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2nd Congress of Pharmaceutical Law & Ethics

Marie-Claire PICKAERT

ATHENS – 8th March 2018

Introduction and Declaration of Interest

- ▶ Marie-Claire Pickaert is an **expert in health systems and policies, and the pharmaceutical sector**. Marie-Claire is an Economist by training.
- ▶ For the bigger part of her career with pharma, she was involved in many platforms, round tables and reflections around **pricing, value-based reimbursement, outcomes research** and **healthcare reforms**, both at European and national levels.
- ▶ In the latter part of her career, she was given the mission to re-engage with medical communities which has expanded into a project **imagining the future of medical learning**.
- ▶ For 10 years, she coordinated **ethics and compliance** activities for the pharmaceutical industry in Europe.
- ▶ On 4th March 2018, she retired from **EFPIA**, where she held the position of Deputy Director General and was a member of the General Management. Throughout her career at EFPIA, Marie-Claire's activities expanded from Financial Management (CFO), HR, Economic & Social Policy, Country Support and Membership advice, and Ethics & Compliance (CECO).
- ▶ Marie-Claire declares having **no direct / indirect financial interest** in any life science company.

POTENTIALLY CONFLICTING INTERESTS

Avoiding Corruption – Open Governance

- Concepts and Principles
- Business Integrity – self-regulation is a privilege
- Corruption watchers – indexes are not created equal
- Better law making – support of international organisations
- OECD: Open Governance

Concepts & Principles

- Interest does not *per se* lead to conflict
- Relationships between operations and policy makers do not *by definition* inherently lead to conflict
- **Corruption** is a form of **dishonest or unethical conduct** by a person entrusted with a position of authority, often to acquire **personal benefit**.
 - Corporate Corruption
 - Government or political corruption



The many faces of Business Conduct Policies



Ethics



Conflicts of interest



Gifts and entertainment



Financial controls



Tendering and contracting



Safe, Health, Environment & Quality



Information disclosure



Safeguarding information and assets



Employee relations



Legal compliance



Political activities



International operations



Drugs and alcohol

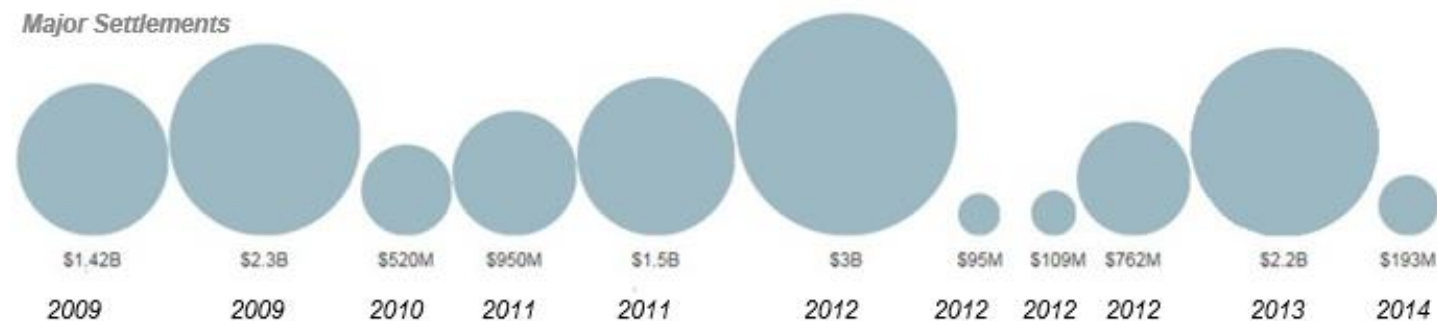


Harassment and intimidation in the workplace

Historical Overview, DPA's, CIA's,...

Prominent public censure of industry malpractice. Industry has now been subjected to numerous regulatory and congressional investigations, billion-dollar fines for illegal marketing, misleading DTC ads, off-label promotion of drugs, enquiries about pricing, lawsuits for the sale of drugs with known safety risks, allegations of price fixing, and arrangements to delay access to generics, and kick-back / corruption.

