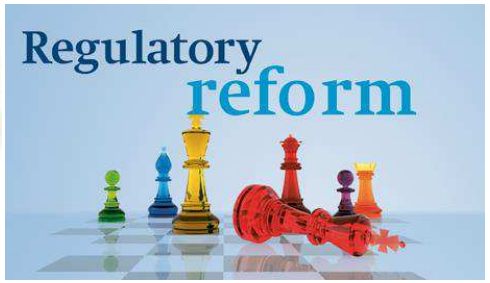
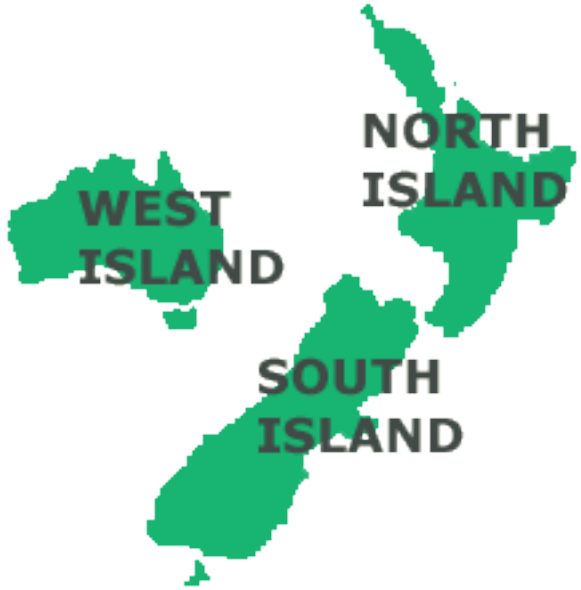
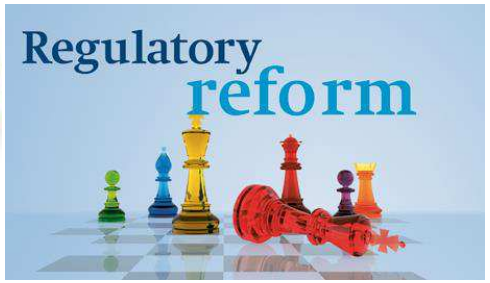


Update from Australia

Review of Medicines and Medical Devices Regulation





Reforms to Australia's Regulatory Framework

October 2014

The Prime Minister announces a Review by an Independent Expert Panel

July 2015

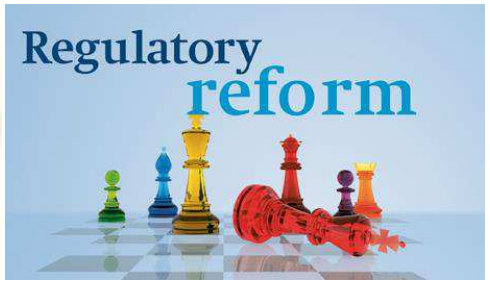
Review into legislative framework commensurate to the levels of risk of products

September 2016

Cabinet review report and accepts Expert Panel Recommendations

March 2018

TGA Stakeholder Forums



Progress on the Parliamentary Bill

House of Representatives:

First Reading 14 September 2017
Second Reading Debate: 25 October 2017
Referred to Federation Chamber
Second Reading Agreed: 4 December 2017

Senate:

First Reading: 4 December 2017
Second Reading; 4 December 2017

House of Representatives:

Third Reading: 4 December 2017

Senate:

Refer to Senate Committee

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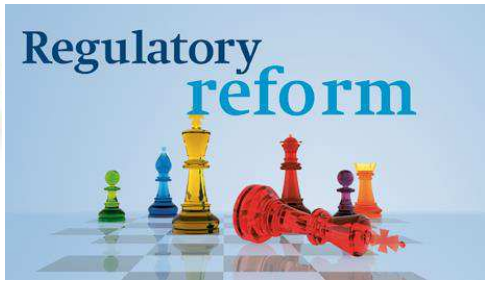

