

# Code for the Marketing of Health Products

## Roadmap 2013

*Dr Haseena Gani  
Executive Officer  
SAAPRA,  
Midrand,  
7<sup>th</sup> June 2013*



# A new era has dawned...



FDA Consumer Health Information  
www.fda.gov/ohrt

## Bad Ad Program

### FDA Aims to Keep Drug Promotion Truthful

**I**f you watch television, surf the Web, or read a magazine, you've likely seen prescription drug advertisements. Drug companies promote their products to consumers through these and other media.

However, drug companies promote their products to health care professionals in other ways. Representatives from drug firms market their products in places such as doctors' offices, hospitals, pharmacies, and at medical conventions.

The pharmaceutical industry spends nearly three times as much on advertising to health care professionals as they do advertising to consumers, according to the Congressional Budget Office.

Responsible professional efforts by pharmaceutical companies can give health care professionals valuable information about the latest drug treatments. But when drug promotion is misleading or unsubstantiated, the Food and Drug Administration (FDA) takes the necessary steps to stop the promotion.

On May 11, 2013, Commissioner of Food and Drug Margaret A. Hamburg, M.D., sent a letter to health-care professionals to announce the launch of the "Bad Ad Program." Through this new effort, FDA is asking these professionals to help it make sure that the promotion of prescription drugs is truthful and not misleading.

"This program will help health-care professionals recognize misleading prescription drug promotion and provide them with an easy way to report this activity to the agency," says Thomas Abrams, Director of

FDA Consumer Health Information / FDA Food and Drug Administration



marketing code authority



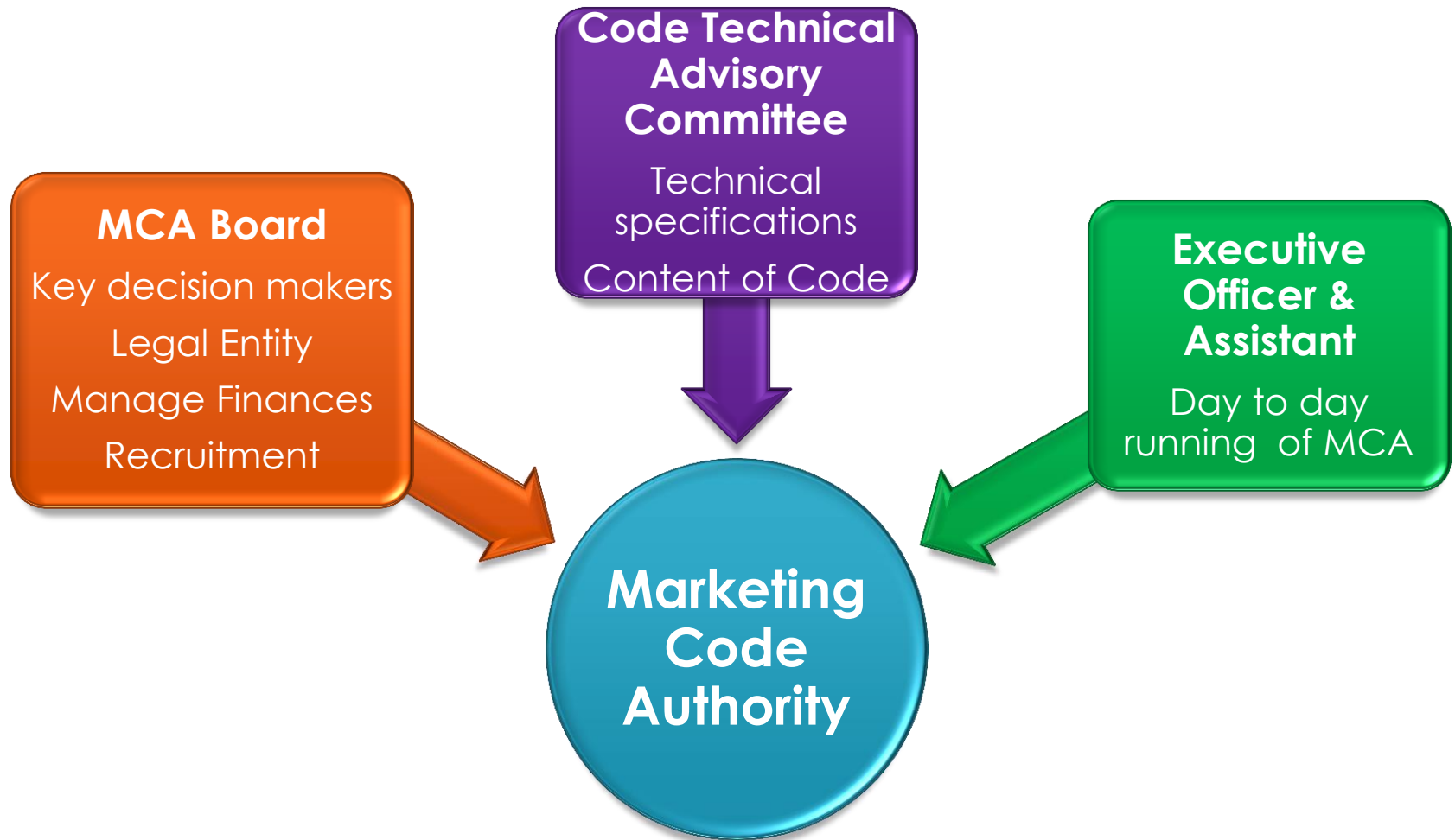
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*"They want us to set up a self  
regulating body."*

# What is the MCA?

- Marketing Code Authority
- Independent **self regulatory** enforcement organisation for the Code
- Set up as legal entity ('**juristic body**')
- **Members of the MCA are the companies,** not the associations
- Associations are key stakeholders

