



INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

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July 21, 2014

Mr. Rajkumar,

Under Secretary to the Government of India,
Department of Pharmaceuticals,
Ministry of Chemicals & Fertilizers,
Shastri Bhavan,
New Delhi 110 01.

**Sub: Strategy to strengthen our economic engagement with Cambodia,
Laos, Myanmar and Vietnam**

Dear Sir,

This has reference to your letter No. 35020/02/2013-PI-III, dated 16th July 2014 on the above subject.

We are giving below our submissions:

Issues in Exporting to Cambodia:

- 1) Product Registration Approval Timeline has been increased from 1 year to 2 years, as MOH does not have enough staffs to evaluate the Asean Common Technical Dossiers (AICD).
- 2) Pharmaceutical Inspection Councils (PICs) approved Facility are getting preference for product registration from the MOH

Suggestion:

1. India should become a PICs member so as to overcome the Export hurdle to Cambodia.
2. Indian authority should request to the MOH Cambodia to increase staffs to fasten the registration process.

Issues in Exporting to Myanmar:

Myanmar issues are similar like Cambodia. Though Myanmar is getting opened up to the global market , US Embargo is still there.

- 1) Product Registration Approval Timeline has been increased up to 2 years. The FDA which has been moved to the new capital City does not have enough staffs to evaluate the ACTD dossiers.
- 2) Myanmar FDA gives preference to the PICs approved manufacturing facilities.

Suggestion:

- 1) India should become a PICs member so as to overcome the Export hurdle to Myanmar.
- 2) Indian authority should request to the Myanmar FDA to increase staffs to fasten the registration process. So that the country can get benefit of the good quality pharmaceutical products from Indian Manufacturers with affordable price.

Issues in Exporting to Laos:

- 1) Laos is too small market with population of 6.6mln.
- 2) People depend on the products from Thailand. People needs to come to Thailand to buy their medicine
- 3) Looking in to the small market size there are not much Indian Suppliers in Laos.

Suggestion:

- 1) Laos Govt should allow the Indian products to get sold in Laos which are already registered in any of the Asian countries.

Issues in Exporting to Vietnam:

- 1) Vietnam is encouraging the Local Manufacturers & getting influenced by Multinationals.
- 2) Restricting the Indian companies to enter by putting lot of barriers through MOH,

- 3) Delaying the registration approval of the products to unlimited time line.
- 4) Preferring PICs approved manufacturing facility.

Suggestion:

1. India should become a PICs member so as to overcome the Export hurdle to Vietnam.
2. Products those are registered as per ACTD guideline compliance, should be one time registration like other Asean countries (Malaysia, Thailand)

Thanking you,

Yours sincerely,



S.V. Veerramani
President