

# Advertising and promotion of health products and the legal and ethical roles and responsibilities for pharmacists

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## Course outline

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- Update on the Code
- Current MCA approaches
- Awareness
- Complaints

- New version 14
  - Alignment with POPIA
  - Audit in respect of complaints
- Assessments – move to one assessment for all health products
  - Supplementary notes
  - Audits on compliance
- Broad reach
  - Students
  - Non-members
  - Associate members
  - Regulators & councils – collaboration on enforcement
  - SAMA & medical profession

## Current MCA approaches

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- Training
  - the Code in context of the legislation
  - Principles based decision making when approving material and events
- Awareness
  - HCP videos
    - Meetings and events
    - Donations and sponsorships

## The Code – a tool for implementing legal compliance

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### **Medicines and Related Substances Act 101 of 1965**

- Act
- General Regulations
- Regulations for medical devices & IVDs
- Medicine schedules

### **Pharmacy Act 53 of 1974**

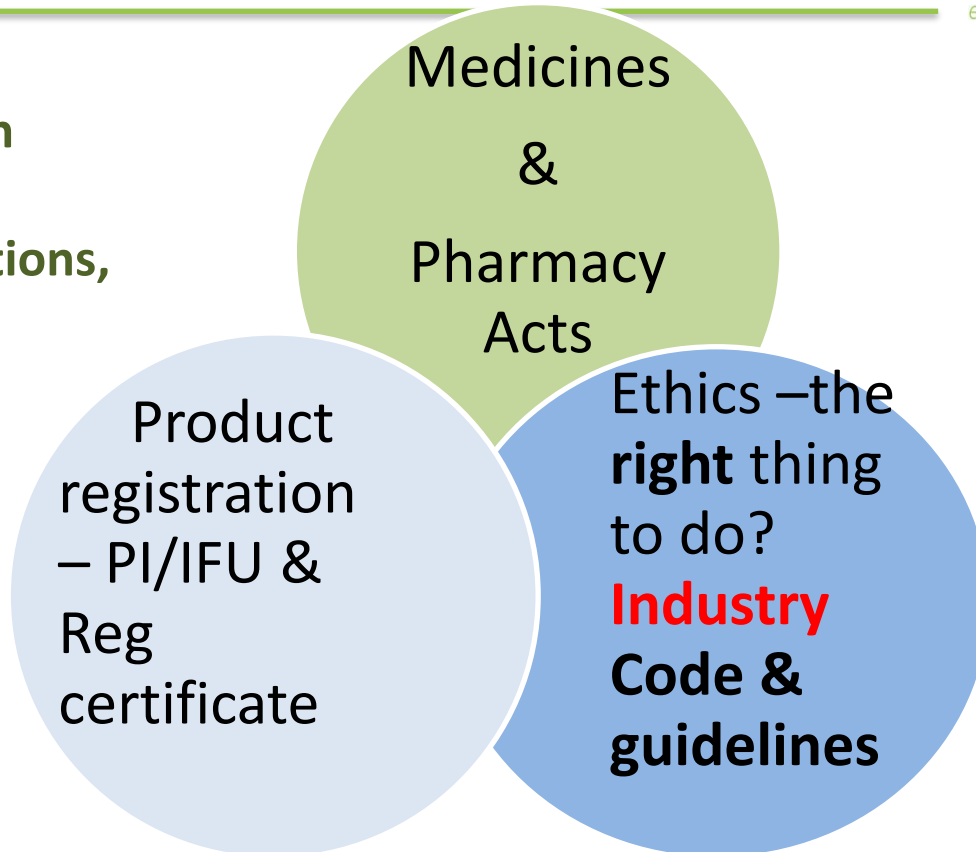
- Key rules & regulations
  - Good Pharmacy Practice (GPP)
  - Code of Conduct
  - Acts and Omissions in respect of which the Council may Take Disciplinary Steps
  - Regulations -Practice of Pharmacy & Disciplinary provisions