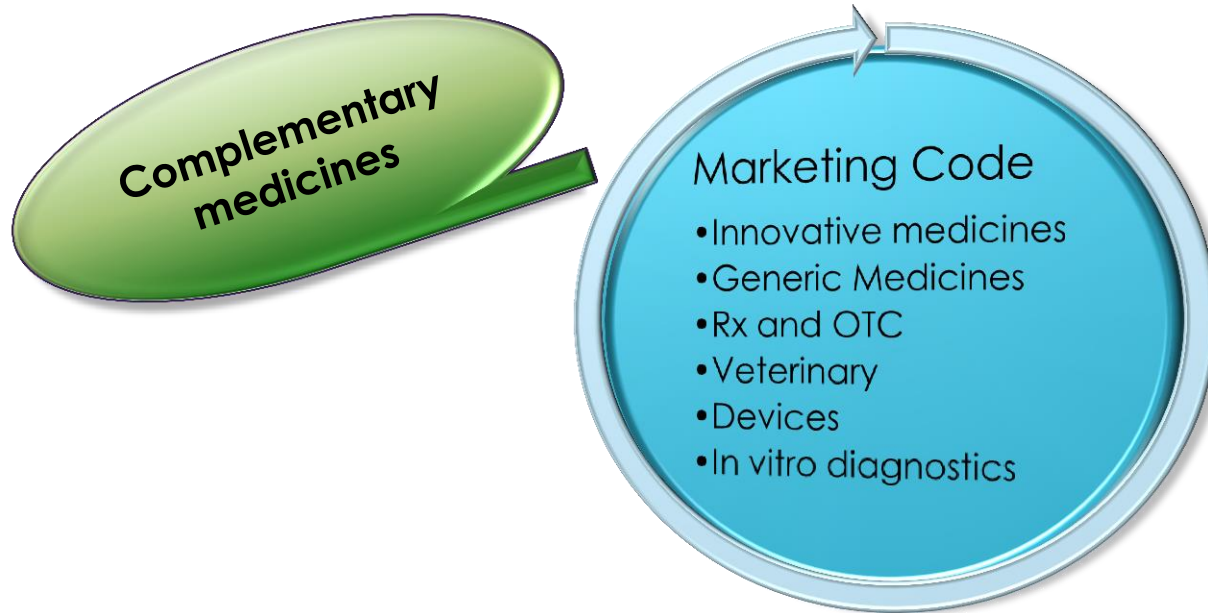
# Structure



# Principles of the Code



# Scope of the Code



# MCA Aligned members

1. INNOVATIVE PHARMACEUTICAL ASSOC. OF SA (IPASA)
2. NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (NAPM)
3. PHARMACEUTICALS MADE IN SA (PHARMISA)
4. SELF-MEDICATION MANUFACTURERS ASSOCIATION OF SA (SMASA)
5. THE SOUTH AFRICAN ANIMAL HEALTH ASSOCIATION (SAAHA)
6. SOUTH AFRICAN MEDICAL DEVICE INDUSTRY ASSOCIATION (SAMEDI)
7. SOUTHERN AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION (SALDA)

## **Support for the initiative and enforcement**

1. PHARMACEUTICAL WHOLESALERS AND DISTRIBUTORS
2. PHARMACEUTICAL SOCIETY OF SOUTHERN AFRICA (PSSA)
3. HPCSA, SAMA, DoH, SAAPRA, SAPC





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Does the Code have  
'teeth'?

