COMPLIANCE AND ETHICAL ISSUES IN PATIENT ACCESS AND SUPPORT PROGRAMS AND ACTIVITIES WITH PATIENTS AND PATIENT ADVOCACY ORGANIZATIONS

Eighth Asia Pacific Pharmaceutical and Medical Device Compliance Congress

10 September 2018

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Agenda

- Introductions
- Setting the Stage: Relevant Laws and Industry Codes
- Ways to identify common Patient Support Programmes (PSP) Definitions and Risk Areas
- Practical Examples of PSPs and How to Build Controls to Manage Risks
- Questions & Discussion

Introductions: Your Panel

- Ann Beasley (Moderator)
- Maija Burtmanis
- Ewa Holker
- Casey Horton
- Mark Wanda
- Angela Xenakis

GETTING TO KNOW THE AUDIENCE

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Questions for the Audience (show of hands)

What size companies are represented in the audience?

- Pre-approval
- 1-product
- More than one-product
- Multi-national company

Individual backgrounds

- Legal
- Compliance
- Commercial
- Medical Affairs
- Other

September 2018

Legal, Compliance & Ethical Issues in Patient Assistance and Support Programs

Angie Xenakis, Partner

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Agenda

- Defining Patient Assistance Programs and Patient Support Programs
- Laws/Regulations/Codes Implicated
- Best Practice Guidance
  - OIG Guidance
  - Recent Settlements/Corporate Integrity Agreements

Defining Patient Assistance and Support Programs

- Patient Assistance Programs
  - Financial Assistance
    - Copay assistance
    - Free drugs/devices
    - Charitable donations
- Patient Support Programs
  - Patient Driven Services
    - Disease awareness
    - Patient Screening
    - Adherence programs (medication management)
    - Product support (billing assistance/reimbursement consultation)
    - Delivery services
    - Data collection
- Programs run by manufacturers, third-party vendors, and charitable organizations

Laws and Regulations Implicated

- Country Specific Healthcare Regulations and Codes
  - Level of sophistication of market
  - Adverse reporting obligations
- Anti-Corruption Laws
  - Third-party intermediaries
  - Grants, sponsorship and donations
  - Increased interaction with public officials
    - Creation of programs
    - HCPs role in programs
      - Transfer of value to HCPs (support normally born by HCP)

Laws and Regulations Implicated

- Consumer Advertising Laws
  - Direct-to-Consumer
    - Countries in Asia generally prohibit direct-to-consumer advertising of prescription products
    - Increased interaction with patients
- Privacy Laws
  - Patient information
- Fraud

OIG Guidance: Donations to Charities

- **2005 Special Advisory Bulletin: Key Safeguards for Donations**
- OIG has long held that pharmaceutical manufacturers can donate to independent, *bona fide* charitable assistance programs
- Under a properly-structured program, donations from a manufacturer to an independent, bona fide charity that provides cost-sharing subsidies should raise less risks, so long as:
  - No direct or indirect influence or control over the charity or the subsidy program;
  - The charity awards assistance in an independent manner (*i.e.*, the assistance provided cannot be attributed to the donating pharmaceutical manufacturer);
  - No regard to pharmaceutical manufacturer's interest or beneficiary's choice of product, provider, practitioner, supplier or insurance plan;
  - Reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and
  - The manufacturer "does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions from its products"

OIG Guidance: Donations to Charities

- **2005 Special Advisory Bulletin: Key Safeguards for Donations**
- Bottom line: "the independent charity must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries drug choices."
  - Independence of the Charity
  - No Interference with patients' choice
- Also admonished from directly or indirectly influencing "the identification of disease or illness categories" supported by the charity
- And cautioned to limit donations solely to charities that "define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products"

OIG Guidance: Donations to Charities

- **2014 Supplemental Special Advisory Bulletin: Key Safeguards for Donations**
  - Disease funds should be consistent with widely recognized clinical standards and cover an array of products (not just subsets and not just expensive or specialty drugs)
  - The cost of the drug for which the patient is applying for assistance should not be the only factor
  - Charities should not give a donor any information that would enable the donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of these products supported by the charity