# The MCA Code supports legislation on pharmacy and medicines



*ethical marketing leadership for health products*

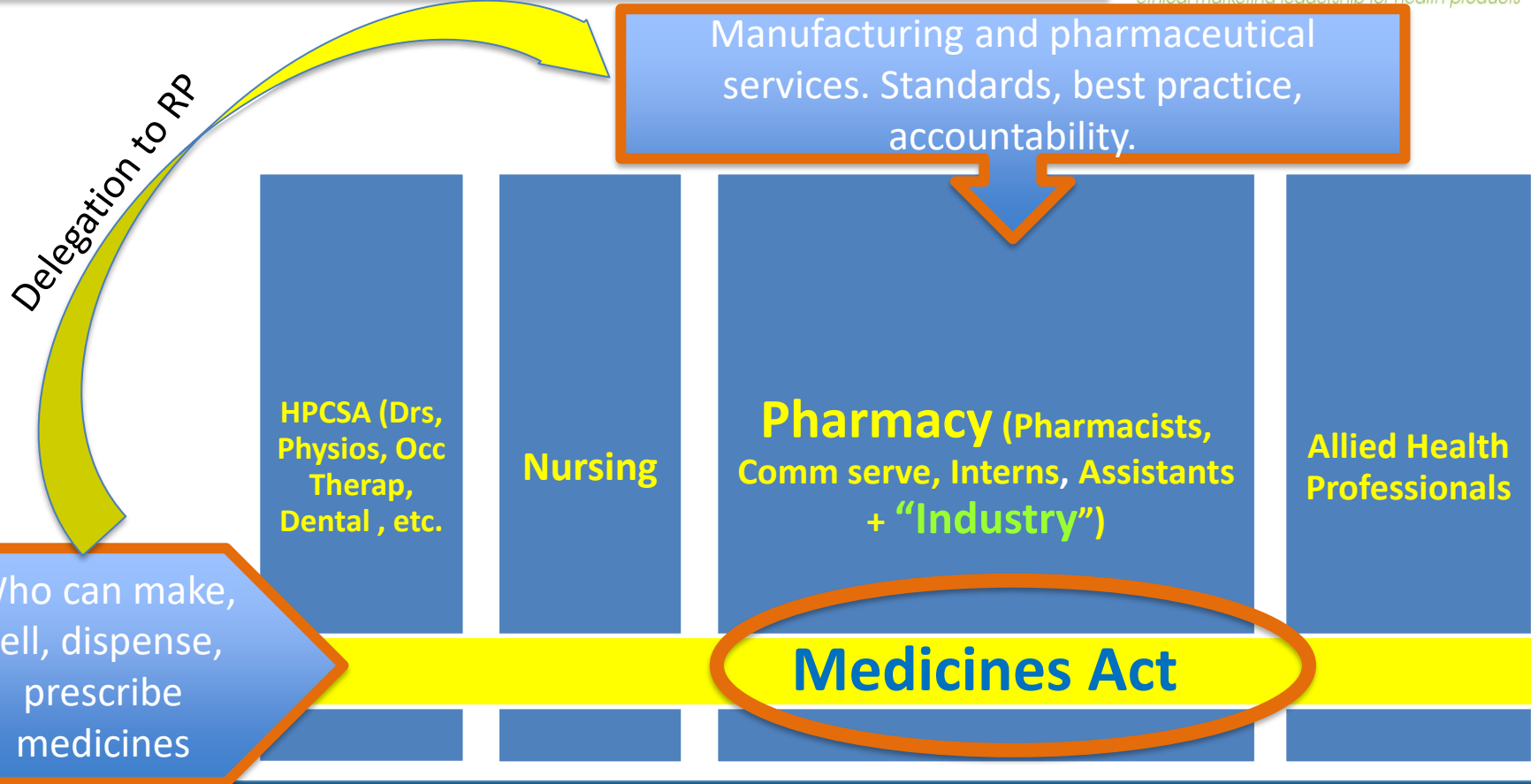
Code:  
Engagement with  
the public,  
patient organisations,  
consumers,  
patients,  
the media &  
HCPs



Code Applies to  
**Medicines - All  
Medical device  
IVDs**

**All health  
establishments**

# Medicines & Pharmacy legislation work together



## Appointment of Responsible Pharmacist

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- **In every pharmacy;**
  - Manufacturing, wholesale, community
- Accountable for **all activities** in a pharmacy which relate to **pharmacy scope of practice**
- Responsible for company compliance with Medicines Act
- Responsible for company compliance with Pharmacy Act
- Informed by GPP, GMP, GWP etc

