

SAPRAA

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04/17



MCA

Marketing | Code | Authority

April, 2017

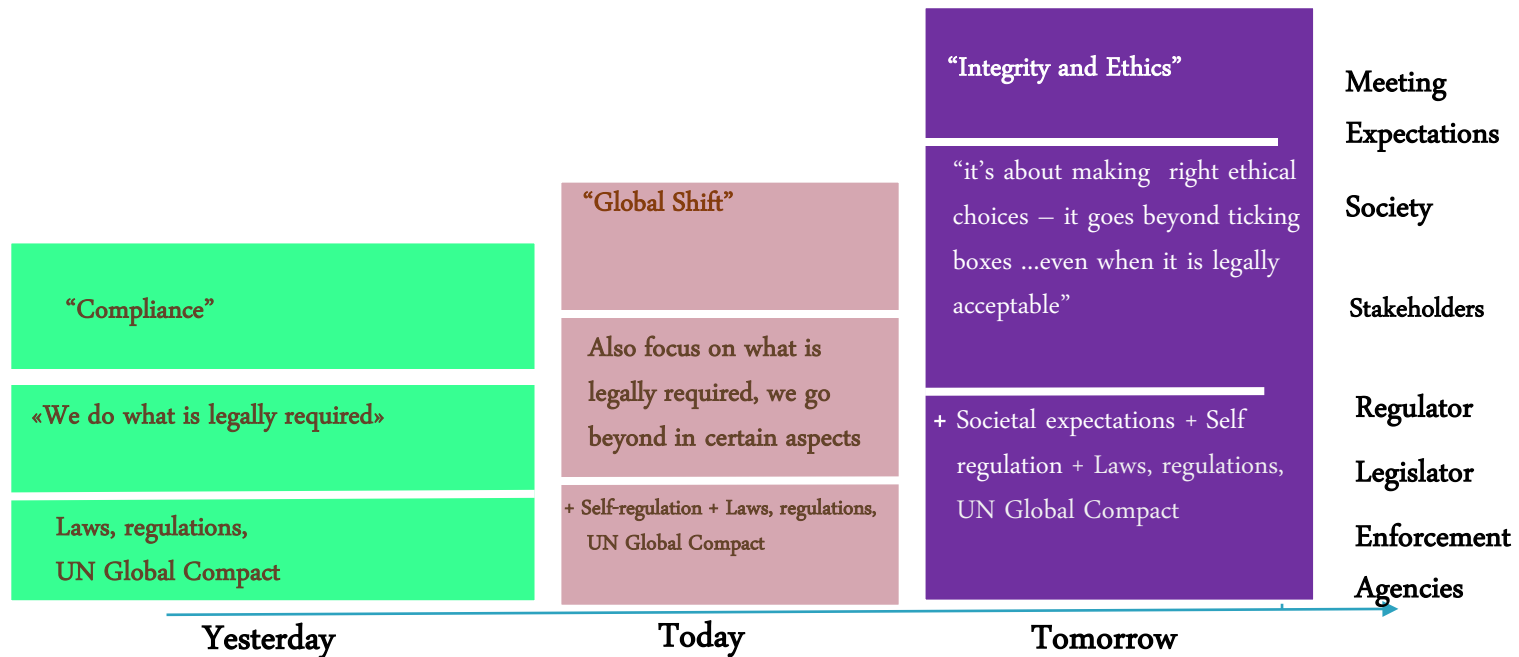
Society's expectations

Are increasingly high for ethical behaviour from

HealthCare Companies – these go beyond legal compliance. Patients and customers (HCP's) demand

ethical behaviour from Pharma companies.

The Evolution of Ethics



Why ethics in pharmaceutical marketing is so important!



