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Abstracts for Oral Presentations

Plenary Session 2: Health Technology Assessment as a Tool for Evidence Based Decision Making in Healthcare	
Dr Shankar Prinja, Additional Professor- Health Economics, Postgraduate Institute of Medical Education and Research (PGIMER) - Chandigarh, India	The setting up of Health Technology Assessment Board in India has placed greater impetus on using evidence-informed decision making. The use of HTA evidence is relevant for a number of stakeholders, including the policy makers, regulators, program managers, clinicians, industry and patient groups. One of the areas, where the HTA evidence has not been used as much is the issue of price regulation by National Pharmaceutical Pricing Authority and setting of standard treatment guidelines by clinicians. In this talk, I will illustrate using 3 HTA case studies, how the evidence from HTA could be used for both price regulation and for determining standard treatment guidelines. These 3 case studies include one medical device - safety engineered syringe, and 2 drugs - trastuzumab for breast cancer and velpatasvir for hepatitis C virus treatment.
THIAGARAJAN Sundararaman, Former Dean, Tata Institute of Social Sciences- Mumbai, India	**The Establishment Of HTA In Indian Policy** In 2017, the government of India constituted a Board for Health Technology Assessment in India (HTA-In). This important milestone signifies the acceptance of the role of Health Technology Assessment in decision-

	making at the policy level. Better choice of technology and program design in government health programs was an immediate driver for the creation of the Board. The other was to facilitate medical reimbursements and improve quality of care in both public services and publicly financed private healthcare. These studies were meant to evaluate the clinical effectiveness, the cost effectiveness, the safety and appropriateness of the proposed technology, so that there is best value for the money in government expenditure. The need for greater health equity has also to be factored in when making the technology choice. Such evaluation is required for available technologies and well as for new technologies, and in the latter context it would be to support the regulatory function of governments. HTA is a widely used methodology internationally for optimization of resource allocation in health, identifying the most cost- effective strategy among available alternatives, and in that way an essential policy tool for progress towards Universal Health Coverage (UHC). As a discipline, HTA is a multidisciplinary process that.
Dr Francoise A Cluzeau, Associate Director, Global Health and Development Group, Imperial College London, United Kingdom	**Promoting Quality Standards Through Quality Improvement Programs** As countries strengthen their health systems and move towards Universal Health Coverage (UHC), quality of care has become a central pillar of this dialogue. The Sustainable Development Goals (SGD) 3.8. on UHC and the WHO Framework on Integrated People Centred Health Services highlight the importance of innovative improvement programmes that include access to safe, effective and quality essential healthcare services for all people. Increasingly countries are embedding quality matrix in their healh care systems, through public health insurance programmes, and at the point of delivery to drive better care in a more efficient and affordable manner. This presentation will set quality improvement in the context of evidence-based decision making, linking health technology assessment with Standard Treatment Guidelines (STGs) and derived Quality Standards (QS). It will draw from the experience with implementing QS in two primary Care settings in India and based on STGs adapted from International evidence to the Indian setting (http://clinicalestablishments.gov.in/En/1068-standard-treatment-guidelines.aspx)

Plenary Session 5: Re-purposing of Medicines for Reduced Approval Timeframe, Decreased Costs and Making Use of Existing Data	
Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom	**Value Of Human Infection Studies** Human infection studies, where healthy adult volunteers are infected with well-characterised pathogens in a controlled and safe environment, can address specific disease related questions and accelerate vaccine and drug development and design. These studies can help us to better understand why vaccines and drugs are effective or not, allow for quicker and more informed decision making around progressing candidates through the pipelines and better inform the design of Phase III trials. Human infection studies have provided landmark data for several registered vaccines alone. The nature of these studies however does mean they pose regulatory and ethical challenges especially with the increasing interest in conducting these in endemic settings. Wellcome has supported the KEMRI-WELLCOME site in Kilifi, Kenya to establish the falciparum malaria human infection study and is keen to further expand human infection studies in low resource settings such that vaccines can be tailored for the target population. Vaccines currently developed in high income countries risk being less effective when transferred to target populations in low income countries due to differences in demographics, environmental factors and comorbidities etc. Wellcome is working with other funders to support the development of harmonised regulatory and ethical frameworks such that human infections studies can be safely performed in the target population to ensure better tailored vaccines and drugs.
Ms Ciska Verbaanderd, University of Leuven & Anticancer Fund, Belgium	**Drug Repurposing To Provide Safe, Affordable And Effective Treatments - Focus On Oncology Products** Repurposing of approved and well-characterised medicines for new therapeutic indications is becoming increasingly popular in cancer research as it could lead to new anticancer treatments relatively quickly and at low cost, thereby meeting the unmet needs of patients, healthcare systems and society at large. Various

	medicines originally developed for non-cancer diseases have shown promise for the treatment of cancer. Thalidomide, a medicine that was withdrawn from the market in the 1960s for its catastrophic adverse events upon use during pregnancy, is one well-known example of a medicine that was successfully repurposed for cancer treatment. The ReDO_DB comprises over 300 non-cancer medicines with some evidence of anticancer activity and about 70 of these medicines are currently being tested in one or more advanced clinical trials (i.e. phase II/III, phase III or phase III/IV) with cancer patients. This pipeline of repurposed medicines is expected to grow, as additional preclinical and clinical research is ongoing. However, so far, efficiently translating the scientific knowledge about repurposed medicines into clinical practice has proven to be quite difficult due to legal, regulatory and financial challenges. To unlock the potential of drug repurposing in oncology, we need to find sustainable solutions to address the current challenges, taking into account the interests of all involved stakeholders, i.e. academia, the non-profit sector, industry, regulators, policy-and decision makers, health technology assessment bodies, payers, healthcare professionals and patients.
Dr Ian Hudson, Senior Adviser, Bill & Melinda Gates Foundation and Former Chief Executive, MHRA, United Kingdom	**Novel Regulatory Approaches In The UK For Re-Purposing Of Medical Products** Repurposing is complex and involves different stakeholders who may have different perspectives, but offers opportunites for faster development times, reduced cost and risk. This area has attracted keen interest in the UK. The UK Governemnt commissioned the Association of Medical Research Charities to review repurposing and the subsequent report contains a series of recommendations and proposed pathways. Multiple different datasources can be used to support repurposing and regulators have flexibility as long as the data supports the claims. Regulatory incentives include additional data exclusivity, Paediatric Use Marketing Authorisations, Orphan designation and advice. Various other initiatives are underway including 3 way partnerships with Academia, Industry and public funders.