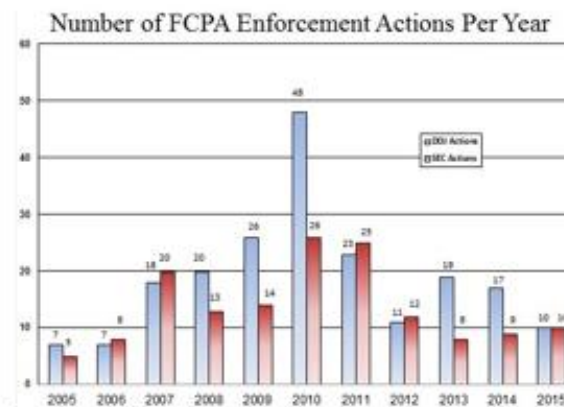
Major Settlements



**= US \$ 13.904 bn
in 5 years**

FCPA/Corruption-investigation for LS:

- Pre-2006
- 2010/2011
- 2014 and beyond



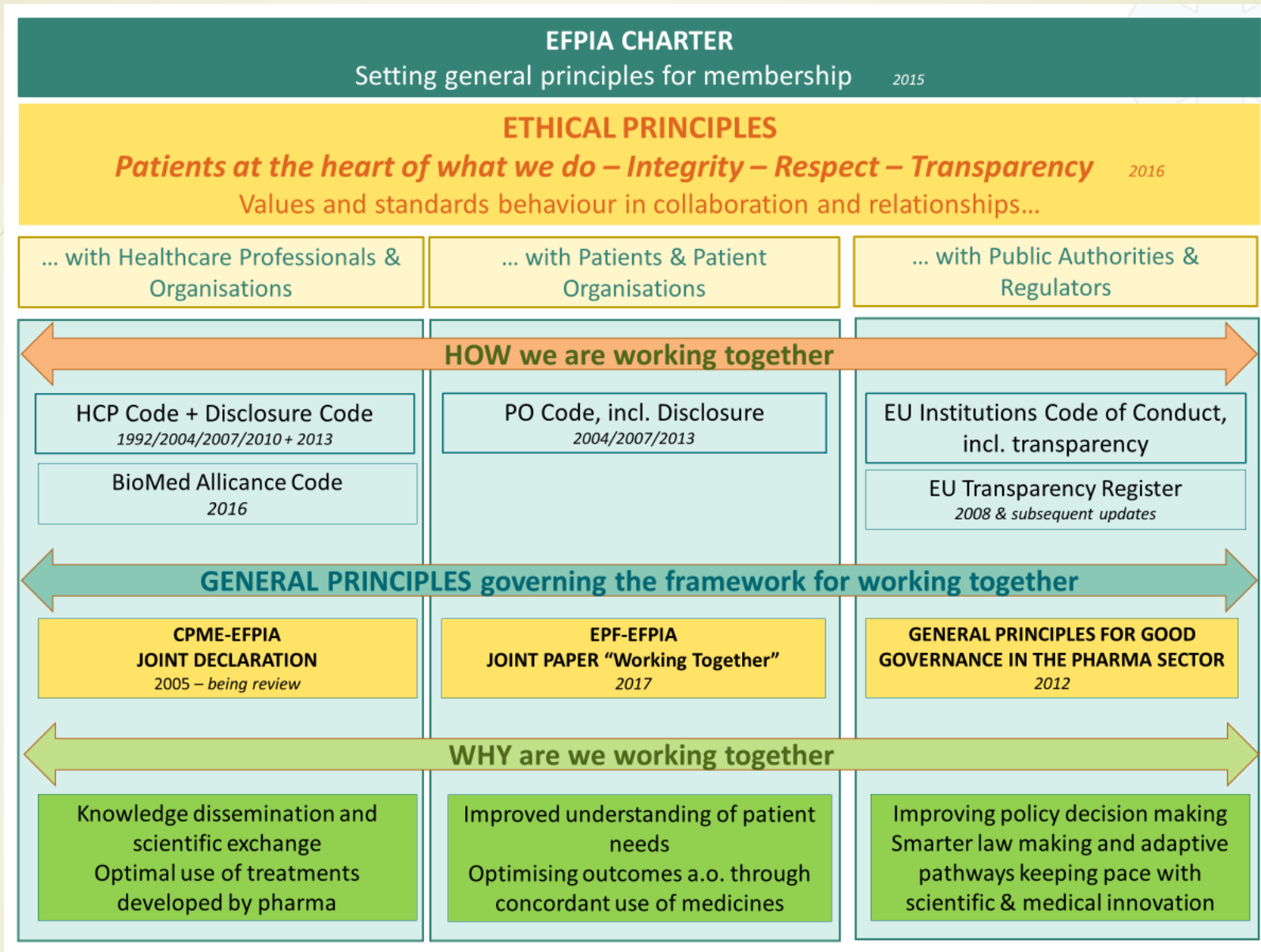
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SELF-REGULATION IS A PRIVILEGE

The right mindset

- Laws and regulation – *“keep us out of trouble”*
- Self-regulation – *“make our business better”*
- **OVER-COMPLYING is not possible**
 - Companies are advised that, where there are doubts, the reasonable solution is to be stricter than applicable codes. Companies would not be criticized for being stricter, but are likely to be in breach when implementing *to the letter* rather than *to the spirit*.



