Fast track approval of vaccines during public health emergencies

06th August, 2018

Presentation By

Dr. S. Eswara Reddy
Drugs Controller General (India), CDSCO
Nipah Virus

• Nipah virus (NiV) is a zoonotic virus.

• It causes a range of illnesses such as,
  - asymptomatic (subclinical) infection,
  - acute respiratory illness and
  - fatal encephalitis

Because of its fatal nature, it requires fast track approval
Regulation of Vaccines

• Permission to import new vaccine is required under Rule 122-A.

• Permission to manufacture new vaccine is required under Rule 122-B.

• All vaccines/r-DNA products are New Drugs which means approval of the DCG(I) is required throughout its lifecycle.
Fast Track Approval during Emergencies

• If a Drug is approved in other countries, approval may be given for marketing without local clinical trial on the basis of data available from other countries.

• In case of drugs indicated in
  ❖ life threatening / serious diseases or
  ❖ diseases of special relevance to the Indian health scenario,

  the toxicological and clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate.

• Waiver of local clinical trial may be considered based on global practices in case of public health emergencies.
Fast Track Mode

- Vaccines for public health emergencies are reviewed on fast track basis.

- Such application are taken on priority, out of the queue for review process from the day of receipt of application.

- The targeted timeline for processing and disposal of such application is 100 days from the date of receipt of application instead of 180 days.

- In case of emergencies import license can be issued without issuance of RC with approval of the Central Government.
New Initiatives By CDSCO

• CDSCO has set up a innovation promotion cell for hand holding start ups/ innovators, for providing information regarding regulatory requirements for commercialisation of their products and provide clarifications.

• Recently, in order to make the system more convenient, it has been decided to provide a direct Video-conferencing (VC) facility at DCG (I) office to entrepreneurs, researchers and innovators.
Draft

New Drugs and Clinical Trials Rules, 2018
Thank You