Plenary Session 6: Patent Landscaping for Health Products (WHA 72/17, 2019)	
Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia	**Intellectual Property and Access to Medicines- Frameworks for Access** The proliferation of regional trade agreements has brought about higher standards of intellectual property protection that may have the effect of eroding the flexibilities that currently exist under the WTO framework for intellectual property governance. The presentation highlights the challenges posed by the intellectual property, especially TRIPS-plus provisions in regional trade agreements (RTAs), to access to affordable medicines. It focuses on TRIPS plus provisions in free trade agreements negotiated by the US with Australia, Morocco, Mexico and Canada. The presentation highlights how TRIPS-plus standards contained in US RTAs may affect access to medicines in globally. It also addresses how investor-state dispute settlement clauses in trade or investment agreements may whittle down the available flexibilities in the TRIPS Agreement. The discussion provides possible policy options that may be explored by countries especially in the global south to address these issues.
Mr Joy Goswami, Assistant Director, Technology Transfer & Corporate Partnerships, Office of Economic Innovation & Partnerships, University of Delaware, United States of America	**Patent Landscaping For Innovations In Life Sciences** The topic will discuss best practices in patenting, employed by institutions to bolster innovation in life science technologies.
Dr Unnat Pandit, Program Director, Atal Innovation Mission, NITI Aayog, Government of India	**Strategic Management Of Intellectual Property, Innovation, Incubation Management And Deployment Of Technologies** In last few years Indiaâ€™s 29-place move up in GII represents the biggest jump by any major economy. India has a unique opportunity among its myriad challenges to become the innovation leader in the world. Such performance is the result of firm measures taken by government with a vision to consistently improve, rejuvenate their performance and build strong IP, Innovation ecosystem. India Innovation Index by NITI

	Aayog would create synergies between different stakeholders in the innovation ecosystem. Indiaâ€™s increase in innovations and startups trend are consistently rising among other leading ecosystem. The expected rise in demand of technology driven innovative solution is to address the need of societal challenges. There is need for indigenous mechanism for getting quality research outcomes and exploring utilization of innovation and procuring the IP driven solution. The development of a matrix bring transparency in the process of assessment, funding, monitoring, especially in terms of qualitative aspects of research and balancing societal need of R&D and commercial use to fill the gap in ecosystem. Disruptive innovation specially in healthcare sector is the need of New India having a vision of futuristic technology development making a stride for consistent, parallel efforts towards building the knowledge driven economy.

Plenary Session 7: Plenary Session 7: Access Strategies, Patent Pool Mechanisms and Licensing for Medical Products and Health Technologies including the Role of Pharmaceutical Sector	
Mr Richard Wilder, General Counsel and Director of Business Development, Coalition for Epidemic Preparedness Innovations, Norway	CEPI's mission is to stimulate and accelerate the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks. Since its launch in January 2017, CEPI has announced for calls for proposals, including calls for candidate vaccines against Lassa virus, Middle East Respiratory Syndrome coronavirus (MERS-CoV), Nipah virus, Rift Valley fever and Chikungunya virus. We have also issue a call for the development of platforms that can be sued for rapid vaccine development against unknown pathogens. CEPI currently has 19 vaccine candidates against its priority pathogens under development along with three vaccine platforms. Central to CEPI's mission is its mandate to ensure the vaccines it developed are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay. Ensuring access starts with the agreements CEPI concludes and runs through their implementation and beyond – including engagement with members of the broader CEPI coalition. Ensuring access means paying close attention to the agreements that are concluded, but also regulatory and technology issues that affect the suitability to needs of affected territories and also when, where, and at what price vacines will be available and accessible.
Professor Brook K Baker, Northeastern University School of Law and Senior Policy Analyst, Health Global Access Project, United States of America	**Expanding And Improving Voluntary Licenses And Accelerating Registration At The Medicines Patent Pool** Although the Medicines Patent Pool has made significant progress in expanding access to HIV antiretrovirals, there is still substantial work to be done to: (1) expand geographical scope of MPP licenses through both direct and indirect coverage provisions, (2) include a broader range of essential medicines not only in MedsPAL but also in its licensing portfolio, (3) explore how to incentivize new fixed-dose, heat-stable, long-lasting, and pediatric formulations through grants, prizes, and improved grant-back clauses, (4) require transparency of global patent landscape for licensors, (5) accelerate and broaden registration and marketing of generic licensees to all relevant LMICs and require more transparency from licensees concerning registration approvals, pending applications, and plans for future approval and market entry, and (6) in the

	case of small and fragmented markets, adopt price control terms to achieve affordability and sustainability of markets.
Dr Manica Balasegaram, Executive Director, Global Antibiotic Research and Development Partnership (GARDP)/ Drugs for Neglected Diseases initiative (DNDi), Switzerland	**The Access Strategies For AMR (Outcomes Of The Workshop)** New drugs alone will not prevent the rapid rise of antibiotic resistance. Unaffordable drugs, insufficient supplies and other challenges put lives at risk and jeopardise progress. Earlier this year, the Global Antibiotic Research and Development Partnership (GARP) in collaboration with the World Health Organization and the Medicines Patent Pool, facilitated a workshop to better understand the challenges, alongside roles and responsibilities of different actors in addressing antibiotic access, from early stage research to delivery and stewardship. The workshop brought together perspectives from industry, academia, civil society and governments. Building on the outcomes of the technical workshop, a high-level panel was organised during the World Health Summit in Berlin to explore practical solutions to questions raised. Dr Manica Balasegaram, Executive Director of GARP, will share the outcomes from the technical workshop and World Health Summit discussion.
Dr K. Bangarurajan, Joint Drugs Controller, Central Drug Standard Control Organization, Government of India	**Access Strategies** Presenting on the subject facilitating access through licensing option for Newer Medicines of Public Health Importance for plenary session 7 in which i will cover the approval process of New Drug in India and provisions of New Drugs and Clinical Trials Rule 2019 for accelerating access of new drugs for Indian public. Points covered in the presentation is - Introduction of New Drugs and Clinical Trials Rule 2019, Provisions for CT of New Drugs and IND, Approval of New Drug, Provision for Accelerated approval, Waiver of local CT, Review of Applications of CT & ND and provision of Pre and Post- submission meeting of New Drugs and Clinical Trials Rule 2019