Last Week Tonight with John Oliver Marketing to Doctors (HBO) - YouTube.mp4v

Evolution of the MCA as self-
Regulatory Authority (Agency)
Code of Practice
all products subject to
Medicines Act

Governance

- ❑ Constitution
- ❑ Board
- ❑ Executive Officer-administrator

Code & Guideline

- ❑ Technical specialists, flexibility

Enforcement (Complaints & Appeals)

- ❑ Panels
- ❑ Sanctions
- ❑ Executive Officer – strictly enforcement processes

Our Members

- Companies committed to code compliance
- Not Trade Associations
- Code Compliance Officers

Broad Community

- Service providers to industry
- HCPs

Functions

- Enforcement
- Code certification via website
- Ex Parte opinions
- Training and awareness

MCA membership



- Membership is open to all companies with products subject to registration with MCC
- Application form and fees on request – Trade association membership not a criteria

Key objectives:

- Recognition of the code by the MCC in terms of S18C of Medicines Act is key
- Stakeholders & relevant constituencies recognise the value of the Code
- Strong stakeholder preference towards companies compliant with the code.
- Stakeholders aware of remedial channels for alleged contraventions
- Self-regulatory with recourse to Authority/MCC/SAHPRA

Statutory vs Self Regulation

- Not mutually exclusive.
- Self-regulation - alternative to detailed legislation, but not to legislation itself.
- Self-regulation designed/developed to work within and to complement statutory controls.
- Produces unique results (that neither system of control could achieve on its own).

Regulatory Frameworks

- ASA as Ombud
- Draft regulations
- MCA proposal on principles

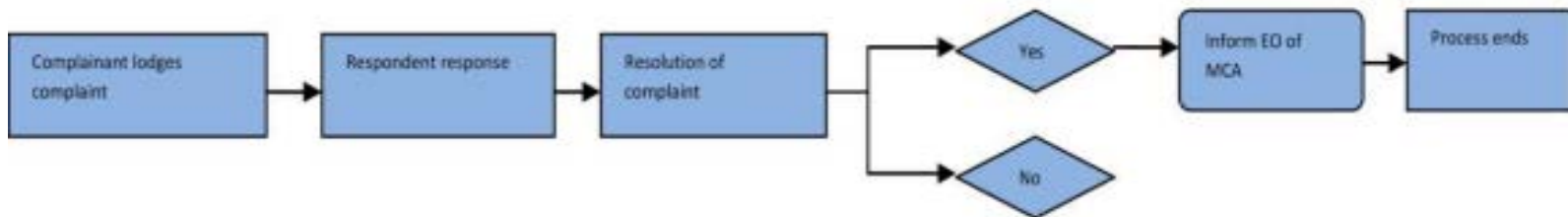
Critical Ingredients



Company-to-Company first!

As in, “if you don’t pass go don’t submit a complaint...”.

- Medical department of one company lodges complaint with medical department of the other
- Genuine attempt to resolve
- Keep records
- Supply evidence when lodging formal complaint
- Don’t frustrate the process