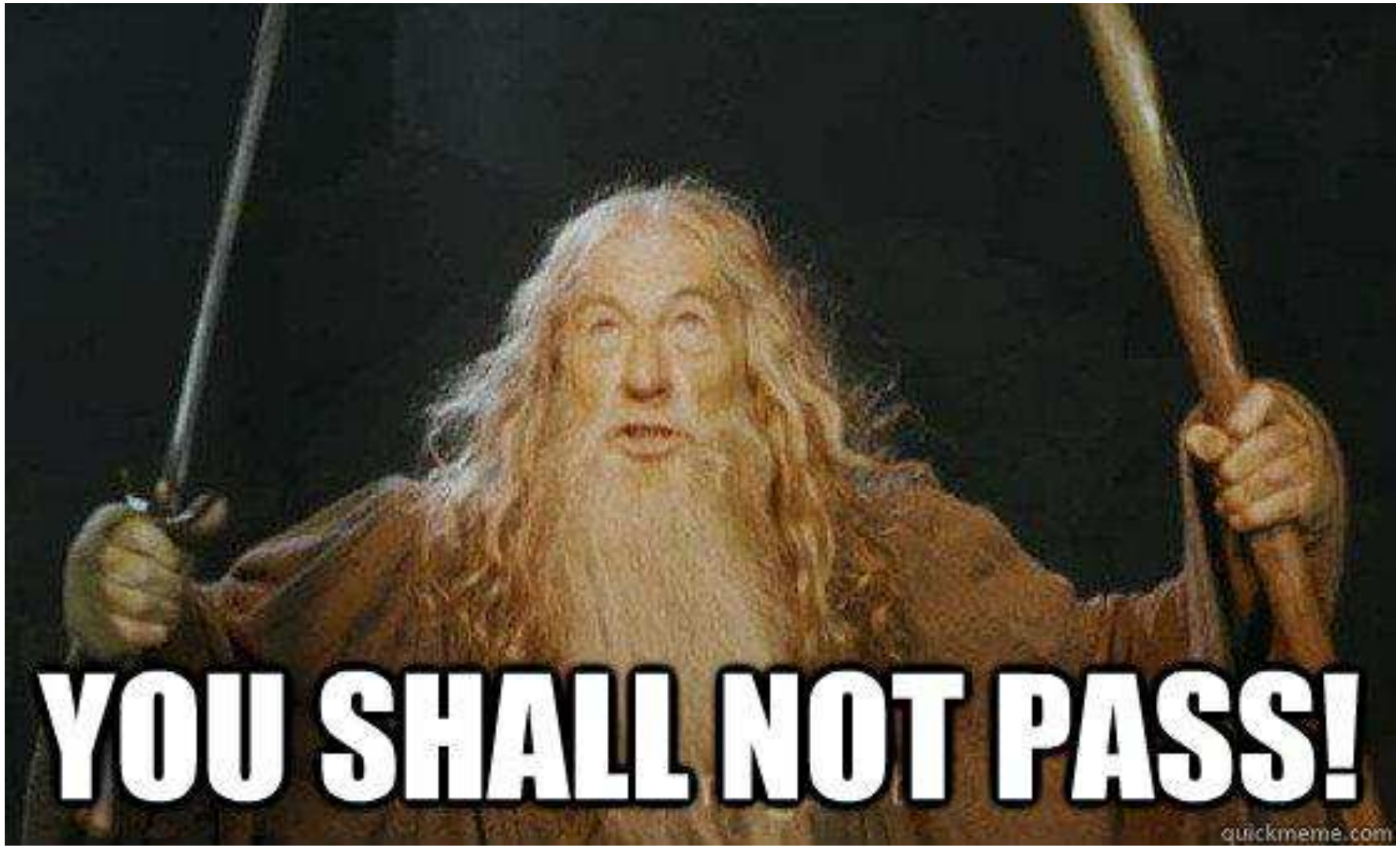

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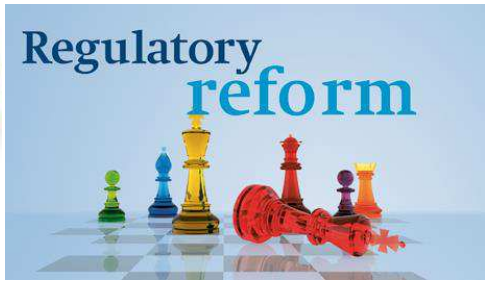
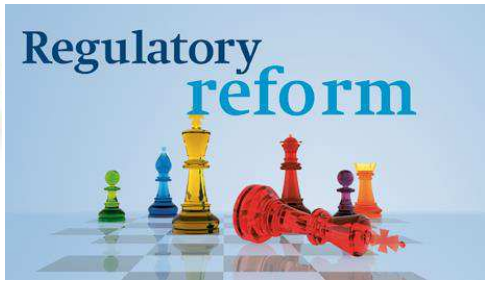


What's in the Bill: Highlights

- A New Registration Pathway
- Permitted Indications
- Improved Access to New Ingredients
- Market Exclusivity
- Use of information from Overseas Regulators
- IP Protection
- Reforms to Advertising
