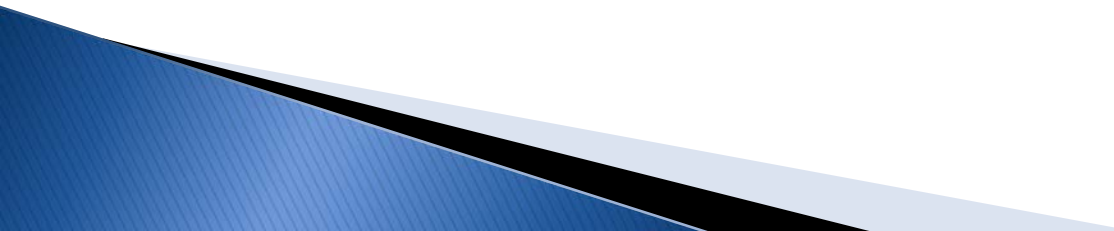


The Industry Task Group (ITG) – an overview

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ITG Chairperson
9 July 2015

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The history of ITG

- ▶ Formed in 2000 at the request of the Registrar, Malebona Precious Matsoso (current DG of NDoH)
- ▶ Called a meeting with all Pharma company CEO's expressing her wish to speak to one voice rather than to different associations
- ▶ Initially driven by NAPM and PMA on industry side
- ▶ Meetings held to strengthen communication and for information sharing on matters such as the backlog, guidelines, licensing, amendments, administration, etc.
- ▶ With the changes in leadership over time, the ITG went through periods where it stopped functioning, although the ITG secretary was still used by the MRA to distribute information
- ▶ Finally re-established in 2010 and held its first meeting with the MRA in August 2010

Membership of ITG

▶ Trade Associations

- founded & funded by companies that manufacture and/or market and/or distribute Health Products and represent the interests of member companies

▶ Professional Associations

- seek to further the interests of a particular profession and the interests of individuals engaged in that profession and which individuals are engaged in Health Products and related matters

Trade Associations (9)

- ▶ **IPASA** (Innovative Pharmaceutical Association SA)
- ▶ **NAPM** (National Association of Pharmaceutical Manufacturers)
- ▶ **PHARMISA** (Pharmaceuticals Made In SA)
- ▶ **SMASA** (Self-Medication Manufacturers' Association of SA)
- ▶ **SAAHA** (South African Animal Health Association)
- ▶ **SAMED** (SA Medical Device Industry Association)
- ▶ **SALDA** (Southern African Laboratory & Diagnostics Association)
- ▶ **HPASA** (Health Products Association SA)
- ▶ **PLASA** (Pharmaceutical Logistics Association of SA)

Professional Associations (3)

- ▶ **SAPRAA**

(Southern African Pharmaceutical Regulatory Affairs Association)

- ▶ **SAAPI**

(South African Association of Pharmacists in Industry – Sector of Pharmaceutical Society)

- ▶ **SACRA**

(South African Clinical Research Association)

Purpose and Objectives

- ▶ **Primary purpose** is to represent the Health Products industry on *technical, operational and policy issues* related to the regulatory aspects of the quality, safety and efficacy of Health Products in SA.
- ▶ Members have a **common objective** to contribute towards an effective and efficient Health Products regulatory environment in SA and to positively influence the regulatory environment.

NB: The ITG does not set policy.

(Health Products = medicines, medical devices and diagnostics and in addition shall broadly cover items similar to and/or related thereto)

Objectives – in scope

- Technical and practical aspects of implementation of proposed amendments to existing and new procedures or guidelines
- Considering changes in requirements proposed by MCC, including the rationale for such changes, and feedback from industry on how this will affect them
- Considering the readiness of industry stakeholders for implementation of new practices, legislation, guidelines etc.
- Clarification of technical matters, including the backlog of registrations, amendments and other applications
- Clarification of communications to industry and vice versa in order to reduce the potential for misunderstanding related to the interpretation of guidelines and regulatory requirements
- Any other business agreed by members of ITG by majority vote at properly constituted meetings

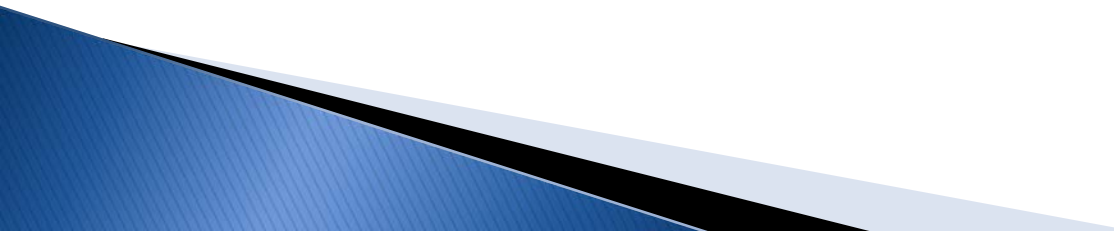
Objectives – in scope *contd.*

ITG is not a substitute for and does not prevent:

- ▶ Bilateral or multilateral engagements between individual ITG members and the Regulatory Authority
- ▶ The rights of the Regulatory Authority to propose or adopt legislation, policy or guidelines related to Health Products
- ▶ The rights of individual Trade Associations or Professional Associations or individual companies from providing individual comment on legislation, policy or guidelines as mandated by their members or principals

(Care should be taken to distinguish between the views and comments of individual associations or individual companies on the one hand and the views and comments of the ITG on the other)

Objectives – out of scope

- ▶ Pricing of Health Products
 - ▶ National Health Insurance
 - ▶ Logistics fees and dispensing fees
 - ▶ Consumer Protection Act
 - ▶ Medical Schemes matters
 - ▶ The SA Code of Marketing Practice
- 

Composition of ITG

ITG Internal Committee

Technical, operational and policy issues

- 3 representatives per Trade Association
 - 2 representatives per Professional Association
-

ITG –MRA Committee

Technical, operational and policy issues

(ITG–MRA Committee shall be responsible for engagements with the Regulatory Authority)

- 2 representatives per Trade Association
 - 1 representative per Professional Association
-

Specialist Committee

Special issues

- Representation depends on the subject matter
-

Chairperson, Vice Chairperson & Secretary

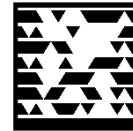
- ▶ Office bearers are elected biennially and serve for a 2 year period
- ▶ Chair nominated from Trade Associations, Vice Chair from Professional Associations & Secretary from either
- ▶ Nominees need to have served for a minimum period of 2 years as ordinary members
- ▶ Member associations shall not be entitled to representation as Chair, Vice Chair or Secretary for consecutive terms and an association shall not be entitled to at any time have its representatives simultaneously hold more than one of the positions of Chair, Vice Chair or Secretary. Rotation amongst all associations is encouraged
- ▶ Chair is responsible for chairing meetings and overseeing overall governance and has casting vote in the event of a tie when making decisions
- ▶ If Chair not available, Vice Chair serves as the acting Chair
- ▶ Secretary is responsible for circulation and record keeping of all ITG communications, including setting of meetings, agenda preparation, drafting and distribution of minutes etc.

Operation of ITG

- ▶ Date and frequency of internal meetings is influenced by those agreed between ITG and MRA (usually quarterly)
- ▶ All items proposed by members are included on the agenda
- ▶ Meetings also called as matters arise which create the need for a common industry position or for urgent matters
- ▶ Any member of ITG may raise a matter and thereby request a meeting to be scheduled by request to the Chairperson or Secretary
- ▶ All meetings to be properly constituted requiring a quorum (minimum of 5 Trade & 2 Professional Associations present). Each association has one vote.
- ▶ While alignment on issues affecting the industry is always sought, where this is not possible, those associations in disagreement are noted for record purposes and on all related correspondence

Past and present initiatives

Inclusion of 2D barcodes on medicine labelling



- ▶ Request sent in March 2014 and authorised by MCC in June 2014 to allow 2D barcodes on packaging to reflect information on the PIL

provided that:

- Applicant to ensure latest MCC approved PIL available via the 2D barcode
- PI & PIL to still be available as a hard copy in the pack
- Applicants' prerogative whether to include 2D barcode or not

Past and present initiatives *contd.*

Inclusion of 2D barcodes on medicine labelling contd.

- On 2 July 2014, presentation made to Expert Scheduling Committee to demonstrate the 2D barcode technology
- On 7 July 2014, ITG appealed Council's resolution and requested companies be allowed to either print the 2D barcode on the pack or supply a hard copy to the patient
- In Aug 2014, Council resolved not to rescind its previous resolution as it regarded:
 - use of 2D barcode technology vs. access to the PIL at the point of dispensing still regarded a pilot study
 - more information needed on national use of 2D barcodes by the public
 - requested the Expert Scheduling Committee to oversee development, monitor implementation & review the data generated

Pilot study in progress...

Past and present initiatives *contd.*

Proposal for a Central PI repository

- ▶ Presented to the Expert Scheduling Committee in Sept 2012 and approved in principle
- ▶ Proposes a secure Central Repository System for PIs so important prescribing information is available to decision makers, i.e. HCPs, dispensers etc.
- ▶ Needs to be access controlled, with full audit and approval processes built in
- ▶ Benefits include *latest approved PIs available via the repository, less space constraints, multiple languages possible etc.*
- ▶ Information for patients, i.e. PILs to be available in the pack or at the point of dispensing
- ▶ ITG Working Group putting together an implementation plan to present to the Committee to take this project forward...

Past and present initiatives *contd.*

Distribution of DHCP letters via electronic media

- ▶ Request for electronic distribution as an alternative to postal delivery began in 2012
- ▶ In June 2014, ITG presented to the PV Committee regarding merits of electronic distribution vs. postal delivery
- ▶ Dual process proposed whereby when “undelivered” messages are received, letters are then faxed and mailed
- ▶ PV Committee not in favour of dual process and expressed concern re guarantee of receipt, as percentage of HCPs with email addresses on record is too low compared with percentage with postal addresses.
- ▶ Debated at length with ITG and finally concluded in June 2015 that *primary method of distribution of DHCPLs remains surface mail*, although a dual process encompassing both surface and electronic mail may be used.

Thank you for listening!

Any questions?