**Responsible also for all advertising & promotion in a company no matter who is behind it.**



# INDUSTRY SELF-REGULATION

Marketing Code is a tool to support compliance and a framework for complaint administration

In summary  
THE MCA AND ITS PURPOSE

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Voluntary, not for profit, **self-regulatory organisation** to:

- Update and publish a code of marketing practice for health products
- promote the ethical marketing/promotion of health products,
- adjudicate on complaints in terms of the Code, and

Key focus: HCP Independence **and The protection of patients**

*Companies adopt codes voluntarily*

Ethical business  
practice

Internal  
controls

Compliance -  
law

## How does self-regulation work?



- Industry sets standards based on legislation – the Code
- Companies appoint CCCOs – link with MCA
- CCOs set company standards and procedures – may go beyond the Code (IFPMA or other global benchmark)
- Training Certification
- Complaint process – adjudication by industry experts

# SOME REMINDERS

HCPs

Health products

Advertisement

## Key concept: Know your HCPs?

- Persons registered with HPCSA – doctors, physios, occupational therapists etc.
- Persons registered with Dental Council
- Person registered with Nursing Council
- Persons registered with Pharmacy Council
  - Pharmacists
  - Interns and community pharmacists
  - Pharmacist’s assistants basic and post- basic
  - Learner pharmacist’s assistants basic and post basic
  - Pharmaceutical technician

# Pharmacists & Support Personnel



Pharmacy professionals registered with SAPC

Subject to Pharmacy Act

- Specialist pharmacist
- Pharmacist
- Pharmacist intern & community pharmacist
- Pharmacy student
- Pharmacist's assistant & learners, basic and post basic
- and soon to come...pharmaceutical technician.

All considered as HCPs

Specific scope of practice for each

Accountable to the Responsible Pharmacist

## Key concept: Health product? Medicines definition

- **Medical devices & IVDs**
- **Medicines (allopathic and complementary)**

### **Medicine definition (important):**

- a) any substance or mixture of substances **used or purporting to be suitable for use or manufactured or sold for use in-**
- I. the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
  - II. restoring, correcting or modifying any somatic or psychic or organic function in humans; and
- (b) includes any veterinary medicine;

## Definition of Advertisement applies also to Complementary Medicine & HS

'advertisement', in relation to any medicine or scheduled substance, means **any written, pictorial, visual or other descriptive matter or verbal statement or reference-**

(a) appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever,

which is **intended to promote the sale of that medicine, Scheduled substance, medical device or IVD**, and “**advertise**” has a corresponding meaning;

Note for clarity: the term medicine currently embraces all allopathic medicines, complementary medicines and health supplements.

The Act, Definition of Advertisement



# COMPLIANCE WITH THE LAW – NOT NEGOTIABLE – ROADMAP FOR ADVERTISING OF HPs

RP  
accountable

Do not promote  
or sell  
unregistered  
product if it  
should be  
registered

Do not make  
claims not  
allowed by law

Get info required  
on advertisements  
correct

SEP (22G)