Increased Attention and Enforcement

- Increase in specialty drugs
- Increase in drug prices
- Increase in charitable donations
- Increase in media attention
- 2015 US DOJ led by the US Attorney's Office in Massachusetts and New York has issued more than a dozen subpoenas to manufacturers related to their donations to charitable patients' assistance programs

Settlements: Aegerion Pharmaceuticals

- Sept 2017
- $35 million DOJ Settlement; 5 yr. Corporate Integrity Agreement
- In part for making payments to an independent charity, Patient Services, Inc. (PSI) for patient co-payment assistance in order to induce purchases to defray the costs
  - Allegedly donated to PSI to create fund
  - PSI allegedly promoted its ability to create a “reimbursement vehicle” for Aegerion

Settlements: United Therapeutics

- Dec 2017
- $210 million DOJ Settlement; 5 yr. Corporate Integrity Agreement
- Related solely to Patient Assistance Program
- Made payments to an independent charity, Caring Voice Coalition (CVC), an independent PAP, as “a conduit to pay the co-pay obligations of thousands of Medicare patients taking [United Therapeutics’] drugs.”
  - United Therapeutics prohibited Medicare patients from participating in United Therapeutics’ free drug program for financially needy patients, and instead referred Medicare patients to CVC
- United Therapeutics had obtained data from CVC detailing the number of patients on each applicable drug, which United Therapeutics then used to determine its level of contributions to CVC

CIA Requirements

- **Establishment of an Independent Charity Group**, in which the company must vest sole responsibility and authority for budgeting and other activities relating to Independent Charity PAPs (including interactions with such PAPs) in a department or group within the company (Independent Charity Group) that is **separate and independent from the commercial business units** of the company (including from the sales and marketing departments)
- **The Independent Charity Group must be the exclusive component of the company that is authorized to or responsible for communicating with, or receiving information from, Independent Charity PAPs**
  - The commercial organization must not influence or be involved in any such communications
  - The Independent Charity Group must not share information related to donations to Independent Charity PAPs or donations to any specific disease state funds with the commercial organization
  - Members of the commercial organization (such as sales representatives) are not permitted to discuss specific Independent Charity PAPs or their disease state funds with HCPs or patients

CIA Requirements

- The Independent Charity Group must **establish a budget process to be followed for donations to Independent Charity PAPs**
  - The Independent Charity Group must develop the annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the Legal Department (with input from the Compliance Department)
  - The commercial organization must have no involvement in the budget process for donations to Independent Charity PAPs
  - The company must approve the annual budget for donations to Independent Charity PAPs at a level above the commercial organization (e.g., at the executive level)
  - After the annual budget is approved, the Independent Charity Group must have sole responsibility (with no involvement from the commercial organization) for allocating the approved budget across donations to Independent Charity PAPs and to any disease state funds established by the Independent Charity PAPs
- The Independent Charity Group must **have sole responsibility for assessing requests for funding from Independent Charity PAPs outside of the annual budget**
  - Requests must be assessed against standardized, objective criteria established by the Independent Charity Group (with input from legal and compliance)
  - Legal and compliance personnel must be involved in the review and approval of requests for additional/supplemental funding, as requested by the Independent Charity Group

CIA Requirements

- The Independent Charity Group (with input from the Legal Department and Compliance Departments) must **establish standardized, objective written criteria that govern donations** to Independent Charity PAPs and any specific disease state funds of such Independent Charity PAPs
  - The criteria must be designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from the company to patients and does not impermissibly influence patients' drug choices
- The Independent Charity Group must **gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control** over the entity operating the Independent Charity PAP or over its assistance program
- The company **must not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease state fund** operated by the Independent Charity PAP