- Complaints Resolution Panel Axed



Implemented Reforms: New Ingredients

- Online catalogue of approved Ingredients
- Ability for review and appeal of decisions for new ingredient applications
- 2 Year Market exclusivity for newly approved ingredients
- TGA can add a new ingredient without an application

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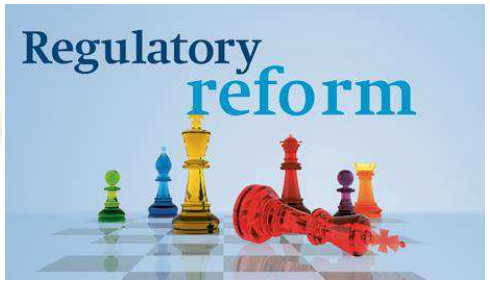
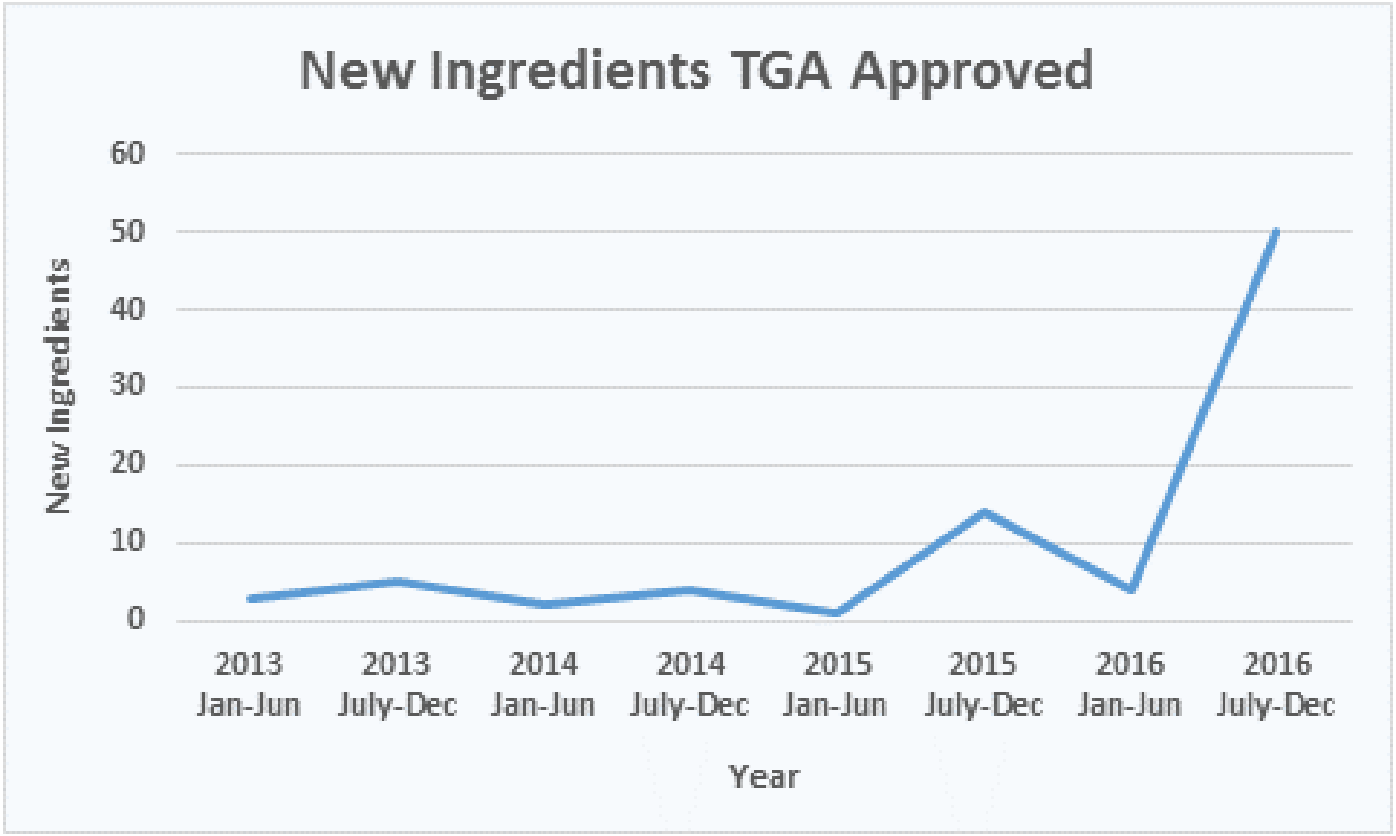