Parallel Session 2: Funding and Investments in Medical Products R&D: Role of Data Tracking Initiatives	
Dr Michael Cheetham, Manager, Division of International Relations, Fogarty International Centre, National Institute of Health, United States of America	**World RePORT - A Global Database Of Biomedical Research Investments** World RePORT is an interactive, open-access database and mapping of global research investments from some of the worldâ€™s largest biomedical funding organizations. The site maps direct awards and indirect global research collaborations by continent, country, funding organization, research organization and year. World RePORT includes funding data from 2012 through 2018, currently about three hundred thousand records from 11 funders to over fifteen thousand research institutions in 181 countries. Users can interact with the map to find projects or use a simple keyword search within titles and abstracts and filter by location (continent, country or city), funding organization, research organization, principal investigator name, or any combination. Users may freely export all data for local use. World RePORT provides a public means to track international research activities and partnered investments, increase awareness of funding opportunities, and share results with the broader research and funding community. The goal is to improve understanding of the research landscape, identify gaps in funding and areas where there might be a duplication of effort, and enable funders to more effectively synergize investments.
Dr Anthony D So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America	**The Role of Transparency in Ensuring Fair Returns from Pharmaceutical R&D** Public sector financing plays a significant role in supporting the discovery of new drugs and vaccines, and healthcare payers or patients, in the end, also foot the costs of procuring these health technologies. Yet there is non-transparency over many aspects of the pharmaceutical value chain. This non-transparency not only includes R&D costs, patents, prices and profits from specific technologies, but also the annotation of compounds. The rationale put forward for non-transparency is that the invention is proprietary, and commercial confidentiality, applies. With disclosure, the motivation for investing and competing to develop better products would purportedly be eroded. Benefits of greater transparency could include more robust analysis of why certain pharmaceutical products command higher prices or faster innovation. Disclosure,

	however, needs to be followed by feedback, accountability or enforcement. Even with transparency, data exclusivity can preclude the use of originator manufacturer information submitted for drug registration from being use for drug regulatory agency approval of a follow-on drug product. The costs of non-transparency might be measured in terms of delayed invention, registration of the pharmaceutical product, or healthcare benefits, including averted harms. Patients may be subject to knowable risks when competing manufacturers fail to share information in a timely manner about the same product or drugs from the same family of compounds. Various approaches are available to ensure greater transparency of the pharmaceutical value chain. These can be applied by the funders of the research, drug regulators, or the purchasers of the end products. Importantly, a framework for assessing the potential benefits and costs of transparency might help policymakers weigh whether such disclosure may help ensure fair returns from pharmaceutical R&D. Such fairness is not only from public investments but also from the promised benefit-sharing of clinical trial participation.
Dr Purnima Sharma, Managing Director, Biotech Consortium India Limited, India	**Holistic Approach for Effective Technology Translation** A holistic understanding of the technology translation process for technologies in healthcare sector, in view of their long gestation period and time-to-market. This can drive much-needed affordability and efficiency in health systems, which continue to remain high due to intricate pathways across clinical and product validation requirements. Innovators struggle to design protocol-based, statistically significant studies, simulated in real-world clinical settings. Early understanding, planning and mentoring for devising clear technical development pathway in line with IP strategy, regulatory strategy, funding raising, and market strategy is the key to expedited technology translation. There is a pressing need for a single window platform to enable and accelerate the holistic development and commercialization of most-promising health care innovations leading to market access and penetration. Such a platform shall provide handholding to innovators/startups/established companies through the multiple valleys of death facing startups/industry and de-risking investors by providing them with the vital domain knowledge for accurate assessments of the risks and rewards. The prevailing systems need to be integrated and strengthened to create such a platform for optimum utilization of the funds and resources. The details and case studies shall be shared during the presentation.

Parallel Session 3: Incentives for Development in Antibiotics, Global Anti-Microbial Resistance R&D Hub	
Dr Anthony D So, Professor of the Practice and Director, IDEA (Innovation + Design Enabling Access) Initiative, Department of International Health, Johns Hopkins Bloomberg School of Public Health, United States of America	**Alternative Production and Delivery Models for Sustainable Access to Antibiotics** The production and delivery of antibiotics today suffers from both a shortfall of novel classes of antibiotics and a shortage of old antibiotics. For novel antibiotics, the pharmaceutical industry faces challenges in ensuring rates of returns comparable to what it has generated in other therapeutic categories. However, this focus on drug-by-drug, company-by-company returns may neglect important concerns: the scientific bottleneck of drug discovery, affordable pricing of end products, effective stewardship, and fair returns on public investment. For old antibiotics, the opportunity costs of keeping stable supplies of these drugs have not been sufficiently attractive. Consequently, even antibiotics like benzathine penicillin Gâ€"a drug that could provide secondary prophylaxis for 33 million with rheumatic heart disease and that could treat pregnant women with syphilisâ€"have experienced shortages. These problems suggest that we need to move beyond current incentive approaches. The concept of delinkageâ€"divorcing drug company returns from price and quantity of antibiotics soldâ€"has proven difficult to operationalize. Moving beyond delinkage, an end-to-end approach might ensure sustainable access to antibiotic innovation. Such an approach will likely entail greater public sector-led interventions, both reshaping the supply and demand sides of the R&D pipeline. On the supply side, the innovation ecosystem might be primed by platform technologies for drug discovery, supported by services that speed the path to first-in-human trials, and enables more efficient recruitment and completion of clinical trials. On the demand side, new business models will be needed to realign incentives to ensure effective stewardship and stable supply of antibiotics. Some of these potential models are emerging, but others will require piloting. For sustainable access to antibiotics to become a reality, we must benchmark the promise of proposed approaches against the twin goals of access and stewardship.
Dr David Kaslow, Vice President, Essential Medicines Director, PATH, United States of	**Incentivizing R&D and Promoting Access** While innovations to address AMR are needed across the continuum of products (e.g., diagnostics, drugs, and biologics, including vaccines), services (e.g., AMR surveillance and monitoring, hospital epidemiology