# Recap - Legal context of the Code

Act 101  
of 1965

Section  
18A

Section  
18B

Section  
18C

Section  
22G

Makes provision  
for a Marketing  
Code

Legal gaps identified

Code will not resolve or eliminate issues around perversities in the market

# Code and guidelines

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## Part A

- Marketing & promotion of health products to **healthcare professionals**

## Part B

- Marketing & promotion of health products to **consumers**

## Part C

- **Medical Devices & IVDs**

## Part D

- **Code Enforcement**



**Guidelines**



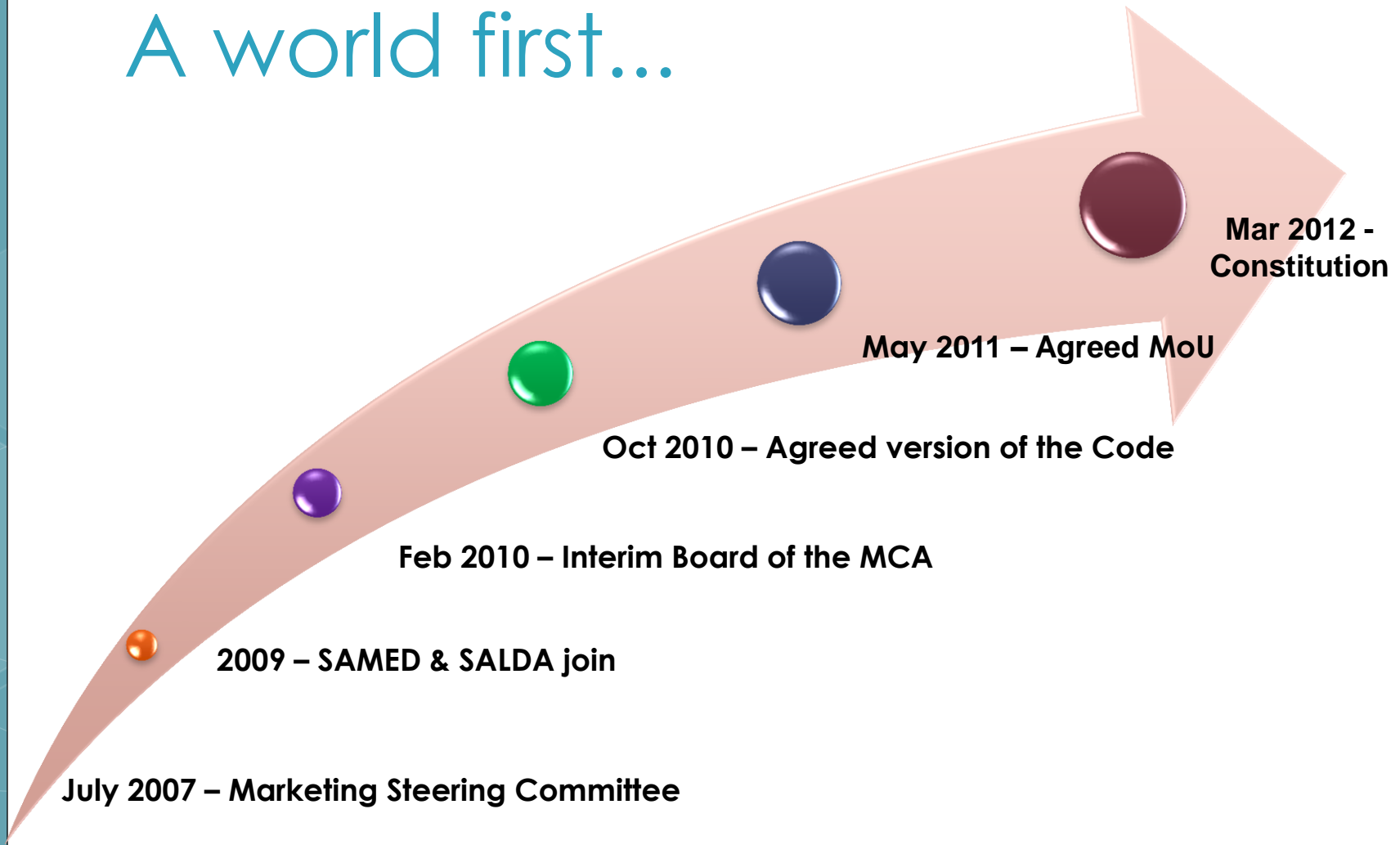
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# Code Journey



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# A world first...



# Milestones achieved

- First **AGM** (September 2012) held with over 200 industry people attending, including HPCSA, SAPC, PSSA, SAMA
- September 2012 – new **board** of MCA appointed
- **EO** appointed in January 2013
- **SGM** (Mar 2013) to revise Constitution (NPC)
- Hosted **IFPMA** meeting in March 2013
- **Enforcement** Structure initiated on 02 May 2013
- Trained **Panelists**

# Milestone Achieved - cont

- **Code & Guidelines –update** is imminent
- Consolidated, current **membership list & fee** methodology is underway
- **Website vendor** selected & project plan is underway
- Proposed changes to the Constitution reviewed by the Board in anticipation of **AGM in Q3/Q4**
- Appointed **part-time EA**

