. We went through each article in light of the progress reported by 12 November, and tried out alternative drafts to find a workable way to achieve a strong IHR, and to take account of the concerns of individual delegations and groups. The process was

robust and exhaustive. Where it seemed that a consensus was unlikely to emerge in the IGWG on a specific proposal, it was not included in the chair's text. On 20 January, I put forward a text about my responsibility as chair; it contained a minimum of square brackets. (The latter related to the definition of disease, the definition of a public health risk, additional health measures, treatment of personal data, information-sharing during a suspected intentional release of a biological, chemical or radionuclear agent, and reservations to the IHR.) The paper represented my view as to where a consensus might be found but all elements, whether bracketed or not, were open to further discussion; this was not a take-it-or-leave-it proposal.

Let me now turn to a number of other important developments in the intersessional period.

The most important of these related to draft Annex 2 of the Secretariat working paper, which had been the basis of the November discussion. Draft Annex 2 contained the decision instrument (algorithm) to be used for assessing and notifying of events which might constitute a public health emergency of international concern. At the end of the first session, it was agreed that an expert group would meet from 17 to 18 February 2005. The group was chaired by Dr Preben Aavitsland of Norway. Considerable progress was made although the political problem remained of how to address non-naturally occurring events which might constitute a public health emergency.

A second development was the appearance, in December 2004, of the report of the High-Level Panel set up by the UN Secretary-General to advise him on Threats, Challenges and Change. Paragraphs 142 to 144 of the report, entitled A more secure world: Our shared responsibility, addressed public health defences and suggests that the UN Security Council should consult with the Director-General of WHO to establish the necessary procedures for working together in the event of a suspicious or overwhelming outbreak of infectious diseases. The text dealt with both the intentional release of an infectious biological agent and an overwhelming natural outbreak of an infectious disease. It referred to the Security Council deploying experts who would report directly to it. It also referred to the Security Council mandating compliance in this area.

From the perspective of the IHR negotiations, which were trying to get over 190 countries to sign up voluntarily to a legally binding instrument in this area, the threat of Security Council action was problematic. Contact was made with those in New York dealing with the Secretary-General's response to the report, and the sensitivity of the negotiations on the IHR was explained.

Prior to the second session, a number of regional and subregional meetings took place. These regional meetings, such as those in Montevideo, were to facilitate progress in a number of areas. They helped to clarify positions and illustrated that delegations were thinking constructively in terms of how they might advance their own positions in light of the concerns of others.

Also during this period, the Director-General's special envoy on the IHR, former EU commissioner David Byrne, carried out useful work in a number of capitals to ensure continued political engagement in support of the process.

The second session, February 2005

The second session of the IGWG began on 21 February 2005. The November meeting had taken place at the Palais des Nations, the seat of the European headquarters of the United Nations in Geneva. Moving the negotiations to WHO itself meant a move to smaller meeting rooms, but also created the more intimate conditions conducive to the necessary interaction and give and take between the negotiators.

At the opening session, regional groups indicated that the chair's text was an acceptable basis on which to work. During this session, our working methods changed. The first reading of the text took place in a Committee of the Whole, which facilitated greater control over the pace of negotiations. When difficult issues were raised, open-ended working groups were established to find a solution. This pro-

ved very effective. The chairs of these groups were invariably from delegations that had shown a strong interest in the issue, but also a strong interest in finding a solution. Considerable progress was made in most areas. It even began to look as if the negotiations might be concluded in February.

However, late on the night of Saturday 26 February, progress began to slow. Some delegations may not have expected the negotiations to have progressed so far and had no instructions on the remaining issues. As we were now into the weekend, consultation with capitals was somewhat more difficult. In the early morning of 27 February, when no delegation responded to a question from the chair as to whether further progress was possible, the meeting was adjourned until 13 May; this was days before the opening of the World Health Assembly. The text on the table at this stage marked agreement on wide areas.

However, as the negotiations followed the well-known principle of nothing being agreed until everything was agreed, despite being tantalizingly close to finalizing a text, there was a danger that some issues apparently agreed in February could be reopened in May. **That this did not happen was because**:

→ the shape of the final document was now clear as was the fact that its overall balance was likely to be acceptable to all
→ should the issue drag on past the WHA, it was likely to become bogged down indefinitely
→ there was a realization that the outstanding issues, although difficult, could be solved

In March 2005, the Secretary-General brought forward his own proposals for UN reform. This text, *In Larger Freedom: Towards Development, Security and Human Rights for All*, moved significantly beyond the High-Level Panel report and contained a call for Member States to agree on the revision of the International Health Regulations at the World Health Assembly to be held in May 2005.