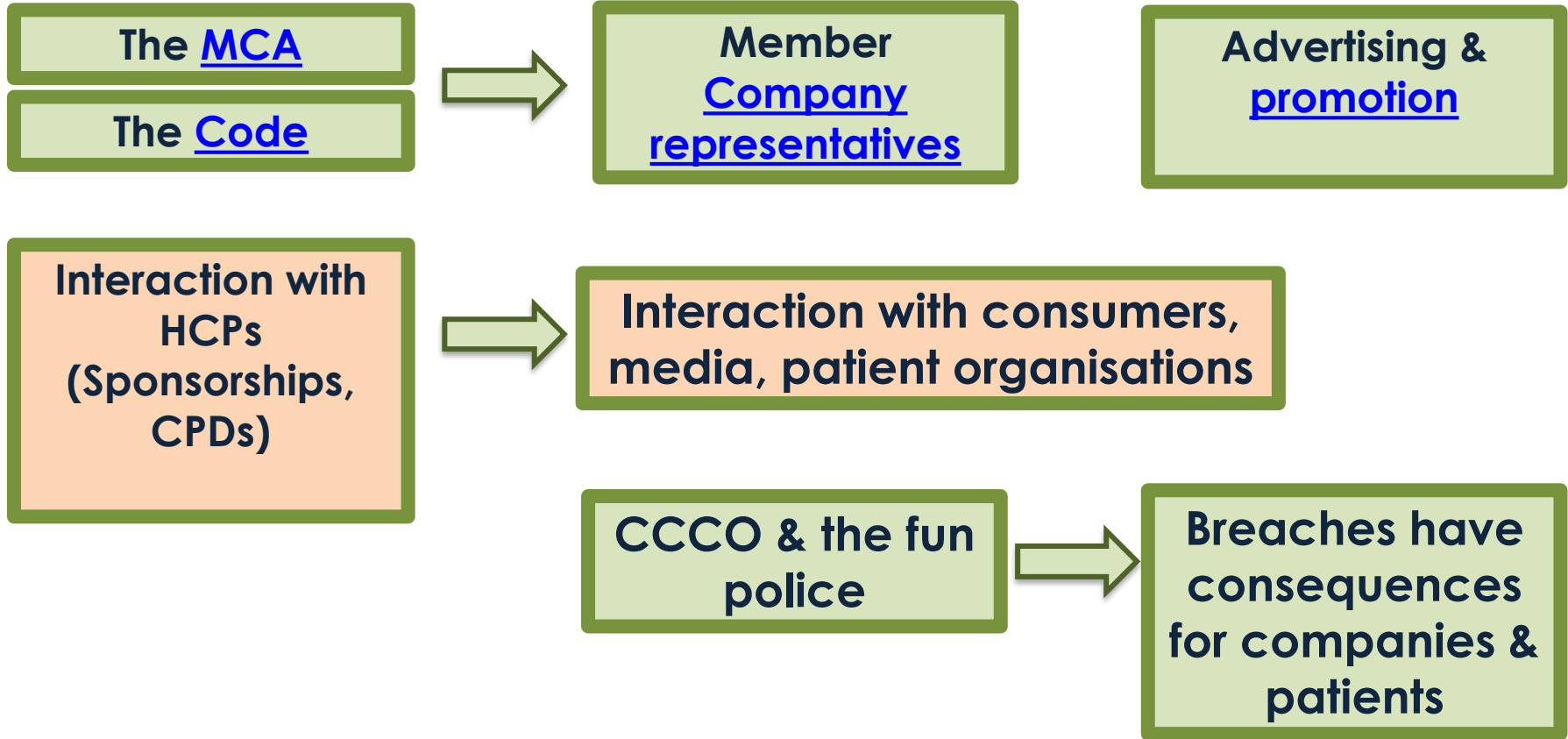
No  
Sampling,  
bonusing,  
discounts

Follow rules for  
conference  
exhibitions

Only supply to  
authorised  
persons

**Break the law  
and face the  
consequences**

# MCA – THE ETHICAL APPROACH



## **MCA CONCERN – COVID CLAIMS**

No medicines have been registered as being effective in preventing or treating Corona virus infections.



The immune system can get worn down by many things typical to a modern life – for example: stress, toxins, lack of exercise, and un... See more