CORPORATE RESPONSIBILITY

Prevention is Better than Cure

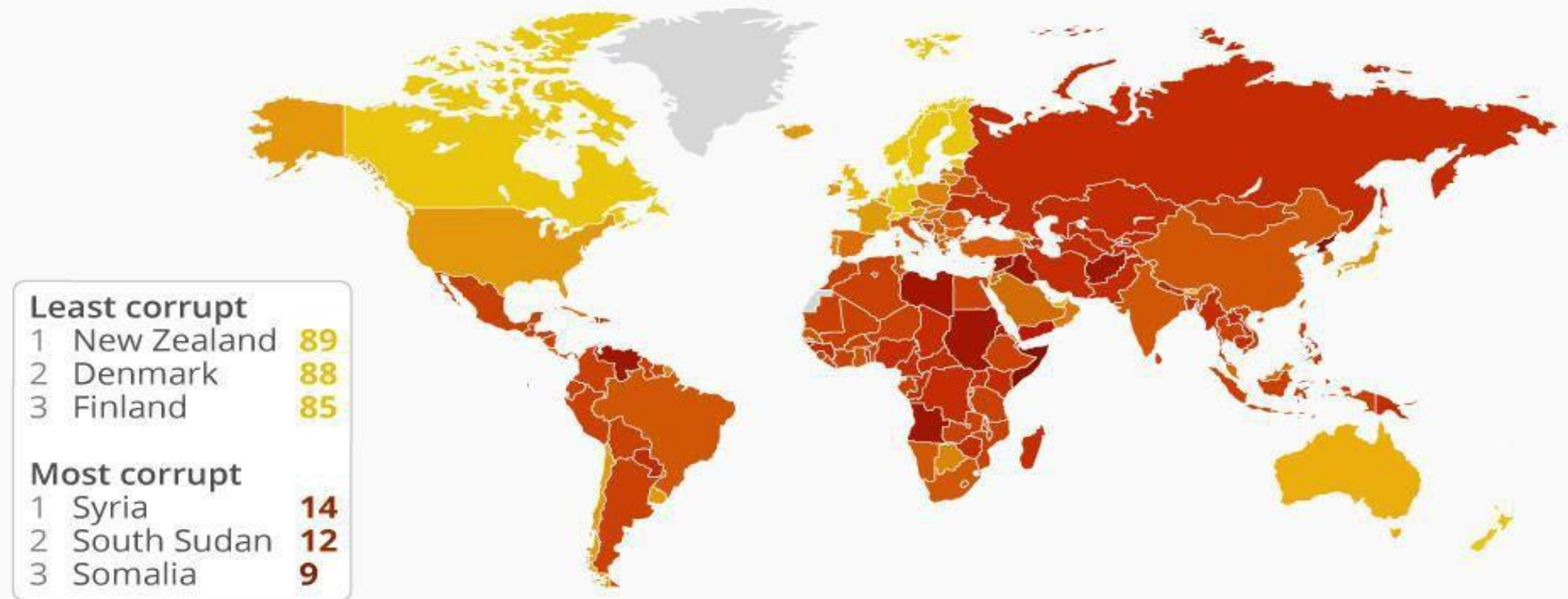
- Create an **ethical culture** within the organisation, and in external relationships.
- Recognize the **importance of compliance**.
- Establish **appropriate anti-bribery and corruption compliance programmes**, including monitoring and corrective measures.
- Use **whistle-blower hotlines** effectively, especially internationally.
- Identify and address bribery and corruption risk **early** on.