Innovating in New Ingredients



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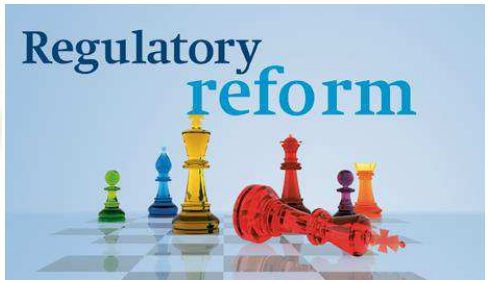
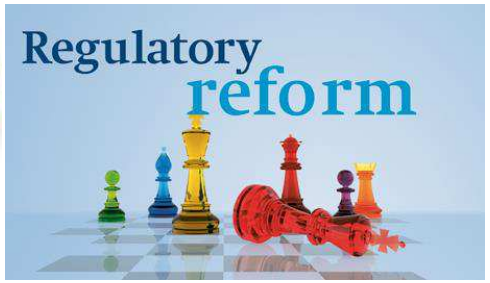


Proposed Reform: Indications

- **Introduce Permitted Indications for low level 'Listed Medicines' that are not pre-market assessed (3 year transition period)**
- **Improves transparency and avoids inadvertent non-compliance Reduces Regulatory Burden**
- **Phasing out of 'Free text' fields**
- **Must be consistent with treatment paradigm** (scientific/ tradition of use)
- **900+ Traditional evidence claims**
- **New Indications Updated Quarterly**



Permitted Indications: Structure

- **Permitted indications describe a therapeutic use**
- **They will have a consistent structure and terminology to describe the therapeutic use**
- **Sponsors must hold evidence for all claims**
- **Permitted indications contain an 'action' and a 'target'**

ACTION
Qualifier
e.g. 'Help'

+

ACTION
'Maintains/Supports'