**GEAR UP FOR ALL THE VIRUSES,  
INCLUDING NEWLY DISCOVERED  
COVID-19<sup>1</sup>**

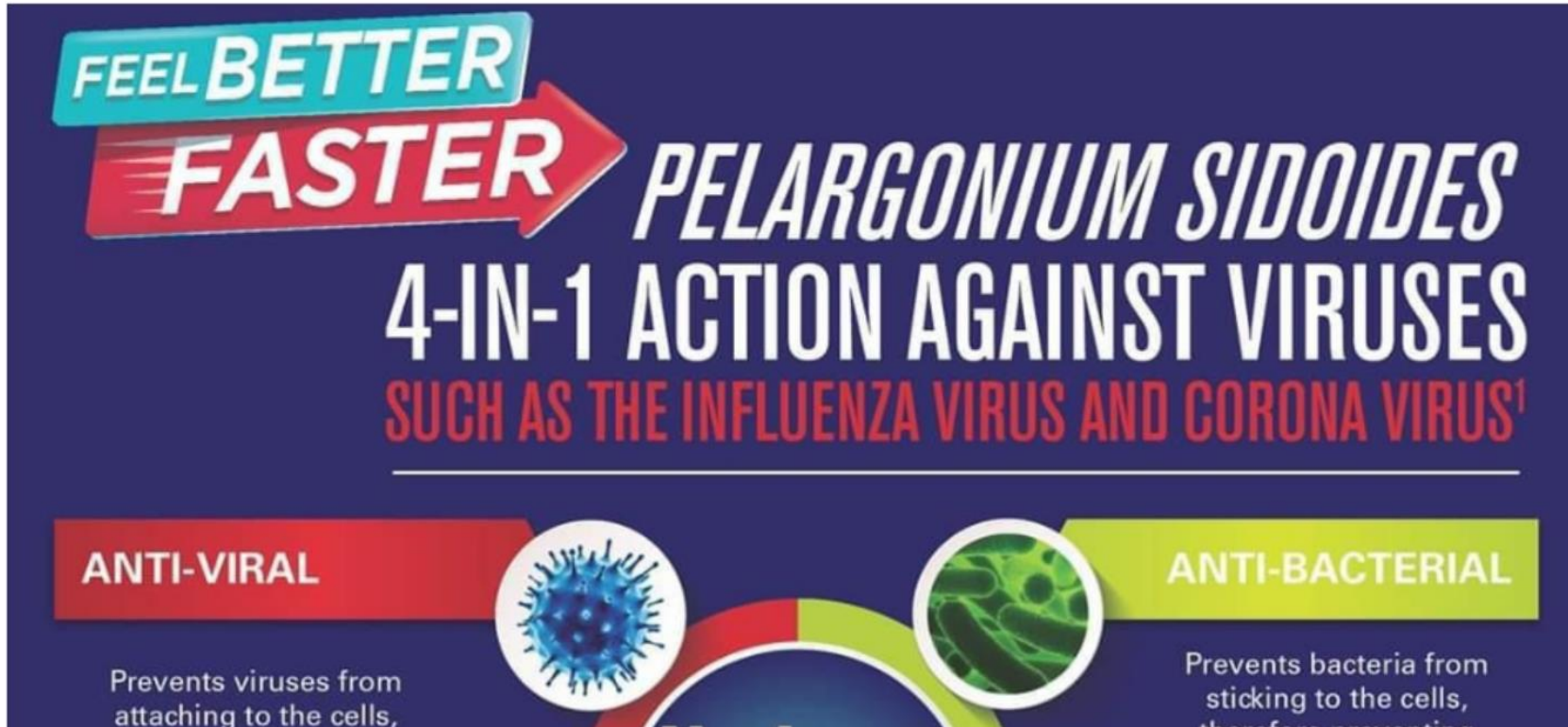
**BEAT THE FLU  
BEFORE IT BEATS YOU**



- herbal ingredients**
- non-drowsy**
- family offering**
- all year round protection**

1. Data on file Feb 2020. Further information available on request from iNova Pharmaceuticals. 011-087 0000. IN1034/20

Reported to SAHPRA



**FEEL BETTER**  
**FASTER** *PELARGONIUM SIDOIDES*  
**4-IN-1 ACTION AGAINST VIRUSES**  
**SUCH AS THE INFLUENZA VIRUS AND CORONA VIRUS<sup>1</sup>**

**ANTI-VIRAL**

Prevents viruses from attaching to the cells,

**ANTI-BACTERIAL**

Prevents bacteria from sticking to the cells,

# Monoflu™ 800

Favipiravir Tablets 800 mg

**READY  
STOCK  
AVAILABLE**



Effective to treat  
**Covid-19**  
Related Infection



**Alu-Alu**  
PACK

#### COMPOSITION

Each film coated tablet contains:

Favipiravir I.P. 800 mg.

Excipients q.s.

Colour : Ferric Oxide USNF Yellow & Titanium Dioxide IP



Use - COVID mild (starting) to Moderate (end) situation.