# Four Key Actions



Special  
General  
Meeting  
13th March



Complaints  
Process  
2<sup>nd</sup> May

Website  
Q3

Certification  
End Q3





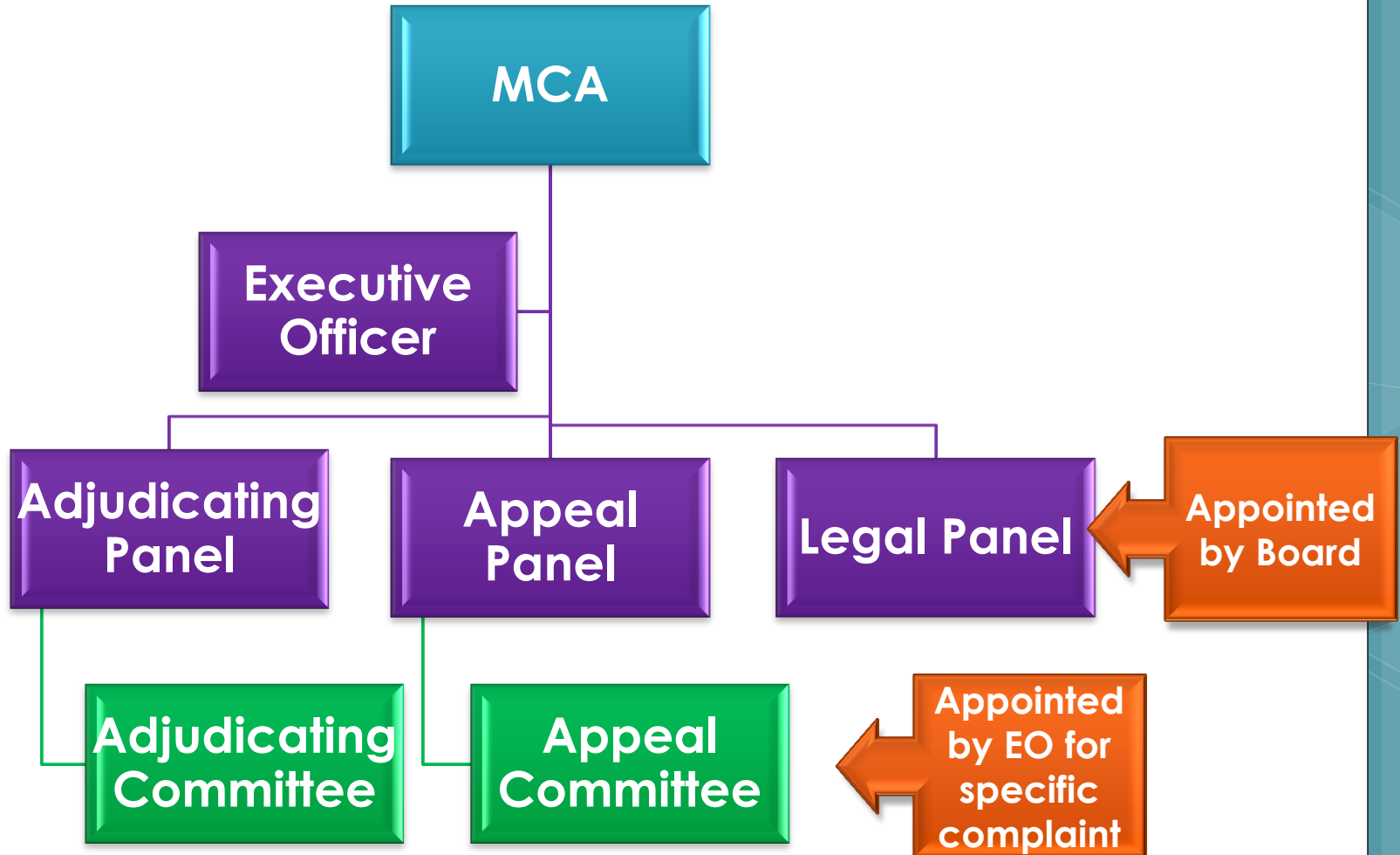
# Code Enforcement



# Principles

- Transparency
- Fairness
- Defined timelines
- Opportunity for recourse

# Enforcement Structure



# Panels

## EXPERTISE

- Adjudication and Appeals = 34
- Legal=8
- Expertise in marketing, medical & regulatory affairs
- Good representation from the different sectors

## UPDATE

- Briefing sessions
- Indemnity
- SLA completed
- NDA/conflict of interest prior to each matter
- Continuous development

# Adjudicating /Appeal Panels

- 12 members minimum
- Eligible to serve for max 5 years
- Executive Board can re-appoint person in its sole discretion for a period they determine
- Panel members appointed to committee by EO (committee quorum is 3)
- Cannot simultaneously serve on both panels



# Legal Panel

- Attorneys and/or advocates of at least 5 years standing in SA
- Substantial experience in health products market and/or health products industry matters
- Serve until resignation