CIA Requirements

- No donations can be made until a **written agreement is executed between the company and the Charity Entity** relating to the donation
  - Must be reviewed and approved by Legal and Compliance prior to execution
  - Donations must be provided only pursuant to, and in a manner consistent with, the written agreement
- The written **agreement must preclude the company from exerting (directly or through any affiliate) any influence or control** over the Charity Entity or its assistance program
- The CIA also specifies exact language that must be included in the written agreement with the Charity Entity

CIA Requirements

- Monitoring Requirements
  - The company must **establish an Independent Charity PAP Review Program (PAP Review Program) through which it must conduct annual audits of donations to Independent Charity PAPs**.
  - Monitoring Personnel must review:
    1. Budget documents;
    2. Documents relating to any decision to provide donations to a particular Independent Charity PAP;
    3. Written agreements in place between the company and the Charity Entities;
    4. Correspondence and other documents reflecting communications and interactions between the company and the Independent Charity PAPs; and
    5. Any other available information relating to the arrangements and interactions between the company and the Independent Charity PAPs.
  - Results from the PAP Review Program, including the identification of potential violations of policies, must be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate

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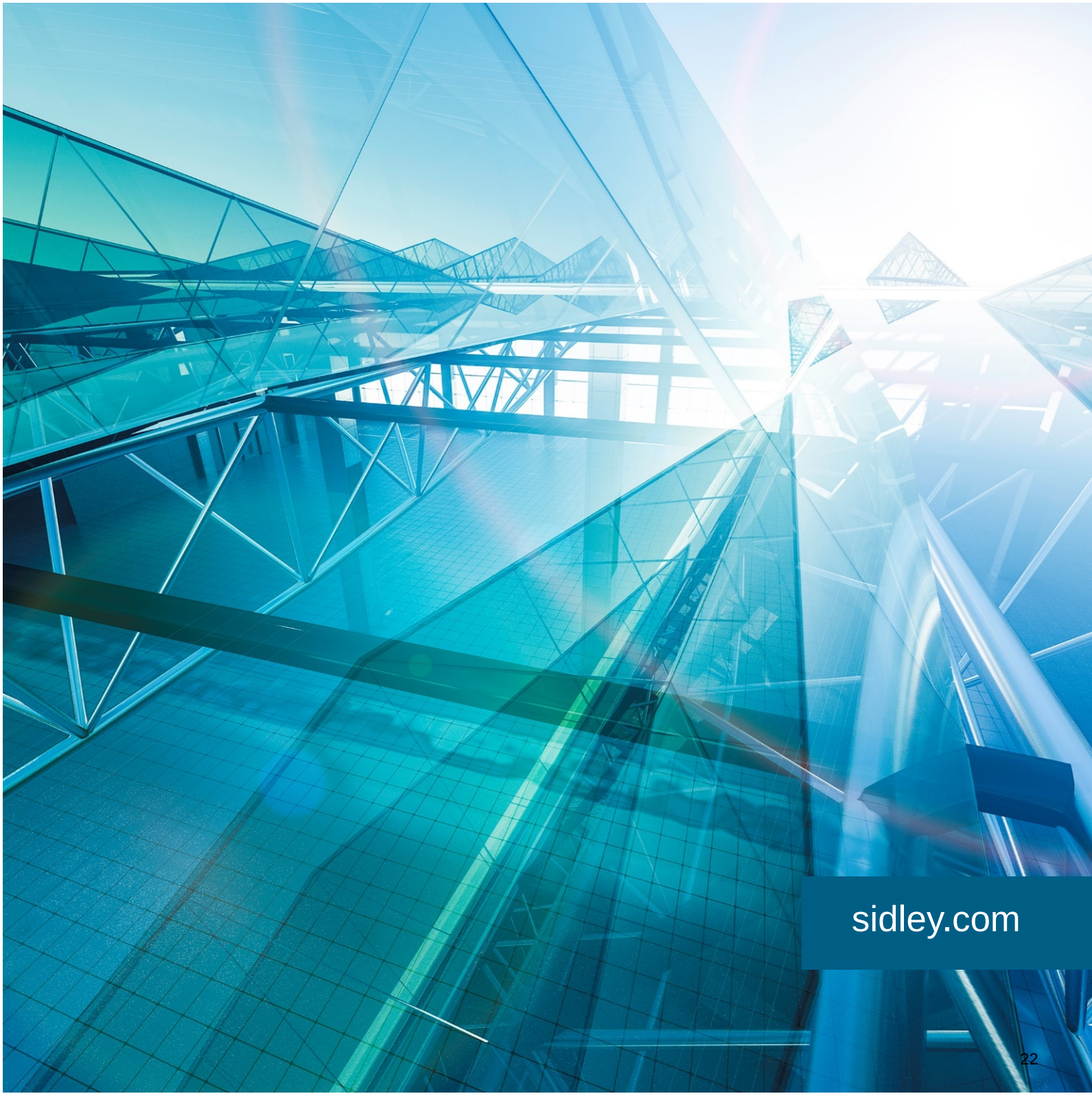