America	and infection control), and practices (e.g., antimicrobial stewardship), the focus of R&D by product development partnerships (PDPs) has historically been on the product. It has become clearer that product R&D, while necessary, is not sufficient to ensure global access, particularly in the context of market failures and in having optimal impact in the lowest resource settings. Understanding the value that a new product brings as a solution in the broader context of the services and practices in which it will be used and then lining up the push initiatives and pull incentives needed to overcome the four major hurdles (discovery to early clinical development; late stage development to initial regulatory filing; licensure, policy and financing introduction; scale-up and sustainability) from an idea to impact are also essential. Lessons learned from a recent attempt to license Tribendimidine, a new soil-transmitted helminth drug with a novel mechanism of action (in part to address the risk of drug-resistance from the current benzimidazoles—mebendazole and albendazole) through a prize incentive--priority review voucher--whose value is market-based will be presented to highlight some of the challenges in incentivizing R&D through the PDP model.
Dr Anand Anandkumar, Chief Executive Officer, Bug Works, India	**Raising Financial Capital For R&D In Anti Microbial Resistance (AMR) Area** Antimicrobial resistance (AMR) is one of the biggest crisis' plaguing humanity. We lose more than 700,000 people per year and LMIC's have the highest disease burden. AMR is beginning to impact the entire health ecosystem and the very edifice of modern medicine is on the verge of developing serious cracks. Despite the huge challenge around AMR and the scientific progress done in recent years, the market forces to bring new diagnostics and therapeutics are simply lacking. This serious economics challenge has made it nearly impossible to attract private capital into this space. This talk will focus on what governments and Private-Public-partnership platforms could do to make AMR an investable area, thereby creating a vibrant innovation ecosystem that will allow for new diagnostics and therapeutics to make it to needy patients all over the world. Without serious changes in the incentive mechanisms (also called 'Pull' incentives), the space will continue to struggle to attract private investors. Governments all over the world, including those in LMIC's will have to step up to the plate to save this industry, thereby, saving the lives of their respective citizens.

Parallel Session 4: Controlled Human Infection Model (CHIM) Studies-Regulatory and Ethical Considerations	
Ms Shobana Balasingam, Programme Officer, Vaccines, Wellcome Trust, United Kingdom	**CHIMS – Present Position And Next Steps For National, Regional And Global Engagement** Human infection studies, where healthy adult volunteers are infected with well-characterised pathogens in a controlled and safe environment, can address specific disease related questions and accelerate vaccine and drug development and design. These studies can help us to better understand why vaccines and drugs are effective or not, allow for quicker and more informed decision making around progressing candidates through the pipelines and better inform the design of Phase 3 trials. Human infection studies have provided landmark data for several registered vaccines alone. The nature of these studies however does mean they pose regulatory and ethical challenges especially with the increasing interest in conducting these in endemic settings. There is regulatory guidance available by the EMA and FDA for the conduct of human infection studies and recently it has been found that there is more synergy than previously thought especially with regards to the grade of challenge agent that is permissible. The guidance provided by the WHO is deemed not sufficiently robust for regions not covered by the FDA and EMA. Considering the different challenges and needs specific to different settings, there is a need to develop national and regional guidance that is then harmonised at a global level. In terms of ethical governance, WHO is currently developing the ethical guidance for human infection studies although there have been several publications relating to the ethical framework that can be considered in the meantime. Increasing interest in developing human infection studies in LMICs means that the governance, both regulatory and ethically, needs to be reviewed, developed and harmonised. Wellcome is taking an active role with the support of other funders in the space to bring regulators, ethicists and researchers both experienced and those new to the field together with the aim of ensuring frameworks and tools are available for human infection studies to be conducted safely.

Dr Wilbur Chen, Associate Professor, University of Maryland School of Medicine, United States of America	**CHIMS To Promote Regulatory Approval: Vaxchora Licensure For Cholera By U.S. FDA** Cholera is an acute watery diarrheal infection caused by Vibrio cholerae O1 or O139 and is transmitted by ingestion of contaminated food or water. The fluid losses with cholera diarrhea can lead to severe dehydration and even death. Cholera is an important public health problem of many developing country settings. Until 2016, no cholera vaccines were available in the U.S. A single dose, live, oral cholera vaccine (Vaxchora) was licensed in the U.S. on the basis of a controlled human infection model (CHIM). A brief overview of the licensure pathway of Vaxchora will be described.
Dr Jeffrey D'Souza, Research Associate, Institute on Ethics & Policy for Innovation, McMaster University, Canada	**Setting the record straight: debunking myths about controlled human infection model studies** With the recent rise in the number of controlled human infection model (CHIM) studies conducted globally, a number of ethical questions and concerns have been raised by sponsors, researchers, and reporters. Chiefly among them are: (1) do CHIM studies contravene ethical guidelines governing research involving human participants?, (2) will the introduction or presence of such research wrongly steer governments and policy-makers away from strengthening existing public health services?, and (3) is such research too risky and potentially harmful to be conducted with human participants? This presentation seeks to debunk myths and misperceptions related to these three concerns, while underscoring the importance of introducing, maintaining and ensuring fidelity to robust research protections, so that wherever CHIM studies take place, they do so in accordance with the highest ethical standards.
Dr Melissa Kapulu, Research Scientist in Infectious Diseases, Kenya Medical Research Institute (KEMRI), Kenya	**Controlled Human Infection Studies In Endemic Populations - Methodological Considerations** Controlled human infections models are a powerful tool for target antigen identification, selection, prioritization and development especially in the context of naturally acquired immunity. These models are important in the vaccine development pipeline and/or pathway with the potential for down-selection of candidate vaccines through efficacy testing and evaluation. These platforms have the potential to further identify correlates of protection in that have remained poorly defined in epidemiological studies. Thus, controlled human infection models provide a rapid means for the identification of antigens to be prioritized for vaccine development. However, as these models are progressed to populations in endemic settings, methodological considerations pertinent to implementation need to be factored into the scientific questions being addressed, design, logistical