# Fee for complaints



Lodging  
fee

**R2 500 to  
MCA**



**Fees**

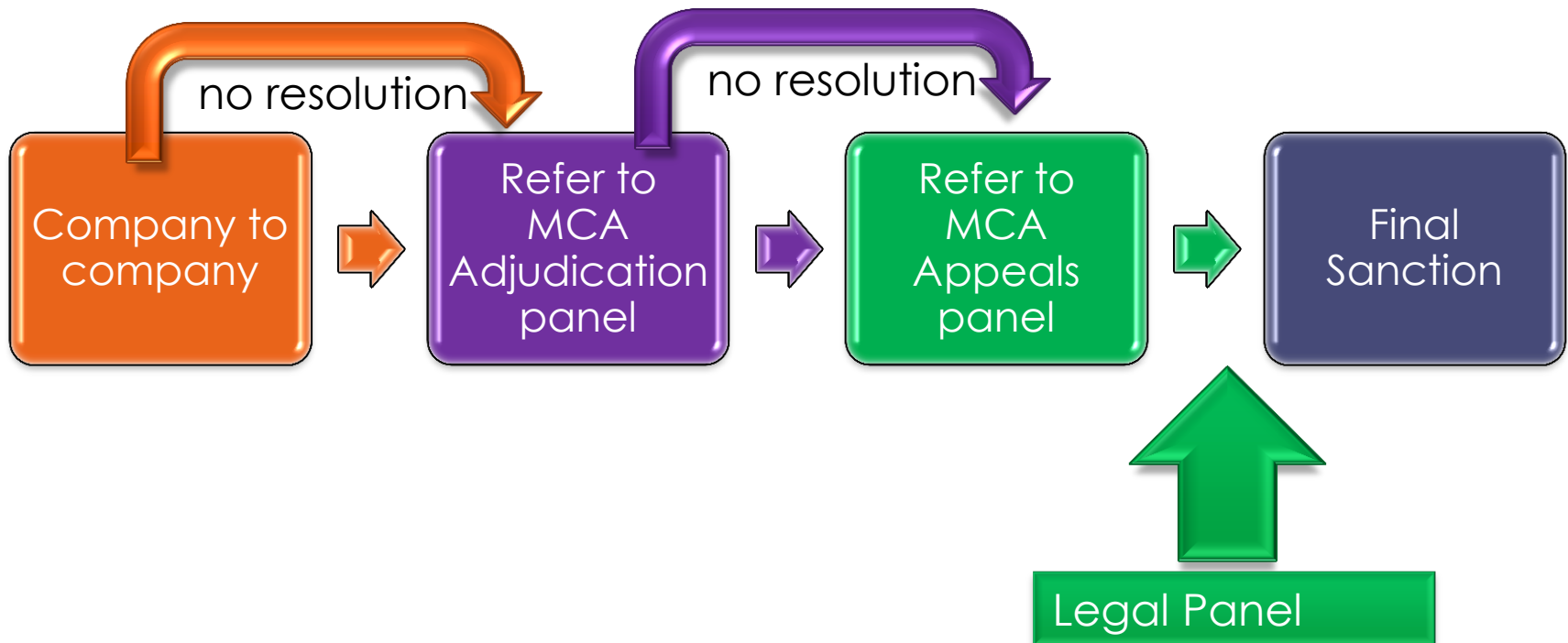
**Adjudication**

**R 20k**

**Appeal**

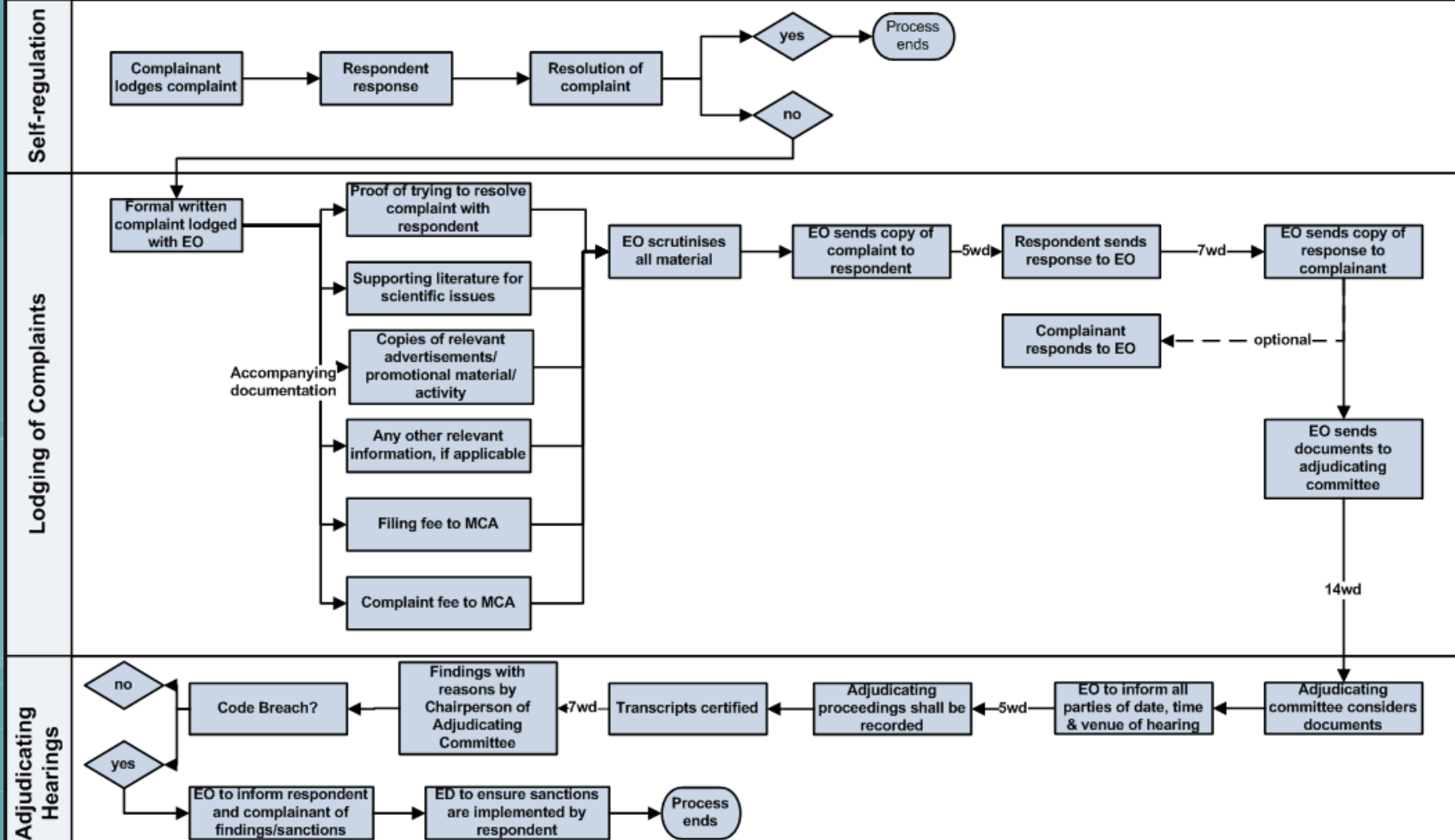
**R 65 k**

# Process flow for complaints



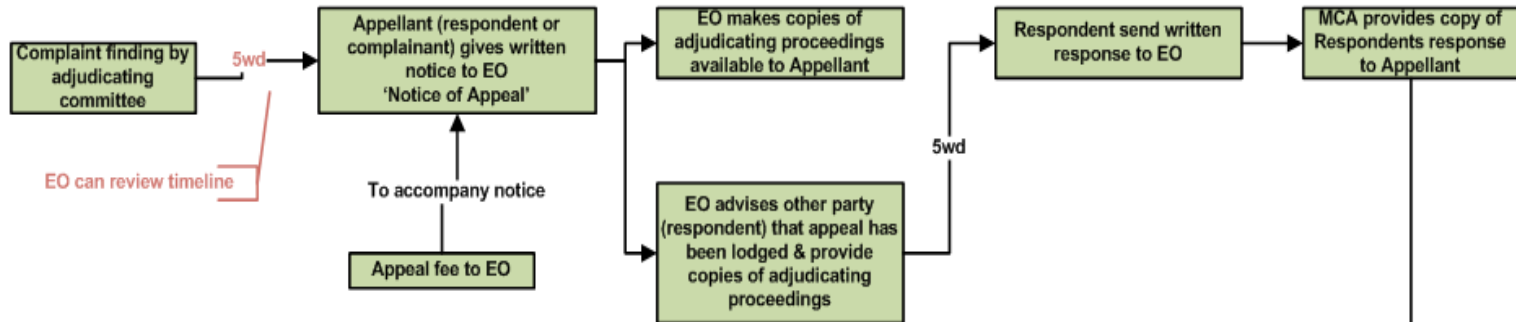


## Process flow for lodging a complaint

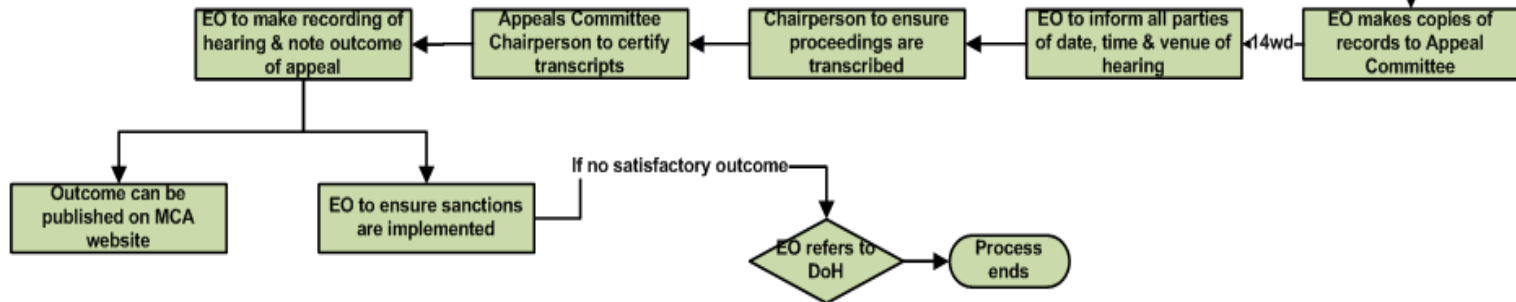