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OVERVIEW OF RELEVANT INDUSTRY CODES

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Guidance Related to PSPs

	 Australian Code	 New Zealand Code	 Taiwan Code	 Korean Code	 Canadian Code
Definition of PSP included?	✓	✓	✓	✗	✓
Guidance is pharmacovigilance-focused?	✗	✗	✗	✗	✗
Includes requirements for designing a compliant PSP?	✓	✓	✓	✓	✓
Includes information on handling data?	✓	✓	✗	✗	✓
Includes information on AE reporting?	✓	✓	✓	✗	✗

The Australian Code of Conduct provides the most information on PSPs

Definitions of PSPs

	Guidance Document	Definition
	**Medicines Australia: Code of Conduct** Section 17 (2015)	A Patient Support Program is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines. Patient Support Programs may only be offered to patients who have already been prescribed a prescription-only Product.
	**Medicines New Zealand Code of Practice** *(2014)*	Companies may arrange or become involved in programmes that support patients already prescribed a prescription medicine to improve positive health outcomes
	**Taiwan IRPMA Code of Practice** *(2018)*	A service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide HCPs with support for their patients. PSPs may also include the Companies providing a service or arranging financial assistance for patients who cannot afford their medication (e.g. reimbursement or discount schemes).
	**Innovative Medicines Canada: Code of Ethical Practices** Section 14 *(2016)*	Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment. Such programs may also serve to ensure or assist with access and/ or reimbursement of a product. The programs must have a primary objective of bettering patient health outcomes. Any benefit experienced by the prescribing or dispensing Health Care Professional must be incidental to the primary objective

Medicines Australia Code of Conduct

Section 17 - Patient Support Programs

- A PSP is a company developed program that is intended to assist patients in gaining benefit from their medical treatment and to improve health outcomes and promote the quality use of medicines.
- PSPs may only be offered to patients who have already been prescribed a prescription-only Product.
- PSPs should be conducted in an open and transparent manner
  - Any payments made to healthcare professionals for facilitating, enrolling or educating patients in a Patient Support Program must be declared to consumers on the enrolment form.
- Information provided to patients may be product specific but not promotional
- There must be:
  - a clinical rationale for the PSP
  - anticipated number of patients to be enrolled in the program
  - the type of educational/informational material to be provided to a patient
  - contact if any (for example phone calls, SMS, email), that may be made to a patient and the duration of the program.
- Companies must ensure compliance with requirements listed in this section
- Data and Outcomes
- Suspected Adverse Drug Reactions noted during monitoring of a Patient Support Program must be reported to the TGA in accordance with the current TGA document Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines (August 2013).

Section 2.5 - Prescribing Software

- A company may pay for the inclusion of medical education for healthcare professionals or patient aids, patient support program registration and patient aids and patient support program materials in a prescribing software package.