	set up, stakeholder engagement, and embedding of empirical ethics sub-studies. Controlled human malaria infection (CHMI) platform has been established in Kenya â€“ in adults with a range of prior exposure to malaria. These volunteers have been infected with intravenous sporozoites and closely monitored clinically and by molecular methods of parasite detection for development of parasitaemia. The outcomes of this approach and considerations undertaken in setting up the platform will be presented including considerations for undertaking an enteric, Shigella, human infection model in the same setting.
Dr Rob Lambkin-Williams, Executive Scientific Advisor, hVIVO & Virology Consult, United Kingdom	**Manufacturing Of Human Viral Challenge Agents For Use In Clinical Studies To Accelerate The Drug Development Process** Possibly the first Human Viral Challenge (HVC) agent came from a cow called Blossom. In 1796, Sir Edward Jenner developed the first successful vaccine using the Human Viral Challenge Model (HVCM) after observing milkmaids, who had become infected previously with cowpox, did not become infected with smallpox. He conducted a simple challenge study inoculating an eight-year-old boy with material from cowpox blisters of a milkmaid, who had been infected by Blossom. He then later inoculated the boy with smallpox who subsequently showed no signs of infection. From this early HCM study, vaccination was born. Manufacturing of HVC agents has occurred over many decades; different standards have been applied over time under different regulatory requirements, depending on the country in which the clinical study was conducted. As yet, a global standard for the manufacture of challenge agents does not exist. The US regulators consider HVC agents as if they are new drugs, and thus studies performed in the US are conducted within the FDA (US Food and Drug Administration) Investigational New Drug (IND) framework. The UK and the EU regulators don’t consider HVC agents as new drugs, resulting in less clarity regarding which guidelines to follow. When an HVC agent is used in the UK, not in conjunction with an investigational medicinal product (IMP), a study is classified as a clinical study and not as a clinical trial. Considering the lack of specific guidance on the production of HVC agents, this talk will consider the key points in the production of HVC agents recently used in the UK, Europe and the USA. In addition, this talk will consider the recommendations from the recent IABS conference held in Frankfurt entitled: Focus on Quality Requirements for Challenge Agents October 22, 2019 Paul-Ehrlich-Institut, Germany.•

Parallel Session 5: Moving Towards Smarter Clinical Trials– Changing the Paradigm in the Context of Global and Multi Regional Clinical Trials	
Dr Francis P Crawley, Coordinator, European Fellowship in Research Ethics (EFRE), Belgium	**Moving From Capacity Building To Capacity Sharing In Clinical Trials: Sharing Knowledge, Frameworks, And Data On The Critical Pathways For Access To Medicines** A fundamental ethical justification for clinical trials is the assurance of a viable pathway from the experimental procedures to patients and communities through public health channels. This requires that the ethical and scientific procedures for testing the safety and efficacy of an intervention are carefully planned, reviewed, and demonstrated to be viable. It also requires an epidemiological and health-needs population-based study is undertaken alongside cost/benefit and health economic studies. The key ethical and scientific consideration is that of 'responsibility': the recognition of one's own proper responsibility as well as the responsibilities of the institutions and organisations, - public and private, governmental and non-governmental - that engage the research in collaboration with patients and communities. For too long the clinical trials needed to develop medical interventions (medicines, vaccines, devices, surgical techniques - and their combinations) have been separated from the discussion as to how these interventions - when finally determined to be safe and efficacious - will be made available to the individuals and populations in need of them. The critical pathways to 'access to medicines' run along, and are intimately tied to, the critical pathways to 'clinical trials development'. We need now to develop critical pathways for sharing knowledge, data, and frameworks of lived experiences & worldviews.
Dr Jeffrey D'Souza, Research Associate, Institute on Ethics & Policy for Innovation, McMaster University, Canada	**How much is too much? A closer look at incentives and undue influence in non-therapeutic research** Non-therapeutic clinical trials often offer monetary incentives to encourage individuals to participate in clinical research. An ongoing challenge for sponsors, researchers, and research ethics committees is determining what constitutes an appropriate amount. Offering too little of an incentive may lead to unmet recruitment targets, prolonged trials, and increased costs, as well as prevent important research from taking place. Offering too large of an incentive, however, can unduly influence individuals to participate in research â€“ thus, undermining the voluntariness of participantsâ€™ consent â€“ and demonstrate a disregard toward

	individualsâ€™ values, preferences, and well-being. While there is no algorithm â€“ and nor should there be â€“ for determining the amount of an incentive in a particular clinical trial, there are important ethical factors to be considered. This presentation lays out those central ethical factors, and demonstrates how they might be applied with an increasingly popular type of non-therapeutic research, controlled human infection model (CHIM) studies.
Ms Catherine Tregunno, Senior Scientific Assessor- Vaccines, Anti-infectives and Advanced Therapies Unit, Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom	**Monitoring Safety In The Post-Marketing Period- Safety Data From Clinical Trials To Form A Risk Management Plan** In EU medicines legislation, marketing authorisation applicants must submit with the application dossier, a description of the proposed risk management system for their product. This is the risk management plan, which although in the EU must be approved by the regulator at the time of first authorisation, is a living document which should be updated throughout the lifecycle of the product. Applicants are encouraged to plan from early on in a productâ€™s life cycle how they will further characterise and minimise the risks associated with the product in the post-authorisation phase. The presentation will briefly outline the main sections of the RMP (safety specification, pharmacovigilance plan and risk minimisation plan), and cover key points on how to consider whether adverse events observed in clinical trials may constitute important safety concerns which should be documented in a risk management plan, and describe the categories of important identified risk, potential risk or missing information. The presentation will also highlight the importance of proactively planning how to characterise or minimise important risks in the post-marketing period, discuss some options and highlight that these plans can be tied into the marketing authorisation.

Parallel Session 6: Medical Technology Pathways for Innovative Medical Devices	
Dr Sandeep Singh, Professor (Cardiology), Executive Director, School of International Biodesign, All India Institute of Medical Sciences-Delhi, India	**The School of International Biodesign (SiB)** School of International Biodesign (SiB) is a flagship program of the Department of Biotechnology, Ministry of Science and Technology, Government of India. This fellowship program is implemented at the All India Institute of Medical Sciences-New Delhi (AIIMS) and Indian Institute of Technology- Delhi (IIT) in collaboration with international partners. Biotech Consortium India Limited (BCIL) manages its techno-legal activities. The mandate of SiB is to train the next generation of medical technology innovators. The focus is on frugal innovation with development of affordable and accessible medical technologies. This interdisciplinary program so far has trained more than 125 medical technology innovators, developed over 40 medical technologies, 21 technologies have been transferred and 12 medical technology start-ups have been set up by the SiB fellows.
Mr Prakash Bachani, Scientist E & Head (Medical Equipment & Hospital Planning Deptt.), Bureau of Indian Standards (BIS), Government of India	**Standardization of Medical Products** Bureau of Indian Standards is the National Standards Body engaged in the process of formulation of Indian Standards in various areas of science and technology under BIS Act 2016. Standardization is a dynamic process involving participation, discussion and contribution of various stakeholders. BIS has so far published over 20,000 Indian standards on various subjects. In the field of medical devices and hospital equipment, the activity is being looked after by Medical Equipment and Hospital Planning Department (MHD) of BIS which has published over 1300 standards on medical devices and related subjects. In its 20 sectional committees, on various fields such as General Surgery, Gyanecology, Orthopaedics, ENT, Opthalmology, Neurology, Dentistry, Radiology, Anatomy etc. there are over 970 product standards and remaining standards are on test methods, code of practice, terminology etc. Out of these standards, more than 400 Indian standards have been harmonized with ISO/IEC standards. Indian standards thus published ensure safe and reliable quality products, eliminating health hazards and encourages greater participation of stakeholders in formulation/revision and implementation of national