Where Corruption Is Raging Around The World

Countries and territories ranked on perceived public sector corruption in 2017*

Highly corrupt  Very clean
0-9 10-19 20-29 30-39 40-49 50-59 60-69 70-79 80-89 90-100



@StatistaCharts

* As perceived by experts and business people

Source: Transparency International

Forbes statista 

CORRUPTION PERCEPTIONS INDEX 2017



GREECE

Corruption
Perceptions
Index 2017

Rank
59 / 180



Score
48 / 100



Up from 36 in 2012

TI Recommendations

- ▶ Governments and businesses must do more to encourage free speech, independent media, political dissent and an open and engaged civil society.
- ▶ Governments should minimise regulations on media, including traditional and new media, and ensure that journalists can work without fear of repression or violence. In addition, international donors should consider press freedom relevant to development aid or access to international organisations.
- ▶ Civil society and governments should promote laws that focus on access to information. This access helps enhance **transparency and accountability** while reducing opportunities for corruption. It is important, however, for governments to not only invest in an appropriate legal framework for such laws, but also commit to their implementation.
- ▶ Activists and governments should take advantage of the momentum generated by the United Nations Sustainable Development Goals (SDGs) to advocate and push for reforms at the national and global level. Specifically, governments must ensure access to information and the protection of fundamental freedoms and align these to international agreements and best practices.
- ▶ Governments and businesses should **proactively disclose relevant public interest information in open data formats**. Proactive disclosure of relevant data, including government budgets, company ownership, public procurement and political party finances allows journalists, civil society and affected communities to identify patterns of corrupt conduct more efficiently.

NOT ALL CORRUPTION INDEXES ARE CREATED EQUAL – The FCPA Blog

- ▶ Businesses have a responsibility to know where corruption risks are and to decide how to confront them, which may be not to do business with high-risk countries:
 - ▶ deprive struggling economies of much-needed foreign investment,
 - ▶ leave the market open to bad actors with no pretence of ethics.
- ▶ Corruption Perception Indexes have largely succeeded in its aim of raising awareness of global corruption. But certain limitations are evident: in providing a single score for each country, it signals that something needs to be done, but does not provide an indication on the specific solution.
- ▶ Corruption indexes supplying more detailed information about (country-) specific business bribery risk would be more useful.



The TRACE Bribery Risk Matrix® (TRACE Matrix) measures business bribery risk in 200 countries. The overall **country risk score is a combined and weighted score of four domains** – Business Interactions with the Government, Anti-bribery Laws and Enforcement, Government and Civil Service Transparency and Capacity for Civil Society Oversight, including the role of the media – as well as nine subdomains. The TRACE Matrix was originally developed in 2014 in collaboration with RAND Corporation. It is updated at least every two years by TRACE.

Rank	Country	Risk Score
80	Greece	44

Domain 1: Interactions with Government	Domain 2 : Anti-Bribery Laws and Enforcement	Domain 3 : Governmental and Civil Service Transparency	Domain 4 : Capacity for Civil Society Oversight
50	32	47	32



GAC – General Affairs Council - Agenda

Tuesday March 15, 2016
Chaired by NL minister Koenders (Foreign Affairs)