## Appeal Process

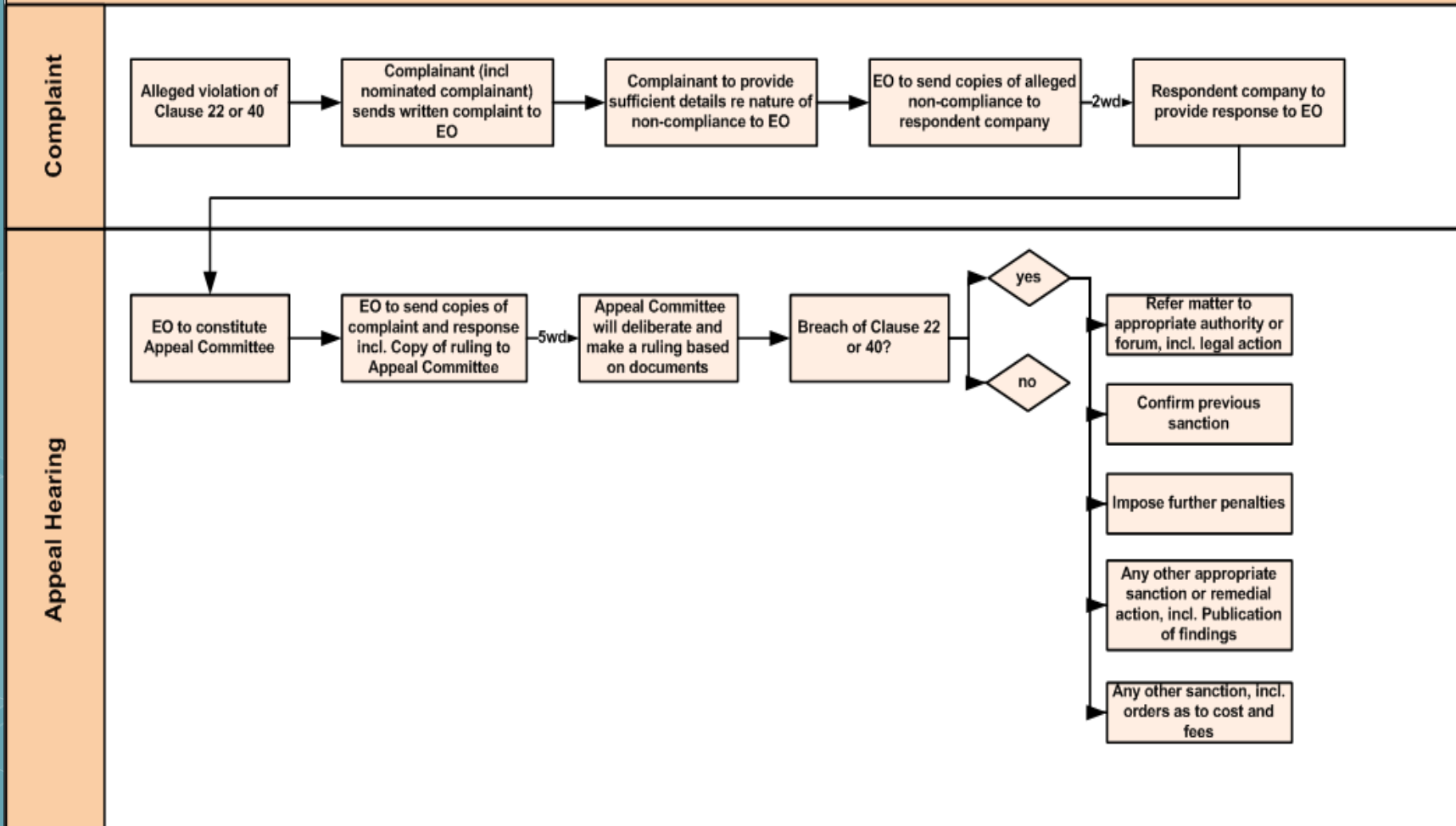
### Lodging an Appeal



### Appeal Hearings



## Expedited Process



# Sanctions : Principles

- Nature and extent of the activity/material
- Breadth of activity or campaign
- Length of time material is in use
- Number and type of breach
- Circumstances in which the activity took place