	standards. As per the Medical Devices Rules 2017 notified by Ministry of Health and Family Welfare, Govt of India, the preference to the medical device for their conformance has been given to the Indian standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1986 (since revised in 2016).
Dr Ravinder Singh, Scientist C, Division of Non Communicable Diseases, Indian Council of Medical Research, Government of India	**Policy Provisions For Assistive Technologies** Assistive technologies can change lives of persons with disabilities (PwDs). Only 10 per cent of PwDs have access to such products while 7% of GDP is affected by not including these people. India has moved ahead of many member countries by framing draft policy briefs. These will help in developing mechanisms for provisions of these technologies through healthcare settings as part of UHC and health as right.
Mr Ajay Pitre, Managing Partner, Pitre Business Ventures LLP, India	**Medical Device Innovation: Serving The Underserved** The talk will cover the Macro situation of Healthcare delivery in India & thereby the needs as well as the recent initiatives. It will also then cover some insights into what should be the role of Medical Device Industry to support these Healthcare objectives / challenges of India & other such countries with underserved populations. It will also cover the challenges that Medical Device Industry face in this regard & the solution that needs to be adopted to be able to serve the underserved while building a sustainable model
Dr Reba Chhabra, Director In-charge, National Institute of Biologicals, Ministry of Health and Family Welfare, Government of India, NOIDA	**Quality Control of Diagnostics & Fostering of Local Production of Innovative Medical Devices** The National Institute of Biologicals, NOIDA is notified Central Drug Laboratory (CDL) and Central Medical Device Testing Laboratory (CMDTL) in accordance with statutory provisions of Drugs & Cosmetics Act 1940 and Rule 1945 amended from time to time for In-Vitro Diagnostics of Human Immunodeficiency Virus, Hepatitis B Surface Antigen, Hepatitis C Virus; Blood Grouping sera; Glucose Test Strip and Fully Automated Analyser based Glucose Reagent. The Institute is a WHO Collaborating Centre for Quality Control of HIV, HCV, HBsAg & Syphilis in-vitro diagnostic assays (WHO CC No.IND-148). The Diagnostic laboratories of the Institute are conducting Quality Control testing of indigenously

	manufactured and imported in- vitro diagnostic kits for HIV, HCV, HBV markers & syphilis; molecular diagnostic kits (Qualitative & Quantitative) indented to be used for blood donor screening/ viral load monitoring for HIV, HBV and HCV; Blood Grouping Reagents and Glucometers specific- Blood Glucose test Strips and fully automated analyzer based Glucose reagent which are forwarded by Central Drugs Standard Control Organization (CDSCO) and its offices, procurement division of NACO and various government medical organizations. The Not of Standard Quality (NSQ) samples reported reiterates the role of the Institute in protecting and promoting public health safety. Institute has Quality Management System in place and is NABL accredited for Biological and Chemical testing in accordance with the standard ISO/IEC 17025:2005 for HIV-Ab, HCV-Ab, HBsAg and Syphilis serology, Blood Grouping Reagents and Glucometers specific- Blood Glucose test Strips and fully automated analyzer based Glucose reagent. The Institute is successfully participating in National/ International Proficiency Testing/ EQAAS. In line with Make in India, Institute regularly supplies plasma performance panels of HIV-Ab, HCV-Ab, HBsAg and Syphilis to indigenous manufacturers for strengthening their in- house Quality Control testing procedures. NIB as a “Support Cell” for WHO Prequalification (PQ) Programme for In-vitro Diagnostics (IVD), is providing necessary hand holding and guidance to Indian manufacturers on the WHO-PQ Programme of IVDs, enabling them to meet global quality standards with regard to quality and documentation activities as per WHO requirement. The Institute is extending technical expertise, training and technical support to the IVD manufacturers and is working actively in co-ordination with WHO, CDSCO and other stakeholders in this regard. NIB scientists as technical expert provide inputs and address the queries from Startups/ innovators in meetings of the Facilitation of Innovation and Regulations for Start-ups and Innovators (FIRST) Hub of Biotechnology Industry Research Assistance Council (BIRAC). The technical expertise and experience of NIB in Quality Control Testing of Diagnostics is an enabler towards Fostering of Local Production of Innovative Medical Devices.

Parallel Session 7: Medical Products for End game for HIV/AIDS, Tuberculosis, Malaria	
Dr Suman Rijal, Director, Drugs for Neglected Diseases initiative (DNDi), India	**Partnerships To Develop And Ensure Access To New Medicines For HIV-Infected Children** Every year, globally, approximately 180,000 children acquire the HIV virus from their mother. Without treatment, 80% of these children will die before they turn 5. At present, very few treatments are adapted to the specific needs of very young infants and children. New adapted treatments are expected to arrive in the near future, including a taste-masked fixed-dose formulation of 4 antiretroviral drugs, developed jointly by the pharmaceutical company Cipla and the Drugs for Neglected Diseases initiative (DNDi). Designing a drug combining 4 active compounds in a formulation that is palatable and easy to swallow by the youngest infants has required several years of efforts, multiple studies and significant investments from several partners. With the registration of this new drug now in sight, DNDi and its partners are now making plans to ensure that this medicine reaches patients that need it. The challenges to be overcome are multiple, spanning all the dimensions of access to medicines, from supply to demand creation to funding. They are made even more complicated by the fact that HIV-infected children represent a small, and diminishing, number of neglected patients who often live in the most resource-limited settings.
Ms Anjali Sharma, Clinical Instructor, Global Health, Centre for Infectious Disease Research in Zambia (CIDRZ)	**Delivering anti-retroviral therapy in low resource settings** Background: Ending AIDS by 2030 through 95-95-95 in low resource settings requires innovative evidence-based strategies to increase access to HIV testing and to anti-retroviral therapy (ART) including for those disengaged from HIV care. The Centre for Infectious Disease Research in Zambia (CIDRZ) provided the evidence needed to formulate national scale-up of innovations by the Ministry of Health (MOH), bringing Zambia closer to achieving global targets. Implementation: These innovations include routine tracing of ART patients with no clinical contact since their last expected visit to more accurately determine their care and health status; improving welcome back for patients disengaged from care; and, reducing waiting time, number of visits and crowding through differentiated service delivery. Facilities also offer differentiated care that goes beyond adherence clubs and multi-scripting to extend hours and venues to better serve students, adolescents, men, and sex workers. Peers reach these populations in the community, schools, workplace,