**Axi Franke** Private Limited  
INDIA

## Wonder Capsules – 11 medicinal claims,

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- a. Fights bacteria, inflammation, fungi and viruses**
- b. Helps reduce and chelate bioaccumulation of aluminium, arsenic, lead, mercury and other**
- c. May counteract Lead-induced Attention Deficit Hyperactivity Disorder (ADHD)**
- d. Can improve intestinal permeability ("leaky gut") and may protect the intestinal function**
- e. Relieves Irritable Bowel Syndrome**
- f. Helps to remove excess urea in the blood with those with uremia and may be more effective than conventional dialysis**
- g. Helps with gastrointestinal side effects**
- h. Reduces symptoms of Gastroesophageal Reflux Disease**
- i. Combats certain cancers and can suppress the growth of certain cancers**
- j. Helps with nutrient absorption**
- k. Helps absorb glucose and may be beneficial for hyperglycemia**

## Wonder capsules – 8 medicinal claims

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- l. Helps with Alzheimer's Disease (AD) and similar neurodegenerative disease**
- m. Helps with lipid levels and body weight in those with Type 1 & 2 Diabetes**
- n. Significantly improves wound healing as its materials are also potent antimicrobials**
- o. Strengthens bones and can be used in bone tissue engineering as can deliver oxygen to cells**
- p. has a protective effect on hepatocytes during anticancer therapy**
- q. Assists the immune system in destroying pathogenic organisms**
- r. Has beneficial uses for the vascular system**
- s. Highly effective in accelerating wound healing**



## Case study : Viraguard (Not real name)

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On website with online direct to consumer sales:

1. *“Viraguard is a clinically proven product which reduces the viral load by up to 99%. Suitable to be used for the whole family from children aged 4 and up”*
2. *“A new in-vitro study shows the ability of Viraguard to deactivate SARSD-CoV-2, the cause of the Covid-19 pandemic”*

# PERVERSE INCENTIVES

What is your intent?

- Product promotion
- CPD
- Incentivisation/bribe?

## Incentivisation of HCPs is unethical & illegal

- ***“Anything where the intent is to incentivise the recommendation, prescribing, sale, dispensing of a specific product”***. So.....
- ***is patient at the heart of the matter?***
- HCPs should **not benefit personally** from advertising or promotional activities e.g.
  - Competitions based on sales
  - Incentives for pharmacists assistants linked to sale of product
  - Incentives for substituting a particular product
  - Discounts related to sales of a product
  - Misleading advertising eg false claims
- Gifts, Air travel, Sporting events, Competitions, Sponsorships & donations,
- Any other form of “bribes

- **Code of Conduct for pharmacists** - Pharmacy professionals may not;
  - accept commission or financial gain or
  - pay commission or render any financial gain, in return for the purchase, sale or supply of any goods,
  - charge or receive a fee for services rendered by the pharmacy (? Data fees)
  - participate in any transactions or agreements not in patient's interest or clinical needs, or which limit patient or health practitioner independence

Should report to the SAPC, unethical behaviour of manufacturers sales reps eg offering incentives or discounts

- **Medicines Act** prohibits the supply of any HP according to a bonus or rebate system or incentive scheme.

# AVOIDING PERVERSITY AND PROTECTING COMPANY & PHARMA REPUTATION – create transparency

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- Question: What is the intent?
- Transparency:
  - written agreement
  - Signed by company & HCP
  - What, when, how
  - Amounts paid over with receipts
  - FMV
  - Retain receipts
  - Payment through 3<sup>rd</sup> party

**The difference between an activity intended to incentivise and a Code sanctioned, legal & ethical activity, is often just the way it is done.**

