The Evolution of the Regulatory Framework of Test Data – From the Property of Intellect to the Intellect of Property

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An Overview of the legal regulation of pharmaceuticals in Oman

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General Information

- Oman is classified among the upper-middle income countries.
- GDP at current prices in 2008 was USD 60,281 million.
- GNI per capita was USD 20,254 (2008).
- It is a member of GCC countries, sharing many health and trade agreements with them.
- WTO accession in Nov. 2000
- Oman-US Free Trade Agreement, 15 October 2006
- Royal Decree No. 67/2008 led to the publication and implementation of the Patent Law on May, 2008.


51°
54°
57°
60°
Iran
Bandar-e Lengeh
Strait of Hormuz
Al Khasab
Ra's Musanda
Iran
Qatar
Al Khawr
Dukhan
Doha
Al Wakrah
Persian Gulf
Ra's al Khaymah
Umm al Qaywayn
Ajman
Jask
Dubayy
Al Fujayrah
Gulf of Oman
Abu Dhabi
Mahdah
Al Buraymi
Suhar
Al Khaburah
24°
United Arab Emirates
Muscat
As Sib
Qurayyat
'Ibri
Izki
Nazwá
Ibra'
Sûr
Mudayrib
Boundary not defined
Jibal
Fahud
Adam
Al Kamil
Al 'Ubeylah
Saudi Arabia
Ghaba
N
Oman
21°
Dawwah
Khaluf
Kalban
Hayma'
Duqm
Boundary not defined
Arabian Sea
Dawkah
Marmul
Sawqirah
18°
Sharbatat
Thamarit
Mudhay
Habarut
0 150 km
0 100 mi
Raysut
Salalah
Sadh
Yemen
Al Ghaydah
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Health related Information

- The population of Oman has very good access to high quality, free public health services.
- Government expenditure accounts for about 80% of the total health costs in the Sultanate.
- 63% of MoH procurement is from Research Companies and 37% is from Generic Companies (2005-2007).
- Savings generated in 2002 were USD 4.89 million

MoH Ministerial Decision No. 86/2000

Registration of pharmaceuticals:

- No documents related to patent protection
- No articles related to Data Protection
- Scientific reports involve drug indication, method of manufacture, side effects (no data of clinical trials)

Pricing Rules:

- CIF plus 45% margin for the local agent and plus 25% margin for the retailer
- Different systems for pricing Innovated Patented products and Generic products

MoH Ministerial Decision No. 86/2000

- Patent protection is provided if the product holds a valid patent invention certificate from any GCC country or by the General Secretariat of the GCC

Article 28

The TCR may cancel registration of any product if :

- The product is found to be harmful
- Discontinued in the country of origin
- Any change without prior approval
- Unavailability without valid reason
- Not complying with the conditions of registration

Market exclusivity

Data exclusivity/ Market exclusivity:

Adoption of specific periods of protection during which health authorities cannot rely on that data to review or grant marketing approval to a second applicant

Protection of test data

Article 65 of Patent Law No. 67/ 2008

Exclusive protection

- From the date of granting marketing approval
- Independent on patent protection
- 5 years for undisclosed test data or any other information concerning safety or efficacy for a new CE.
- 3 years for new clinical information (other than bioequivalence) for existing CE.
- The periods of 5 and 3 years of protection are also applicable when reliance of the approval is based on another country
- Linkage between test data and patent protection

Protection of test data

Article 71 (Enforcement Measures)

- Cancellation of Marketing Approval
- MoH to pay adequate damages (unauthorized disclosure)
- The competitor to pay adequate damages (marketing of the product)
- The competitor to cease marketing of the product

Recommendations

1. Application for marketing approval of NCE to be submitted to MoH within two years of first approval elsewhere.

2. Amendment of Article 28 to be read as: The TCR may cancel registration of any product *and data protection will cease to be granted*

3. 3 years data protection for the new use is not for the product itself, MoH could register any generic drug provided that the new indication is not claimed for this generic.

Recommendations

4. In case of public health emergency, governments should have the right to waive off any obstacle related to data protection.

5. The provision of data protection should not be applied for the exportation of pharmaceuticals made by a local manufacturer.

6. Setting up the bases and standards to assure drug security.

7. A Bolar provision allowing application for marketing approval even during the period of data exclusivity.

Recommendations

8. Termination of data exclusivity following a grant of a voluntary license by the originator.

9. An automatic waiver of data protection in case of compulsory license.

10. Careful evaluation for requests submitted by the originators to obtain approvals for new indications. New therapeutic indication with unpublished (undisclosed) data and considerable efforts is to be considered.

Recommendations

11. Since the 5 yrs data protection is calculated from the date of marketing approval (Registration Certificate), MoH should prioritize registration of unregistered pharmaceuticals imported to meet the requirement of any health institution.

THANK YOU