As during the earlier intersessional period, some regional and subregional meetings took place before the final session. Again, these were helpful in defining the way forward.

The final negotiations

Prior to the final negotiating session, the bureau met on a number of occasions and, from this process, it became clear that we would be in a position to take up on 12 May from where we had finished on 27 February. This virtually ensured agreement.

The final session officially covered two days: 12 and 13 May. In fact, it spilled over into the early hours of 14 May. The outstanding issues fell into three groups. The first group related to the treatment of non-naturally occurring outbreaks of disease, the second group related to additional measures, and the third to the final articles on entry into force and reservations. In addition, there were a number of loose ends to sort out.

Some issues were discussed and negotiated in the Committee of the Whole, while other outstanding issues were remitted to informal open-ended groups, which were to report back. Agreement was reached on all outstanding issues by the early hours of Saturday 14 May. This agreement was recorded on a paragraph-by-paragraph basis – a process which ended at around 5 o'clock in the morning. One delegation made clear throughout this lengthy process that it was not associating itself with the consensus adoption of the text.

On 23 May 2005, the World Health Assembly unanimously adopted the Regulations, which entered into force in June 2007.

One of the issues that we have been asked to consider during this symposium is whether there is such a concept as health diplomacy.

I have dealt at length with the negotiating process. The question is whether the process differed from other multilateral negotiations and whether we can speak of distinctive public health diplomacy.

The process brought together legal, medical and other experts, as well as representatives of international organizations and diplomats. Such a mix of expertise is not unique. In the area of trade or the environment, similar ranges of expertise will be required. There are many negotiations which involve extensive inter-agency consultations.

What may have made the IHR negotiations unique is the absolute common sense of purpose that allowed the elaboration of an internationally, universally, legally binding agreement, which touched very closely on issues of sovereignty and which could impact on vital interests across a broad range of economic, social and political policies. It was exceptional that governments, on this occasion, agreed on the nature of the threat and the nature of the solution. Perhaps it is only the specific issue of overwhelming health threats that could force the realization of the necessity for such action. Even then, such common purpose may only be possible when governments are forced to deal with very great threats of a non-specific nature, and may not recur when a health threat is specific and likely to affect different countries to varying degrees. I am not at all sure that outside this very defined area, even, for example, in the case of a specific PHEIC, that it would be possible to recreate the unity of purpose. We can unite against the fear of the unknown, but it may be more difficult to unite against a real and present threat.

Agreement may also have been possible because the issue was dealt with outside the usual glare of foreign policy. While the issues were political, the forum was regarded as technical. The experts present throughout the negotiations included medical and legal experts, public health officials, experts from various capitals, and diplomats who had direct responsibility for WHO.

At the same time, I would argue that the IHR reaffirmed the fact that diplomacy is a unique profession. The negotiations would not have been concluded within the time frame that they did without the active participation of Geneva-based mission personnel. They helped to build the essential trust between delegations, they worked to bring coherence to divergences in national and group positions, and to find ways of meeting the concerns of others.

Other international organizations played an important role, although they were not always able to think outside their own particular policy box. Diplomats should see their generalist role as an advantage and look at the overall picture.

I want to touch on another unique aspect of the negotiations: the calibre of the secretariat that supported the process. For every issue there were real technical and legal experts who had only one agenda: to obtain a strong instrument to deal with both known and unknown threats to human health. The quality of the organizational structures that supported the process is also fairly unique. The WHO regional network played an important role in building a shared sense of the direction in which the process must go to be successful.

Did these negotiations highlight the link between foreign policy and health policy? Yes and no. In its widest sense, foreign policy is the expression of a state's domestic policies as they impact on or are impacted by the external environment. In that sense, governments have always been mindful of the permeability of their borders to disease. Can one suggest that following the successful conclusion of the IHR and the Framework Convention on Tobacco Control (FCTC), that there is a unique area of international health diplomacy? I would hesitate to go so far. Governments will always find ways of cooperating against a common threat and ways of avoiding negotiations if they do not share a common perception of the threat or a common appreciation of how best to respond.

Negotiations can seldom be forced. Agreements are seldom reached under false deadlines or when there is no sense of an agreed objective. A common sense of purpose, mutual trust and the capacity to seize the right moment are essential in order to find solutions to cooperation on health or any other issue.