Australia wishes to provide additional comments and inputs on the document prepared by the Intergovernmental Working Group (IGWG), entitled *Elements of a global strategy and plan of action – Progress to date in the Intergovernmental Working Group* (A/PHI/IGWG/1/5), as requested in the World Health Organization’s Circular Letter dated 12 January 2007.

Australia’s comments highlight proposals in four of the areas for action in the Elements of a Plan of Action (A/PHI/IGWG/1/5, Annex 1).

- Promoting research and development
- Management of intellectual property
- Improving delivery and access - regulatory capacity
- Ensuring sustainable financing mechanisms

This Submission focuses on proposals in these four areas. Australia reserves its position on other proposals in the document.

**Co-ordination**

Co-ordination is an issue which cuts across most of the eight areas for the Plan of Action. Australia emphasises the need to ensure and enhance co-ordination with existing bodies undertaking activities covered under the eight areas.

**Early implementation priorities**

Australia considers that prioritization for early implementation of some activities is necessary for the World Health Organization and its Member States to continue to demonstrate a commitment to the objectives set by the World Health Assembly when establishing the IGWG (WHA59.24).

In this context, Australia considers that early implementation activities should focus on objectives which the WHO (in co-operation with other international organisations, where necessary) can achieve (or commence) within existing mandates. These activities should be practical in nature. Specific priorities for early implementation are identified below.
Promoting research and development

Australia endorses the proposal to enhance existing forums, in order to improve the coordination and sharing of information and coordinate stakeholders’ research and development through WHO’s endeavours (A/PHI/IGWG/1/5, Annex 1, paragraph 3 (d)).

Australia also endorses the proposals to undertake further work, taking into account existing mechanisms, to improve global coordination and financing of medical research and development in order to inform the decisions of governments and policymakers (paragraph 3 (h)).

These two areas are appropriate for early implementation. The current draft World Health Assembly resolution *WHO’s role and responsibilities in health research* (EB120.R15) provides good examples of how co-ordination in research can be put in place within the WHO.

It is not clear to Australia that a new forum is necessary, as is also proposed in paragraph 3(d). The capacity of existing coordination arrangements should be assessed, and if appropriate, enhanced before making any decisions to establish a new forum.

Management of Intellectual Property

The draft Elements of a Plan of Action proposes a number of areas of action for the management of intellectual property and technologies in developing countries under paragraphs 3(g), 5(d) & (e), 6, 7(i) & (j) and 10. For ease of reference, Australia’s comments on key IP issues and specific proposals are grouped together.

Australia considers that references in the draft Plan of Action to the management and implementation of intellectual property policy should reflect the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) that developing countries need to decide in the light of their own circumstances, what provisions, consistent with the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), would benefit public health, weighing the positive effects against the negative effects (CIPIH/2006/1, Recommendation 4.20).

Australia strongly endorses the proposal for cooperation with WIPO, the WTO and other international bodies, taking into account their mandates (A/PHI/IGWG/1/5, Annex 1, paragraph 10). Specific areas in which more effective outcomes may be derived from considered discussion and co-operation between the WHO, the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) are detailed below.

Specific proposals

paragraph 3(g) - Australia supports the proposal for countries to consider the appropriateness of introducing a research exemption into their patent law, taking into
account their domestic circumstances. Australia is considering the appropriateness of implementing an explicit exemption in its national law.

paragraph 5(d) – Australia considers that ensuring compliance with obligations under the TRIPS Agreement is outside the mandate of the WHO.

paragraph 5(e) - the proposal for the promotion of patent pools would benefit from considered discussion and co-operation between the WHO, WIPO and the WTO.

paragraph 6(b) - Australia supports in part the proposal to work within national and/or regional institutional frameworks to promote and manage intellectual property. Consistent with the comments on paragraph 3(d), Australia’s view is that the capacity of existing arrangements should be explored before establishing new ones.

paragraph 6(d) - the proposal for the compilation and update of databases on patent status would benefit from considered discussion and co-operation between the WHO, WIPO and the WTO. In particular, an analysis of the usefulness of establishing patent status databases is recommended. Investigations into how databases that are already available could be used may provide an effective approach for considering this proposal.

paragraph 6(e) – to avoid duplication and to ensure the most effective use of WHO resources, Australia considers that any work to strengthen education and funding in the management of intellectual property must be done in close co-operation with WIPO and the WTO.