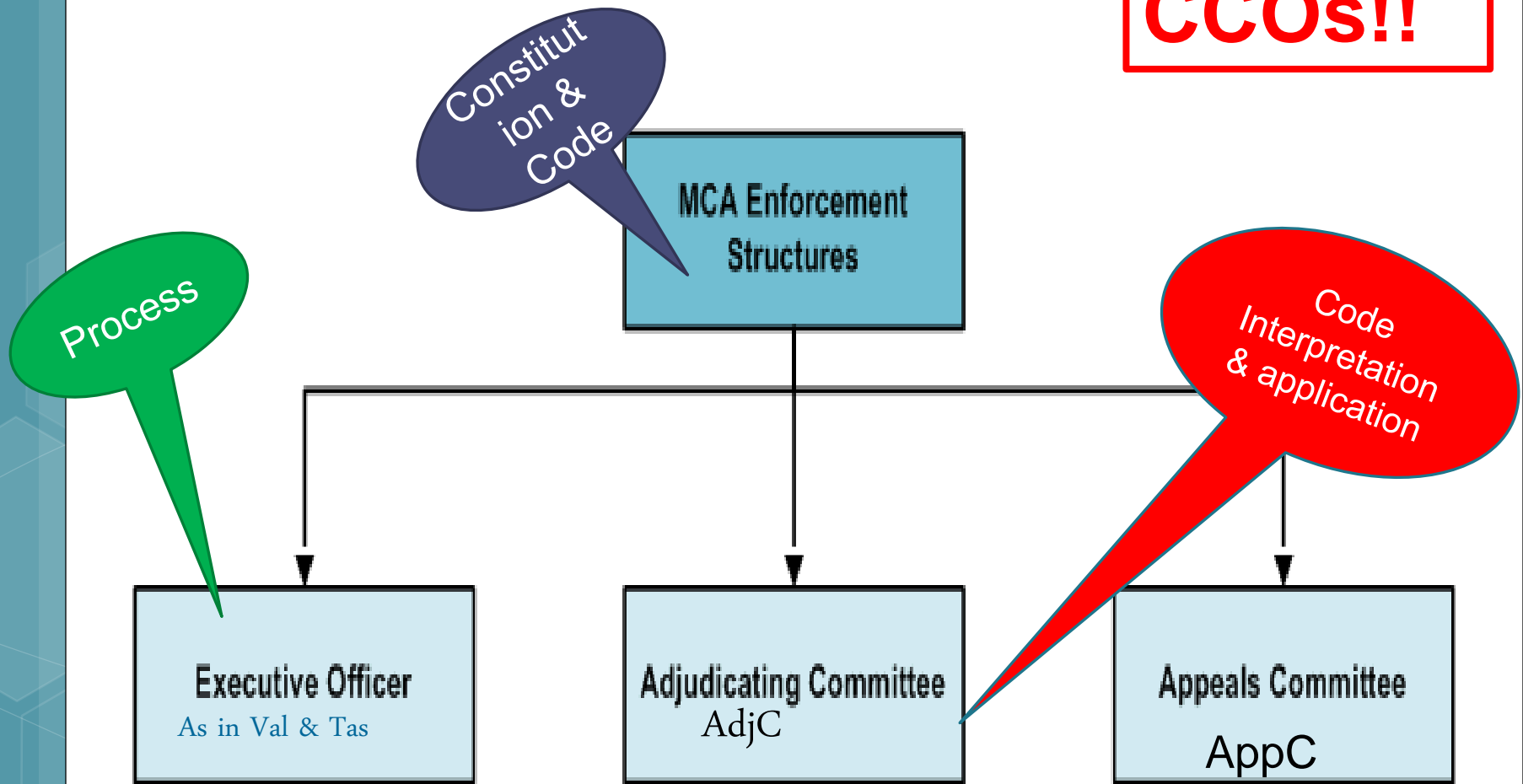
Lodge formal complaint

Lodging a Complaint with the MCA

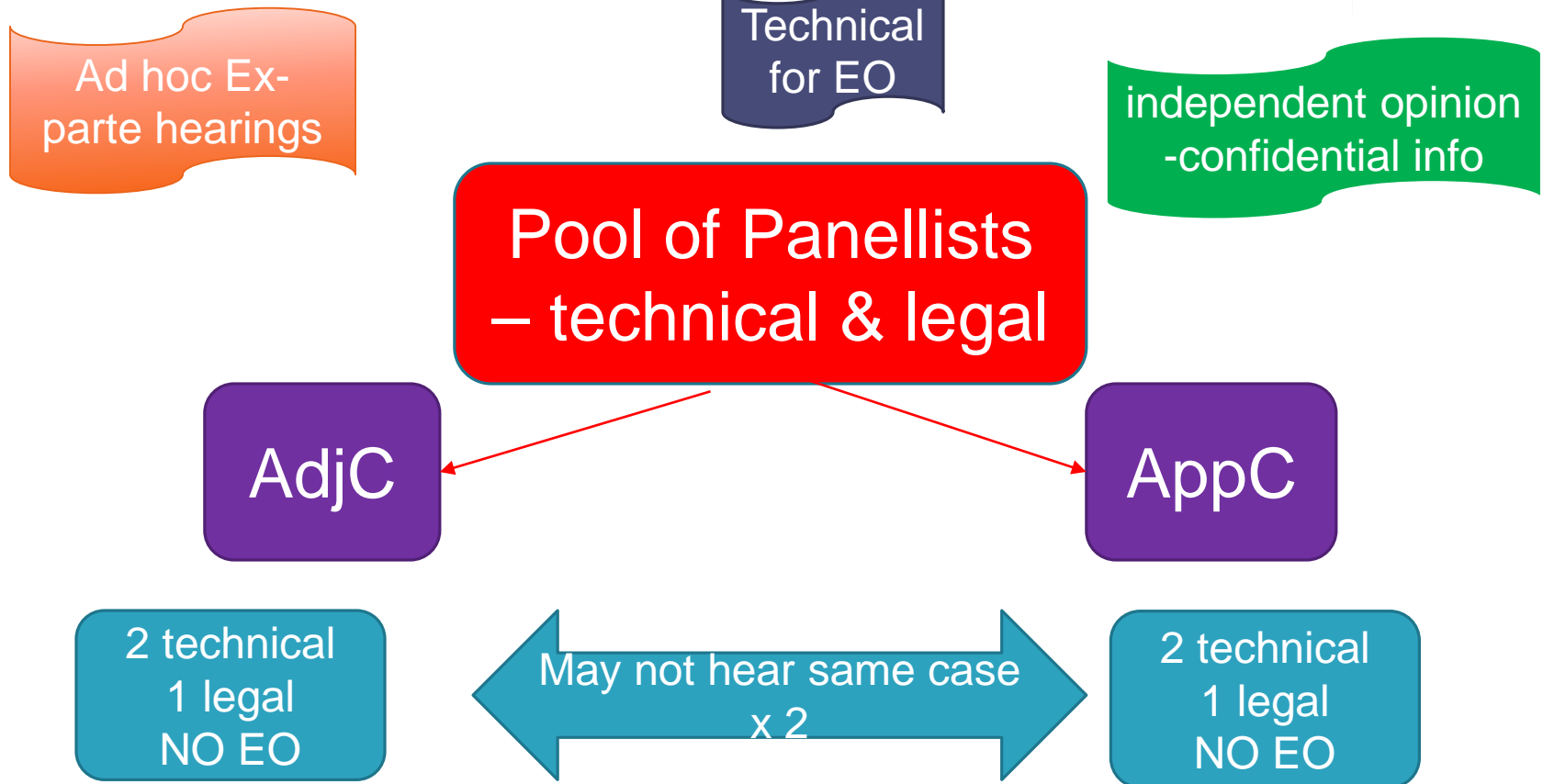
- Use MCA form – electronic submission is OK.
- Demonstrate exhaustion of Co-Co process
- Demonstrate compliance with certification requirements.
- Formulate complaint with clarity – not an unstructured “winge”
- Support each component of the complaint with accurate reference to Code and Guideline
- Think through your submission carefully – the committees may only consider what you put on the table and what is substantiated with references.
- Number and index pages so material is easily identified by committees.
- Pay filing fee/deposit
- Make sure received by MCA

MCA Enforcement structures

CCOs!!



Panels



- Panellists appointed by MCA structures – permanent pool
- Code certified and trained as panellists
- Committees appointed by EO. Process driven by EO.

MCA Toolkit for compliance officers

- Your MCA toolkit is
 - Constitution
 - Code
 - Guidelines
 - Sanctions document &
 - Complaint and Appeal forms
- Invitation to become pro-active in framing code development – code forums

Thank You



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Back up slides