International Law Association

Report of the Global Health Law Committee

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Mandate of the Committee

- Help to establish the international law relating to public health as a recognized discipline, as are international economic law, international environmental law, international intellectual property law
- The protection and promotion of public health often treated as ancillary concerns in intergovernmental negotiations
- Incommensurate with the importance of the field to individuals and groups around the world
- Disparate treatment manifest in negotiations concerning trade, investment, finance and intellectual property rights (IPRs)

Breadth and Complexity of Global Health Law

- The protection and promotion of health encompasses a wide range of subject matter, including:
  - Establishment and functioning of national healthcare systems
  - Production and distribution of health goods and services, including cross-border movement
  - Innovation and access to health-related technologies
  - Preparation for and response to health emergencies
  - Addressing the impact of environmental degradation and climate change
  - Addressing disparate treatment of groups

Public health is a heavily regulated field

- Few subject matter areas are as heavily regulated as healthcare
  - Implementation of national healthcare schemes, including access to goods and services, insurance and reimbursement
  - Approval of new health technologies, including medicines
  - Regulation of production and distribution, including approval of manufacturing facilities, supply chain, prescribing and pricing
  - Regulation of professional services, Including cross-border provision
  - Innovation and transfer of technology, including patents and regulatory market exclusivity, and related competitive market aspects
- The systems of regulation are interrelated

The nexus between trade and public health

- Establishment of WTO and adoption of TRIPS Agreement represented "sea change" in international regulation of public health
- Authority to make rules directly affecting important health interests were moved from international organization regulating health (WHO) to international organization promoting mercantile interests (WTO)
- Trade negotiations since formation of WTO, including preferential trade agreements, increasing focus on restricting public health flexibilities, e.g., terms of Transpacific Partnership Agreement
- Rules on extension of market exclusivity to biologic drugs the most contentious element of the TPP negotiations
  - Other key aspects include ISDS and intervention in public health formularies/reimbursement determinations

GHLC Focus

- Committee initially focusing on 4 subject matter tracks
- Legal issues surrounding access to research materials, including biological materials and results of clinical research
- Legal issues surrounding access to essential medicines
- Legal issues surrounding tensions between trade/investment agreements and global public health
- State obligations in the field of health and links with human rights law, including non-communicable diseases and sustainable development

Meeting on Global Health Security

- First major activity of Committee was organizing multi-stakeholder meeting on Global Health Security in midst of Ebola crisis, Geneva, February 2015
  - Consensus on 1st order priority building up national healthcare systems
  - Critical need to accelerate R&D and approval pathways for new vaccines and treatments
  - Critical need to improve management of crisis intervention services
  - Need to integrate work of international organizations and NGOs, without establishing new international organization
- Zika outbreak represents latest challenge to emergency response system; certainly not the last

UN Secretary General's High Level Panel on Access to Medicines

- Established fall of 2015 with objective to deliver report in June 2016
- Mandate of the High Level Panel "to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."
- Call for submissions: Members of GHLC prepare two submissions to HLP
  - Access to essential medicines
  - Framework Agreement on Pharmaceutical Innovation and Related Protocols

Submissions

- The HLP received 180 submissions from a wide range of interested stakeholders
- Both GHLC submissions selected for presentation at HLP hearings in London
- Presentations by Rapporteurs ('t Hoen and Seuba) made at hearings before the HLP and EAG in London and Johannesburg
- Public Global Dialogues also convened in London and Johannesburg to further elicit ideas and recommendations from interested stakeholders. Live webcast, and recordings of the webcasts posted on the HLP website:
- http://www.unsgaccessmeds.org

Access to Essential Medicines

- Essential medicines list (EML) established by WHO with recommendation for all governments to make available to address priority health care needs of country
- National governments establish their own EMLs taking into account WHO,
  - Over 150 countries have adopted EMLs
- Right of access to essential medicines recognized as core obligation of right to health under Article 12 of International Convenant on Civil Economic Social and Cultural Rights (164 state parties), General Comment 14

Access to Essential Medicines

- Most essential medicines are available as generics, and most are available at reasonable prices
- Notable exceptions include newer antiretroviral treatments, treatment for Hepatitis C, anticancer and TB treatments
  - 16 anticancer drugs added to EML in 2015
- Newer patented drugs often very expensive, including sofosbuvir (Sovaldi) for Hep C, imatinib (Gleevec), rituximab (Rituxan), and trastuzumab (Herceptin)
- Can we reconcile a fundamental human right to access to essential medicines and sharply limiting availability on the basis of patents?

GHLC First HLP Submission

- GHLC submission seeks to assure affordability of newer essential medicines by encouraging voluntary licensing, including to Medicines Patent Pool, but providing alternative of effectively automatic compulsory licensing with socially responsible royalty to assure availability (royalties scale based on capacity to pay)
- Implementation can be accomplished through TRIPS-compliant measures
- Alternative of authoritative interpretation by WTO of Articles 27 and 30 of TRIPS Agreement

The Current Model

- All stakeholders recognize present system does not fulfill all needs appropriately
- Predominant model for innovation relies on patents and regulatory market exclusivity to provide funds for R&D through higher than competitive market pricing
- Many stakeholders question whether current model adequate and/or sustainable, including for non-communicable diseases and high income markets
- Alternative models in use, but in limited way

The Human Right to Health

- Many submissions urge approaching access to health technologies as a human rights matter
- Prioritizing right to health over right to exploit and commercial interests
- Urge establishment of accountability mechanisms

Alternative Delinkage Models

- Separating production and distribution from research and development
- Enable sale and distribution at marginal cost – similar to generics sector
- Key issue is funding R&D without reliance on prices above competitive market (patent-based exclusivity)
- Substantial R&D undertaken without reliance on patents
- Including PPPs and push-pull-pooling

GHLC Plan to Propose Resolution

- Committee Members expressed interest in formulating a resolution for adoption by the ILA based on anticipated HLP report
- Report not issued as of August 8, 2016
- Laws of time and space appear to preclude proposal of ILA resolution based on report that does not yet exist ("Einstein's HLP paradox")