For example, the WHO could consider mechanisms to ensure greater awareness of capacity building programmes on health-related intellectual property policy issues for developing countries conducted by itself, WIPO, the WTO and other international organisations, through bilateral country programmes and through foundations and institutions. This could improve access for developing country policy-makers to the information necessary to make decisions consistent with their individual national interest.

As an example of such a programme by an individual country, Australia has offered to assist developing countries’ governments to draft legislation to facilitate access to antiretroviral drugs, consistent with the TRIPS Agreement, through its *International HIV/AIDS Strategy*. Australian Government policy is to negotiate all aid program priorities with partner governments.

paragraph 6(f) - Australia cannot accept any binding proposal that bilateral agreements not contain ‘TRIPS-plus’ provisions.

paragraph 6(i) – the proposal in relation to test data exclusivity, “me-too” patents and patent linkages would benefit from considered discussion and co-operation between the WHO, WIPO and the WTO.

paragraph 7(i) - Australia supports the use of the flexibilities in the TRIPS Agreement. However, we consider that paragraph 7(i), as currently drafted, is not appropriate. As noted above, Australia considers that countries need to be able to
decide, in the light of their own circumstances, what provisions would benefit public health and best suit their needs.

paragraph 7(j) - Australia supports the proposal to consider the appropriateness of measures that encourage generic entry on patent expiry. Australia’s ‘springboarding’ provisions provide that, for a wide range of pharmaceuticals, manufacturers can undertake certain activities prior to patent expiry solely for the purposes of meeting regulatory approval requirements. Australia would encourage other countries to consider, in light of their own domestic circumstances, the appropriateness of introducing TRIPS-consistent ‘early working’ exception measures.

**Improving delivery and access - regulatory capacity**

Australia endorses the proposals to:

- support product introduction in developing countries through improved regulation at national and international levels (paragraph 7(a))
- encourage manufacturing in developing countries that complies with good manufacturing practices (paragraph 7(g))
- devise ways to curb counterfeiting of medicines and technology (paragraph 7(h))

The CIPIH Report highlighted the problem of counterfeiting in its commentary on quality as a determinant of acceptability (CIPIH/2006/1, Chapter 4 and Recommendation 4.4). A particular focus of Australia’s capacity building program is reducing the incidence of substandard and counterfeit therapeutic products in the Asia-Pacific.

Australia also endorses the related proposal, made under Building and improving innovative capacity, to strengthen product regulatory capacity in developing countries, including improvement of ethical-review standards and clinical-trials capacity (A/PHI/IGWG/1/5, Annex 1, paragraph 4(d)).

The WHO should explore early implementation of proposals in paragraphs 4(d) and 7(a) through the International Medical Products Anti-Counterfeiting Taskforce and International Conference of Drug Regulatory Authorities.

Australia would consider requests for assistance in relation to improving regulatory capacity, within the framework of its existing assistance programmes. This may include training, short-term work placements, support for WHO Fellows in the area of therapeutic products regulation.

**Ensuring financing mechanisms**

Australia endorses the range of proposals on ensuring sustainable financing mechanisms (A/PHI/IGWG/1/5, Annex 1, paragraph 8).

When considering the draft Plan of Action, CIPIH’s useful analysis should be borne in mind. The Commission assessed the institutional frameworks, including public and private sectors and partnership, current funding arrangements and funding requirements. (Chapter 3, Recommendations 3.2 and 3.3).
Drawing on this background, Australia sees value in exploring practical initiatives, for example the contributions of public-private partnerships funded by organisations such as the Bill and Melinda Gates Foundation and pharmaceutical companies.

Applied research, rather than basic biomedical research or clinical trials, is the focus of Australian international health-related development assistance.

These proposals for ensuring sustainable financing mechanisms should also be linked with the proposal, under promoting research and development (A/PHI/IGWG/1/5, Annex 1, paragraph 3 (h)), to undertake further work to improve global coordination and financing of medical research and development in order to inform the decisions of governments and policy-makers.

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