# Sanctions

## Breaches



- Minor
- Moderate
- Serious
- Severe
- Fines not paid
- Corrective Action not implemented
- Repeated Breaches
- Multiple breaches
- Invalid / unjustified / vexatious complaints
- Bringing the Code into disrepute

## Corrective Action



- Immediate withdrawal of material/activity
- Written reprimand
- Publication of corrective advertisement,
- Issue a corrective letter to healthcare professionals/public

## Fines / Timelines



- R 6 - R300K
- 30 -60 days

# Four Key Actions



Special  
General  
Meeting  
13th March



Complaints  
Process  
2<sup>nd</sup> May

Website  
Q3

Certification  
End Q3

# Website Phase I

- Basic public website
- Downloadable documents
- Complaints process & associated forms

## Website Phase II

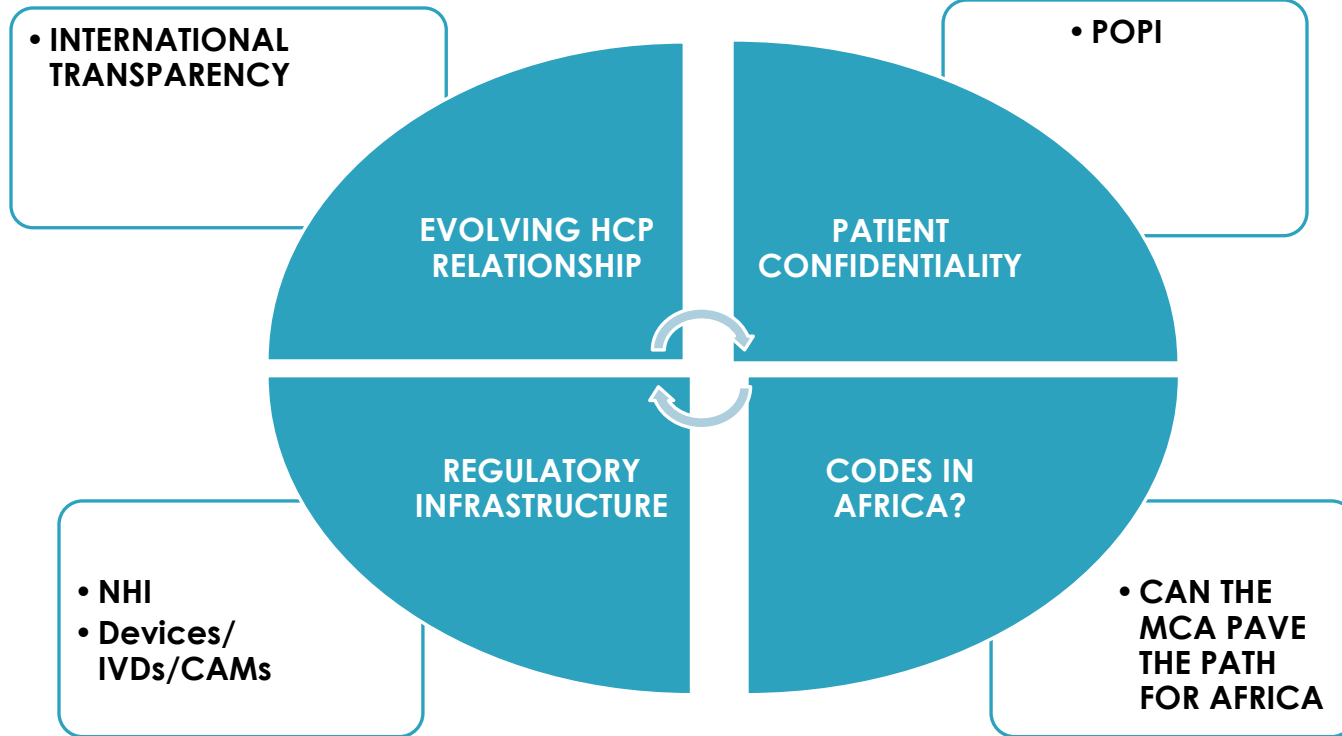
- Assessment, certification & online payment gateway
- Intranet for authorised members to share documents
- Links to international compliance websites
- ?Resuscitate the e-learning / training manual



# So what can you expect for 2013?

1. New version of the Code & Guidelines
2. Digital presence
3. Certification process implemented
4. Case outcomes summarised on the website
5. Panels 'sharpen their saw'
6. AGM in Q3/4 - Constitution revised

# Future





DilbertCartoonist@gmail.com

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Thank you kindly...  
Any Questions?