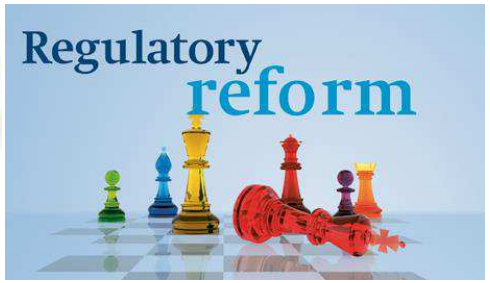
+

TARGET
Qualifier
e.g. 'healthy'

+

TARGET
e.g. 'Joints'

Examples in Action:
Helps to Maintain/Support Healthy Joints
Traditionally used to relieve muscle aches and pains in healthy individuals



1. Select Tradition of Use

Indications that do not specify a tradition of use are by default scientific

2. Select Core Permitted Indication

At least one core indication is selected in ELF using drop down lists or key word search

3. Select Specifying Qualifiers

Sponsors can choose to apply one or more pre-approved qualifies from a drop down list

'Traditionally Used'

'Relieves muscle aches and pains'

Healthy Target Population: 'in healthy individuals'
Use: 'after exercise'

Final Permitted indication Claim:
Relives muscle aches and pains after exercise in healthy individuals

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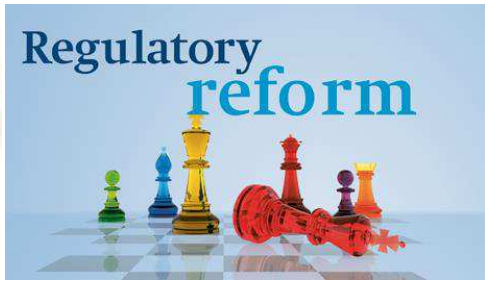

Proposed Reform:

A New Intermediate Registration Pathway

The new Assessment Pathway will provide:

- Intermediate level indications that exceed the permitted indications list
- Reference to a serious disease (ie restricted representation)
- Prevention or alleviation of a disease, ailment defect other than a serious disease
- Protects research and rewards investment
- Recognition of efficacy
- Allow Sponsors to use a Positive Claimer **"Assessed for Efficacy"**

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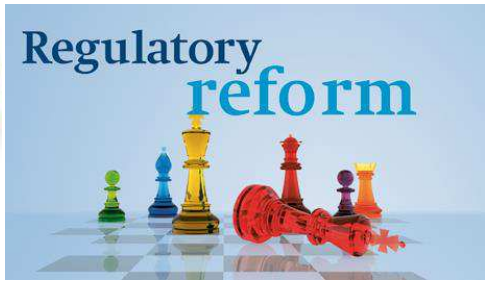
Complementary Medicines Australia



Australian Register of Therapeutic Goods

LISTED

No Premarket Evaluation

GMP

Pre-Approved Ingredients

Permitted Indications

NEW ASSESSED

Premarket Evaluation for Efficacy

GMP

Pre-Approved Ingredients

Use of 'Claimer'

REGISTERED

Premarket Evaluation for:

Quality

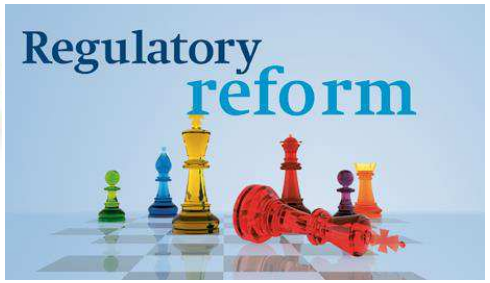
Safety

Efficacy

Use of 'Claimer'

Complementary Medicines Australia

Complementary Medicines Australia



Australian Register of Therapeutic Goods

$800

LISTED

Low Level Indications

Health enhancement
Health Maintenance
Prevention/alleviation of dietary deficiency
Non-serious disease or condition

Example: Maintains/Supports Healthy Bones

NEW

ASSESSED

Intermediate Level Indications

Health benefit for a **Serious** disease
Prevention, alleviation or management of a non-serious condition