	entertainment and leisure centres, and homes to provide HIV counseling and testing, distributing HIV self-test kits if preferred. Men in the general population are reached through index test and in stand-alone, fast track and integrated health services which are also made available after hours. Using social networks, a larger number of sexual minorities have tested for the first time and those who tested positive were swiftly linked to services by personnel trained to serve stigmatized populations. Lessons learned: These Innovative strategies have increased ART access for populations that previously have not engaged with the healthcare system. Early collaboration between the MOH, communities, research team and other stakeholders is necessary to ensure rapid uptake of effective innovative strategies in the public sector. Continuous retention requires recognition of personhood and shared decision-making. Health care workers need access to stress management and counseling services. Modern creative communication materials are needed to improve prevention efforts.
Parallel Session 8: Global Partnerships for Drug Discovery, Innovation and Technology Development: Scaling up Adaptive Technology Solutions for Medical Products	
Professor Stephen Matlin, Visiting Professor, Institute of Global Health Innovation, Imperial College London, United Kingdom	**Chemistry And Health: Realigning Partnerships For A Comprehensive Approach** Chemistry has made many outstanding contributions to health that have greatly enhanced both the quality and length of life of human beings during the last 1-2 centuries. Health benefits to which chemistry has contributed include effective and safe medicines and anaesthetic agents, relief of pain and suffering, prosthetics to improve impaired functions, better nutrition, fertility regulation and a cleaner and safer environment. In chemistry terms, an extremely rich variety of examples can be drawn from diverse fields where chemistry plays a fundamental role â€“ including, among others: medicinal and pharmaceutical chemistry and pharmacology; analytical and clinical chemistry; biological and nutritional chemistry; materials science; and physical chemistry. There are major current and emerging global threats to health that require strong contributions from chemistry. However, while chemistry's potential to go on making contributions is huge: its actual capacity is constrained by a number of current systemic factors and threats, so that its delivery is likely to be substantially less than optimal. The most serious threats involve three systemic fragmentations: (1) in the science discipline; (2) in the industrial sector; and (3) in the regulatory sector. The

	diversity and scale of problems and challenges is such that piecemeal fixes are insufficient â€“ a comprehensive overall approach is required, that employs systems thinking and engages wide scale, systemic reform to achieve ambitious goals in “chemistry for health”. In responding to each of the three systemic fragmentations discussed, a realignment of partnerships will be presented as an essential contribution to overcoming the barriers to progress.
Dr Mohammad Ameel, Senior Consultant, Healthcare Technologies (Medical Devices), National Health Systems Resource Centre, Government of India	**Energy Efficient Medical Devices** A medical device is an instrument used to diagnose, treat, monitor, prevent, or alleviate disease or injury. It may range from an MRI to a dialysis machine, or a spectacle to a condom. Over the years the manufacturers of medical devices have paid little attention to its energy requirements because access and affordability challenges have been insignificant in countries where these are primarily produced. We all know availability of power is a key component to ensure functionality of these medical devices, which is major concern in low and middle income countries. However there is an increasing trend of portable devices which primarily run on DC power batteries or solar voltaic systems. Such devices range from solar powered vaccine refrigerators, battery powered blood pressure monitors, finger tip pulse oxymeters, LED fluorescence microscopes amongst many others. Such devices are very useful in areas where access to grid is limited or unavailable. Energy efficient devices have the potential to ensure savings to health facilities, reduce carbon foot prints and ensure access and equity by making such health technologies available to those areas where its reach was limited due to power unavailability.
Mr Igor Da Silva Barbosa, Premier-secrétaire, Permanent Mission of Brazil to the UNOG and other organizations in Geneva	**Re-Purposing Of Medicines - Potential Benefits And Challenges Associated To The Practice** As is widely known, high costs and a considerable amount of time to develop new medicines and therapies represent a steep hurdle for the introduction and marketing of innovative medical products. A way to circumvent this hurdle is to re-purpose (or reposition) "existing medicines" or "old/abandoned drugs". Trying to re-purpose medicines for additional indications has proved to be more economical than developing new drugs from the scratch. The practice is even more laudable if we consider that several promising active pharmaceutical ingredients which have been studied for years â€“ with considerable resources spent â€“ end-up abandoned when trials for primary indications fail or when another more promising drug surfaces. The presentation will try to spur debate on the existing practices related to re-purposing and when it can be

	used for the benefit of public health and patients, especially because, in theory, re-purposed medicines can be developed, registered and marketed faster, thus offering more convenient solutions or more options to prescribers and patients. The practice also incentivizes the use of already known compounds or medicines, which have been already tested and are considered to be harmless to human health. As for the challenges, it is also convenient to incentivize the debate on potential difficulties associated to re-purposing, with special regard to questions about patentability. There is ongoing debate on how re-purposing should be dealt with when used to extend patent protection, even when there are doubts if the re-purposed drug should be considered patentable subject matter. The presentation will also analyze successful cases of repurposing and how they were legally dealt with, as well as comment on the reality of re-purposing in developing countries, especially Brazil, where a huge debate occurred in relation to second use patents.
Parallel Session 9: Regulatory Approaches for Approval of Pharma & Biosimilar Drugs, and Gene and Cell Therapies- USFDA, EMA Models	
Dr Ian Hudson, Senior Adviser, Regulatory Affairs, Integrated Development, Bill & Melinda Gates Foundation	**EMA Regulatory Guidance For Biosimilars And Other Advanced Therapies** Biosimilars and Advanced Therapies are increasingly important therapeutic products. Europe established a framework for biosimilars in 2003 and since then 62 have been approved. The regulatory approach involves comprehensive comparability studies against a reference biological medicine to demonstrate a high degree of similarity and no clinically meaningful differences, reducing the need for repetition of the clinical trails already caried out with the reference medicine. A range of different biosimilars have been approved including including growth hormones, colony stimulating factors, EPOs, FSH, PTH, insulin, MAbs. Extensive guidance is available on EMA website. The international Regulatory Community, through the International Coalition of Medicines Regulatory Authorities has issued a statement aimed at reassurance on the status of biosimilar medicines and supporting their introduction. Europe also has a specific legal framework for Advanced Therapies which include gene therapy, cell therapy and tissue engineered products. European National Agencies remain responsible for Clinical Trials and can also provide scientific advice and support for ATMPs, Authorisations are handled by the EMA and its scientific committee, the Committee on Advanced Therapies (CAT) and CHMP. The role of the CAT also includes certification, classification and