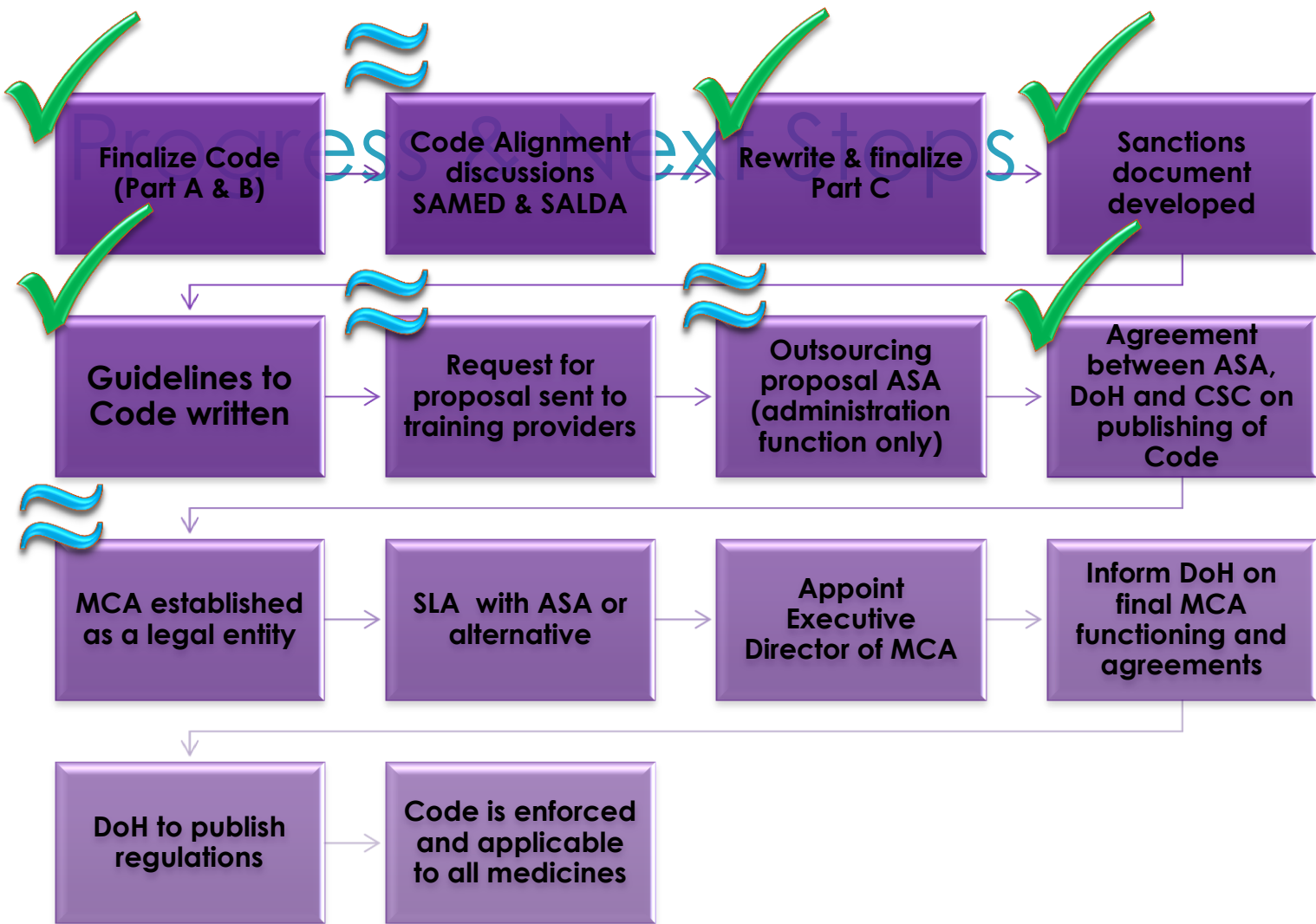


marketing code authority

- BACKUP



marketing code authority



# Training vendor –IP concerns

- Distribution control of the Content
- Helpdesk
- Domain registration
- Registration procedure
- Platform for assessment and certification
- Website hosting & maintenance
- Programme maintenance & CD duplication

# MCA dispensing advisory opinions with respect to interpretation of the Code

- An increasing demand from companies for “nonbinding” advisory opinions from the MCA
- Currently the Code does not make provision for, or regulate, the furnishing of non-binding, advisory opinions by the MCA. Accordingly, the status of these advisory opinions (ie the extent to which the advice contained therein is binding on the MCA or the parties requesting them), may be unclear.



# Considerations

- Revise the Code
- Clearly stipulate 'guidance', non-binding. Limitation of liability clause
- Resources & competence of those providing the opinion
- Procedural aspects
- Avoiding divergent views from the same competent authority ie. Adjudication outcome vs. opinion

# Considerations

- The Code be amended in order to regulate the process of providing advisory opinion, as well as to indicate the status (whether binding or non-binding) of such advisory opinions
- That the so-called advisory opinions are for guidance purposes only and are not binding on the MCA (including the persons furnishing it), and that persons relying on the advice do so at their own risk. A limitation of liability clause should be considered
- That the opinions are formulated on the basis of the facts disclosed to the MCA at the time; and that, should the facts change in any way, the MCA may revise its position
- Even if these advisory opinions are provided on a “*non-binding*” basis, persons will tend to place reliance on advisory opinions received from the MCA, which is a competent authority
- Procedural aspects should also be set out in the code, ie that a party seeking an advisory opinion is required to submit a written request outlining the facts in question, the contact details for the submission

# Considerations

- Accordingly, in the event that the MCA adjudicating committee subsequently sought to prosecute a company for a contravention of the Code, arising from the company's reliance, in good faith, on an advisory opinion of the MCA which turns out to be incorrect, it is our view that the company in question should not be penalised for having relied on the advisory opinion in good faith
- Sufficient resources should be allocated to ensuring that there
- are sufficient qualified persons to provide the advisory opinions, and ensuring that the persons who furnish advisory opinions are properly equipped and trained to do so. A review process
- should also be set up, so that an advisory opinion can be assessed at various stages by different persons at the MCA before it is finalised.

# COMPLAINTS' PROCESS

- Constitution -Clause 11
  - Process as per the slides
  - 'hearings' at adjudication & appeal levels
- Part D- Provision for Enforcement of the Code Clause 48 – 59
  - Lodging, Hearings and Powers of the adjudication and appeals committees
- Guidelines to Part D Clause 1-5 & associated process flows
- Alignment & best practice from IFPMA, ASA