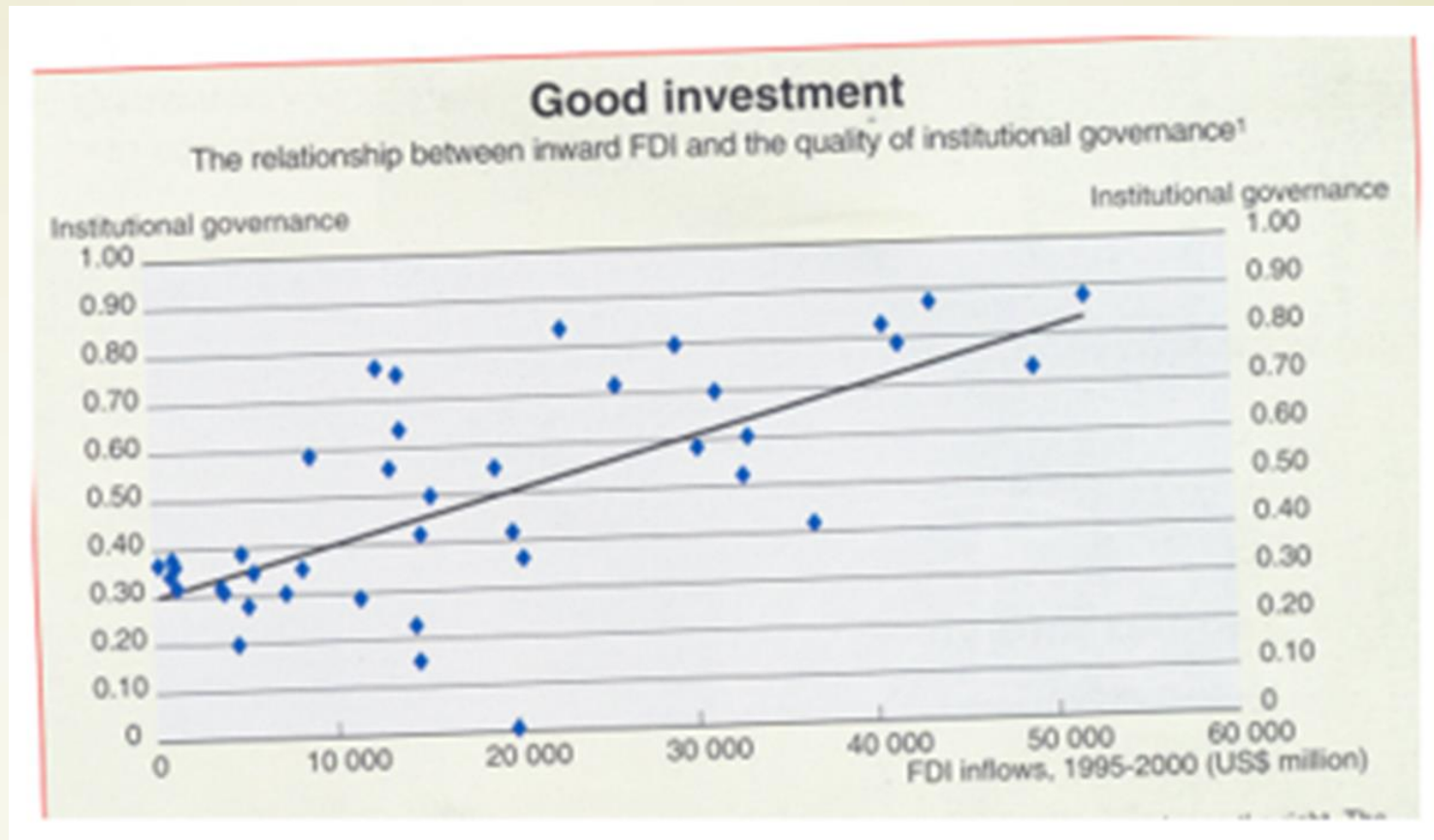
- Preparation of **European Council** 17-18/03 (discussion on steps how to address migration crisis)
- **European Semester 2016** (discussion on Council input on EU's annual cycle of economic policy surveillance)
- Interinstitutional Agreement of **Better Law-making** (Council is likely to adopt agreement that improves the way the EU legislates & that is signed between 3 EU Institutions)
- **Growth & jobs** (presentation by European Commission on how EU should invest for economic growth & more jobs)
- **Emergency support** mechanism (EU humanitarian assistance to EU Member States, in this case notably to Greece for refugee crisis)





The Group of States against Corruption (GRECO) was established in 1999 by the **Council of Europe** to monitor States' compliance with the organisation's anti-corruption standards.

GRECO's objective is **to improve the capacity of its members to fight corruption by monitoring their compliance with Council of Europe anti-corruption standards** through a dynamic process of mutual evaluation and peer pressure. It helps to identify deficiencies in national anti-corruption policies, prompting the necessary legislative, institutional and practical reforms. GRECO also provides a **platform for the sharing of best practice in the prevention and detection of corruption.**



“... data estimates of the **relationship between indicators of governance and foreign direct investment (FDI)** using a sample of countries from Asia and Latin America. While controlling for standard FDI variables, the results provide strong confirmation that the rule of law; control of corruption; regulatory quality; government effectiveness and political stability are positively correlated with FDI...”

OECD Open Government



- **PURPOSE:** Helping governments design and implement strategic, evidence-based and innovative policies to strengthen public governance, respond effectively to diverse and disruptive economic, social and environmental challenges and deliver on government's commitments to citizens.
- For more than 15 years, the OECD has **supported countries in their efforts to build more transparent, participatory and accountable governments that can restore citizens' trust and promote inclusive growth.**



2018 OECD GLOBAL
ANTI-CORRUPTION
& INTEGRITY FORUM

ENGAGE

SHARE

CONTRIBUTE

**BECOME A PARTNER OF THE OECD GLOBAL ANTI-CORRUPTION
& INTEGRITY FORUM (27-28 MARCH 2018)**

Under the theme “Planet Integrity”, the Forum will debate how integrity cultivates a level playing field for business, reduces socio-economic inequalities, and makes public policies more effective - enhancing the benefits of globalisation for all. The debates will also focus on the **governance of globalisation and its role in curbing corruption and unethical practices in areas such as trade, competition, infrastructure, development co-operation, and revenue collection.**