	advice as well as supporting follow up. Extensive guidance is available from EMA website.
Dr Anurag S. Rathore, Coordinator, DBT Center of Excellence for Biopharmaceutical Technology & Professor, Department of Chemical Engineering, Indian Institute of Technology, Delhi, India	**Affordability Of Biosimilars** Biosimilars or follow-on protein products refer to “follow-on” versions of other licensed protein products that are already on the market. This talk will address three topics. First, the economic drivers for the biosimilars will be discussed. The unique requirements of the emerging markets will be highlighted. Next, key factors that contribute to pricing of biotherapeutics will be discussed. These vary from R&D risks to mergers and acquisitions to regulatory hurdles and complexity of biotherapeutic products as well as shadow pricing and monopolies committed by major biopharmaceutical manufacturers. Finally, thoughts on making biosimilars affordable will be presented. It is evident that regulators, industry, and the government need to work together to achieve this. Role of technology in facilitating this will also be highlighted.

Dr Rob Lambkin-Williams, Executive Scientific Advisor, hVIVO & Virology Consult, United Kingdom	**Human Viral Challenge Model For Accelerating Drug Development Process** Sir Edward Jenner, in 1796, developed the first successful vaccine using the Human Viral Challenge Model (HVCM) after observing that milkmaids who had become infected with cowpox previously, did not become infected with smallpox. He conducted a simple challenge study inoculating an eight-year-old boy with material from the cowpox blisters of a milkmaid. He then later inoculated the boy with smallpox who subsequently showed no signs of infection. From this early HVCM study vaccination was born. The HVCM for respiratory viruses is arguably the best-known model due to the Common Cold Unit (CCU) in the UK; from 1946 until it closed in 1989, over 20,000 volunteers were inoculated with a variety of viruses. Its research contributed to a better understanding of respiratory viruses, viral lifecycle, possible vaccines as well as the first licensed anti-influenza compound amantadine. After the closure of the CCU, HVCM studies continued in the USA using small motels and hotels which replaced the huts on Salisbury Plain. Subsequently, studies were conducted in Phase 1 units that were retrofitted and finally, in a purpose-built unit. This experimental model enables proof of concept work to be undertaken on novel therapeutics, including vaccines, immunomodulators and antivirals, as well as new diagnostics. The breadth of data generated from HVC studies allows for exploration of a wide range of variables and endpoints that can then be taken through and guide the design of subsequent field studies and pivotal phase 3 studies. This talk will consider recent studies that have given valuable insights into the different approaches in the management or treatment of viral respiratory disease.

Parallel Session 10: National Regulation and International Agreements including Pricing of Medical Products for Affordable Access	
Professor Brook K Baker, Northeastern University School of Law and Senior Policy Analyst, Health Global Access Project, United States of America	**Overcoming Monopolies On Medicines In Domestic Legislation And Treaties And Allowing Price Controls** International and regional agreements and national intellectual property regimes can aid or hinder affordable access to medical technologies. Although all WTO Members, other than LDCs, must now be TRIPS-compliant and although TRIPS constrains countries' ability to more easily ensure access to affordable medicines by, for example, allowing unfettered generic competition, TRIPS has numerous public health flexibilities that should be adopted, used, and protected to accelerate more affordable access to needed medicines and other health technologies. These flexibilities include LDC transition periods, strict standards of patentability, exclusions and limited exceptions, opposition procedures, compulsory licensing, and parallel importation. Unfortunately, many countries have not yet adopted the full panoply of allowable flexibilities and have instead adopted undesirable policy restraints through trade agreements and other means. In particular, countries have broad discretion under TRIPS to enact measures that restrain monopoly pricing of medicines, including various forms of price control and restricted formularies. Countries can do so not only through competition-based and anti-abuse measures, but more broadly through other consumer protection laws. They can as well require transparency in pricing, restrict inflation in the price of medicines, and limit mark-ups along the value chain. Countries should resist trade and other pressures that would restrict their freedom to control predatory pricing and to advance sustainable supplies of affordable health technologies.
Dr Olasupo Owoeye, Senior Lecturer, Law, RMIT Graduate School of Business and Law, Australia	**Patents and Intellectual Property Standards to Facilitate Affordable Access to Medicines** The presentation addresses the major TRIPS flexibilities that are relevant to the promotion of public health objectives and access to medicines. Particular focus will be given to the principles and objectives of the TRIPS Agreement, patentability criteria, the compulsory licensing framework and the exhaustion doctrine. It also discusses the transitional arrangements in place for least developed countries and the challenges associated with the use of the existing structures, under the TRIPS Agreement, for improving access to

	medicines.
Mr Harry Krishna Bucktowar, Deputy Director Pharmaceutical Services, Ministry of Health and Quality of Life, The Republic of Mauritius	**Strengthening the supply chain Management of Pharmaceuticals - The Mauritius Perspective** Our public procurement system has evolved over the last decade in line with the country's economic development and government initiative to optimize the use of public resources. The introduction of the Public Procurement Act (PPA) in 2006 was a major step in Government's reforms plan as it allowed Mauritius to harmonize its system with international norms and best practices. . This is due to a large extent to the fact that most developing countries do not have the technical, human, managerial and financial capacity to protect their supply chains. In order to address this challenge in an effective manner and to achieve sustainable results, the following strategic approaches need to be put in place: I. Strengthen national quality assurance systems In order to achieve this objective, it is necessary to address the different points in the pharmaceutical supply system where quality can be affected. This varies from ensuring adequate quality assurance considerations in registration, to training national quality control laboratories in Good Laboratory Practices, to introducing a post-marketing surveillance system and/or pharmacovigilance. II. Increase the supply of good-quality medicines In order to ensure the quality of pharmaceutical products, the manufacture and subsequent handling of the products, including their distribution within the domestic market and their movement in international commerce, a fully functioning system of premarket evaluation and market authorization, particularly in the assessment and authorization of multisource (generic) pharmaceutical products needs to be put in place. III. Combat the availability of counterfeit and sub-standard medicines While it is essential that countries strengthen their national quality assurance systems, combating trade in substandard and counterfeit medicines also requires interventions at regional and international level. The latter implies coordination and cooperation among national authorities, relevant regional mechanisms, international organizations, and other stakeholders.