Medicines New Zealand Code of Practice

Section 5.13 Patient Support Programmes (PSPs)

- Companies may arrange or become involved in PSPs for patients already prescribed a prescription medicine to improve positive health outcomes

- PSPs must ensure that any statements made or materials provided to the general public are not promotional or perceived to have intentions of promoting a prescription medicine to members of the general public, unless they comply with direct-to-consumer advertising rules

- Companies must comply with the following requirements
  - Any payment for work undertaken by HCPs involved in such programmes is commensurate with the work undertaken
  - No incentives, other than educational materials or items that will enhance positive health outcomes and adherence, are provided to patients to become involved in these programmes
  - The programme complies with New Zealand privacy legislation and ethics committee requirements where appropriate
  - Any adverse events disclosed in the conduct of any PSP must be reported in accordance with relevant laws and this Code (see section 2.4)
  - All information provided to patients must comply with relevant sections of this Code
  - The duration of these programmes is appropriate to the disease state treated by the product involved
  - Collective and anonymised data from such programmes may be presented to HCPs to convey the impact (e.g. benefits or risks) of such programmes on patient outcomes

Taiwan IRPMA Code of Practice

- Definition of a PSP
  - A service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g. adherence, awareness and education), or to provide HCPs with support for their patients. PSPs may also include the Companies providing a service or arranging financial assistance for patients who cannot afford their medication (e.g. reimbursement or discount schemes).
  - PSPs should be designed and used to enhance patient care, benefit healthcare system and achieve healthcare outcome rather than to promote pharmaceutical products and/or influence prescribing decisions

- Basic Requirements for a PSP
  - Patients and physicians written informed consent required if PSPs involve collection of personal data
  - Patient privacy must be protected
  - Recommended to be conducted by a third party, and that third party is capable of ensuring appropriate patient data privacy protection and identifying and reporting of AEs
  - Initiation and management of PSPs requires the involvement of the personnel in charge of PV to ensure appropriate monitoring and reporting of AEs
  - HCPs should not be paid or obtain anything of value for enrolling patients in PSPs

Korea Pharmaceutical Manufacturers Association Code of Practices

Article 19 – Patient Support

- The Members may provide medical and pharmaceutical information on diseases to patients or provide economic support to improve patient welfare.

- The Members shall take caution so that patient support is not used for the purpose of providing improper economic benefits to healthcare professionals, carrying out direct-to-consumer advertising of prescription drugs, soliciting or inducing medical institutions, preventing competitors' market entrance, etc. Patient support shall be in compliance with the Medical Services Act, the Monopoly Regulation and Fair Trade Act, the Personal Information Protection Act and other relevant laws and regulations.

Innovative Medicines Canada Code of Ethical Practice

Section 14 – Patient Support Programs and Medical Practice Activities

- 14.1 – Definitions
  - Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment.

- 14.2 – General Principals
  - Intent
    - *These programs / services must not serve solely to cover day to day activities or resources considered part of the practice's operational expenses nor should they replace or compete with services or resources provided and funded by the existing healthcare system. Effort should be made for the healthcare system to absorb the cost of long term initiatives.*
  - Ensure Integrity of the Industry
  - Conflict of Interest
  - Design and Oversight

- 14.3 – Standards
  - Patient Support Programs or Medical Practice Activities must have clear objectives, timelines and scope
  - Reasonable efforts should be made to ensure Patient Confidentiality, Transparency and Privacy
  - Data and Outcomes