**Apply the Code correctly**

# COMPLAINTS

Submitting a complaint  
Defending a complaint

# MCA Complaints & enforcement – anyone can complain



**Board & CTAC**

**CCOs in company**

**Expert Panels**

Constitution & Code

**MCA Enforcement Structures**



**Sanctions**

Process / can refer

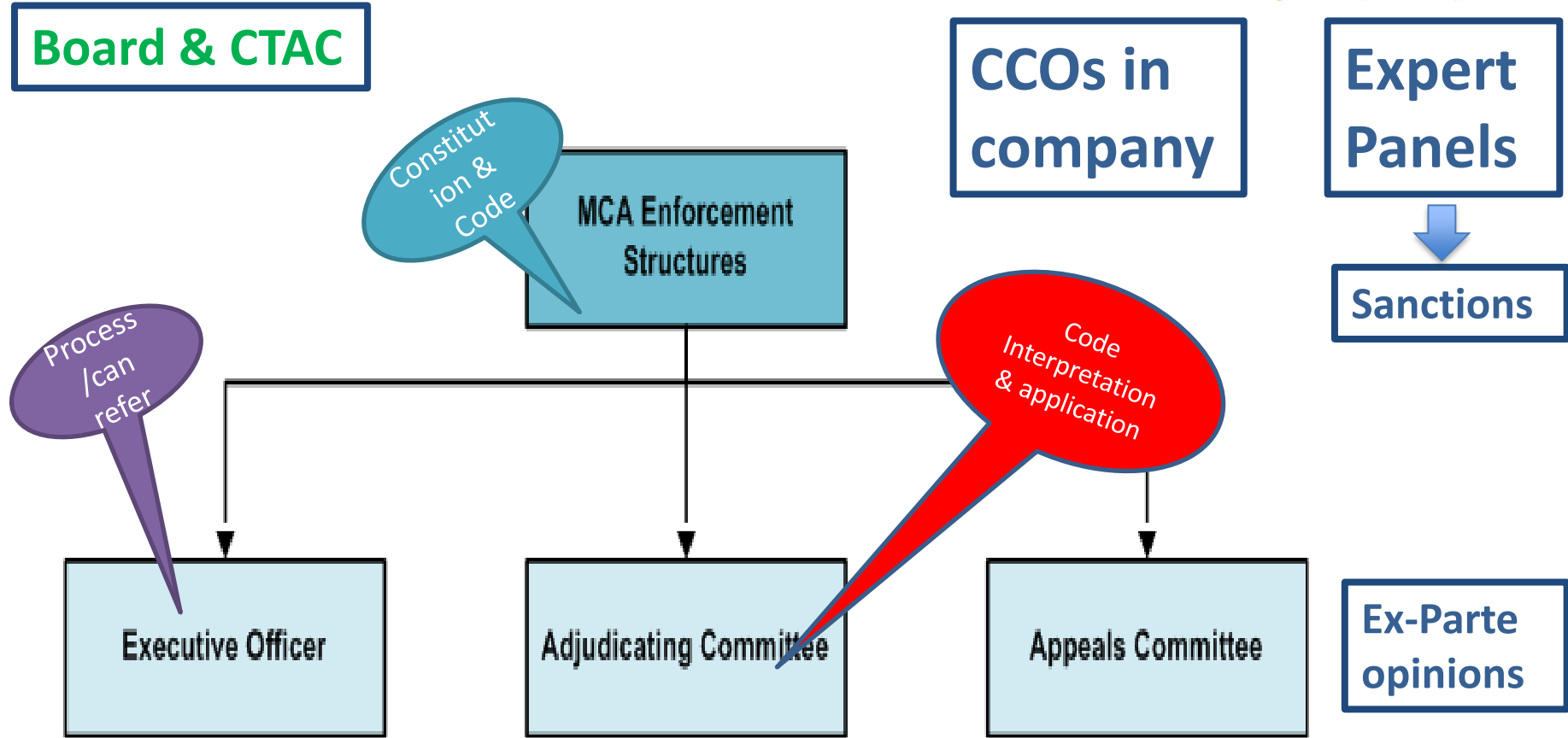
**Executive Officer**

Code Interpretation & application

**Adjudicating Committee**

**Appeals Committee**

**Ex-Parte opinions**



# Why is the Code & self regulation important to industry?

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- Essential to have fair and balanced promotion of medicines for both healthcare professionals and patients
- Mechanism for compliance with Medicines & Pharmacy Acts
- Critical for Industry to make a success of the implementation and enforcement ethical marketing practices
  - To retain the key privilege of self-regulation
  - To prevent enforced Government regulation
  - To ensure adherence and respect of the Code by all stakeholders so that the commercial 'playing fields' are levelled
  - To ensure that reliable scientific information is made available to healthcare practitioners, patients...consumers in general



## Feedback and questions

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