$15,000

REGISTERED

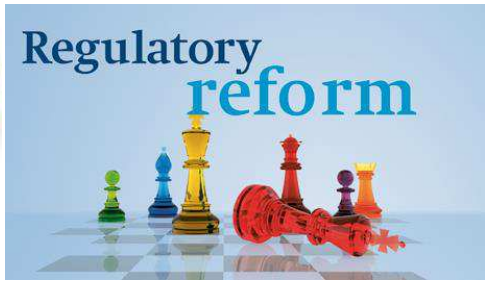
$40,000+

High Level Indications

Prevention
Alleviation
Cure or
Management

Example: Prevention of a disease (restricted rep)

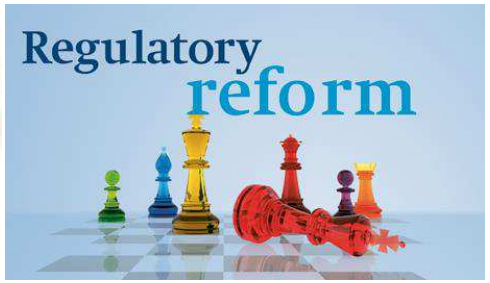
Complementary Medicines Australia



Proposed Reform:

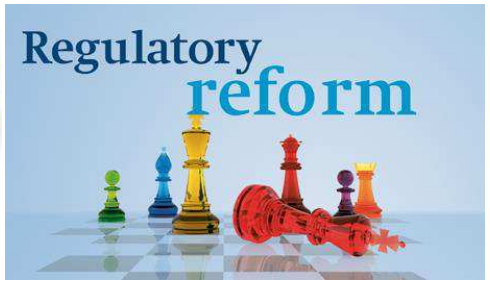
Easier Assessments

- **Timeframes for Pre-Market Assessments**
- **Partial refunds if timeframes not met**
- **A standard application and evaluation process**
- **Increased flexibility allowing de novo assessment and overseas assessment**



Proposed Reform: Advertising

- Reforms to Advertising Pre-Approvals phased out over 2 years
- Complaints Resolution Panel to be abolished
- CRP Replaced with TGA Complaints System
- Enhanced Sanctions and Penalties



Transition Dates

8 March 2018 Free Text turned off

8 March 2018 Permitted Indications Introduced

8 March 2018 Market Exclusivity for New Ingredients

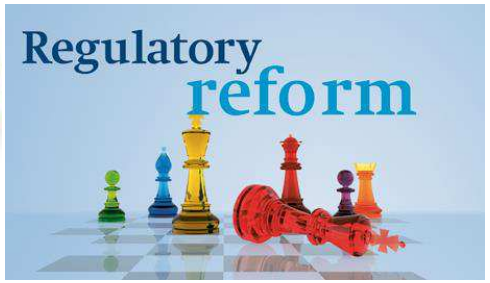
30 June 2019 Indications change Fee $1,000 Waiver expires

5 March 2021 Transition Period to relist ALL products with permitted indications

6 March 2021 Listed Medicines not transitioned will be cancelled

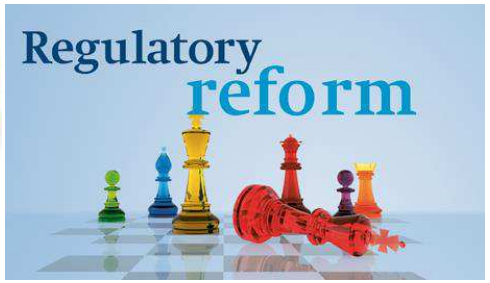
Advertising /Complaints

30 June 2018	**Complaints Resolution Panel Abolished**
1 July 2018	**New Complaints System run by TGA**
2 July 2020	**Advertising Approvals System to end**



2018 Industry Events

2 May 2018:	**CMA/Lipa Innovation Day**
20-22 June 2018:	**China HealthPlex**
19 Sept 2018:	**CMA Annual Conference & Industry Awards**



Questions