- 14.4 – Request for Support by Stakeholders

WAYS TO IDENTIFY COMMON PATIENT SUPPORT PROGRAMMES (PSP) DEFINITIONS AND RISK AREAS

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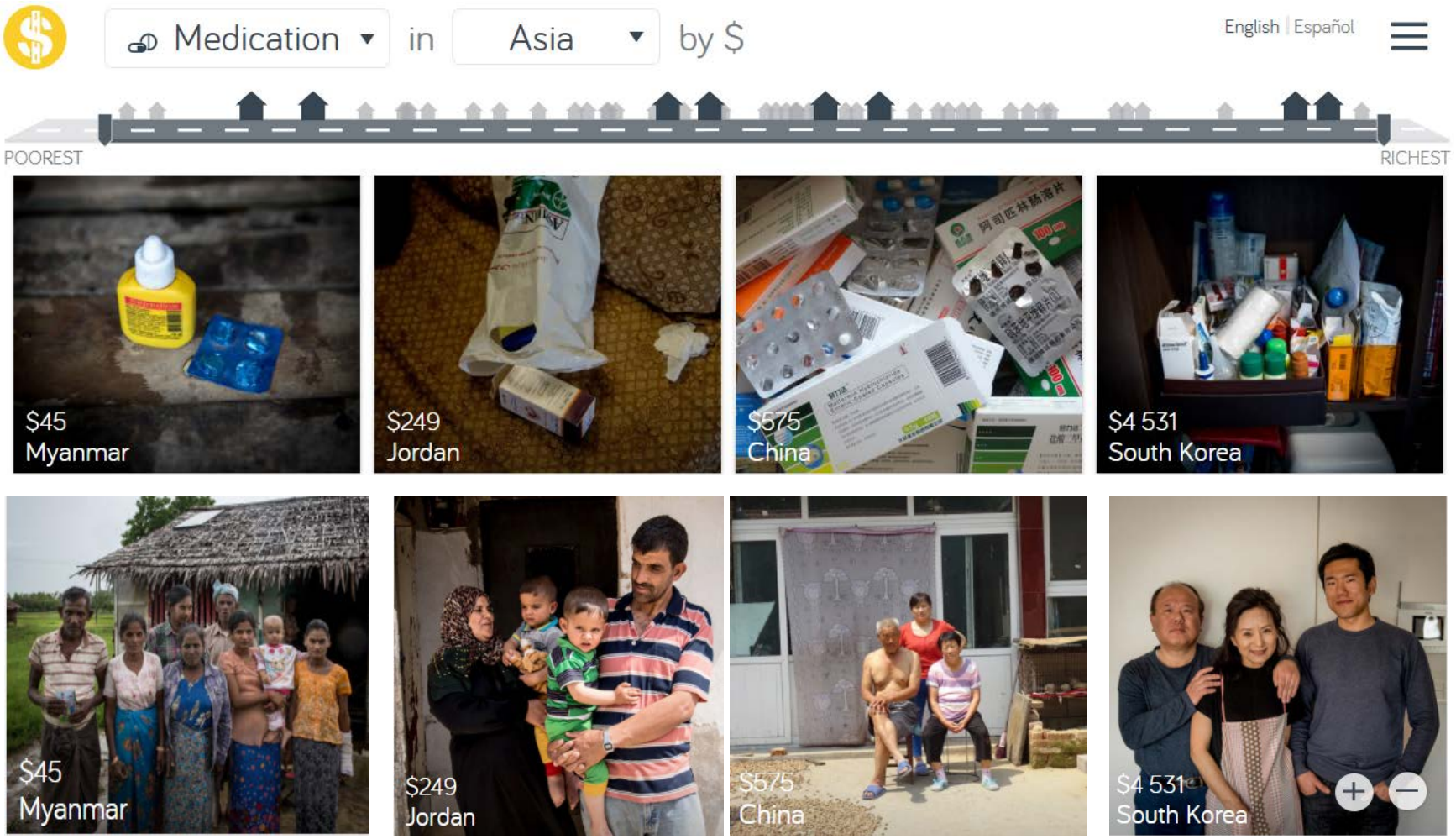
Dollar Street (Gapminder)



Next Generation of Patient Support Programmes – Shifting Focus to Patient Centric Offerings

PRACTICAL EXAMPLES OF PSPS AND HOW TO BUILD CONTROLS TO MANAGE RISKS

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QUESTIONS & DISCUSSION

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