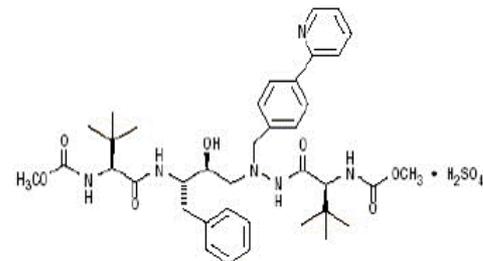
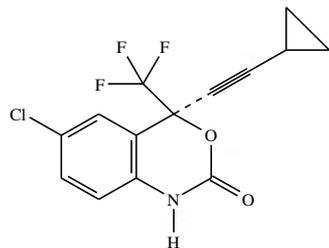


Cipla



YEARS OF
CARING

1935 - 2010



CIPLA's experience with WHO Medicine Pre-Qualification Programme



Cipla's birth

- *Cipla was founded by Dr. K A Hamied in the year 1935.*
- *Do visit our website : www.cipla.com*



Cipla's facilities

- ***Headquarters at Mumbai Central***
- ***R&D center at Vikhroli, Mumbai***
- ***API sites***
- ***Patalganga, Kurkumbh (Western India)***
- ***Bangalore and Bommasandra (Southern India)***
- ***FPP sites :-***
- ***Patalganga, Kurkumbh, Goa, (Western India)***
- ***Baddi, Sikkim, (North East India)***
- ***Indore (Central India)***



The PQP journey begins

Cipla has been actively associated with the WHO since 2001, when the first of the pre-qualification dossiers were submitted.

Cipla is one of the first Indian generic companies to be prequalified by WHO. (The first dossier was pre-qualified by the WHO in March 2002)



WHO PQP at a glance....

The WHO pre-qualification process now comprises of the following steps :-

API MF submission (APIMF+PQIF), review by the WHO and compliance.

Now the APIMFs are also reviewed independent of the dossiers. This is a proactive move and is of a great benefit for the FPP manufacturers, in terms of qualifying a supplier.

FPP submission (Dossier+BTIF+BE report) review by the WHO and compliance.

Site inspection by the WHO and compliance (API site + FPP site + CRO)



Looking back

For Cipla the WHO's Pre-qualification programme has been an ongoing journey and not a destination.

The partnership with the WHO took off and gained momentum after Cipla's Chairman and Managing Director Dr. Y K Hamied proudly announced the world about Cipla's capability to provide the "triple cocktail" of Anti-retroviral drugs at "a dollar a day".

*Thus was born Triomune comprising of
LAMIVUDINE 150MG + STAVUDINE 30MG +
NEVIRAPINE 200MG TABLETS*



- *Triomune, is the worlds first ARV cocktail therapy to be included in the WHO pre-qualification list. The inclusion of 3 ARVs in a single pill resulted in a better patient compliance, millions of patients receiving affordable and quality treatment*
- *Today more than 4.5 million HIV positive patients are being treated, whereas in the year 2001 only about 2000 – 4000 patients could afford such a similar treatment.*
- *The total number of patients who shall be having access to this treatment is likely to expand to more than 9 million, which is a major achievement for Cipla.*



TRIOMUNE : The path to approval.....

All the 3 APIs Lamivudine, Stavudine, Nevirapine were manufactured by Cipla. Additional API sources have been qualified through the PQP,

- The API sites, the FPP sites and the CRO involved in the BE study were successfully inspected in the year 2004, as a part of the pre-qualification.***
- It was a challenge compiling the dossier, since it was the first time three anti-retroviral APIs were being submitted for review.***
- The three APIMFs (Nevirapine, Stavudine, Lamivudine) were reviewed by the WHO and the deficiencies raised were responded by Cipla.....***
- finally leading to an approval by the WHO.***



Path ahead

Like all generic companies , Cipla also has to

Constantly upgrade facilities,

Qualify new sites, Qualify multiple API suppliers, Qualify multiple starting material suppliers.

Constantly improvise the process for better yield and quality and output

Improve our specifications to meet the increasing GLP requirements.

To internally qualify these changes resources like raw material, utilities, manpower etc are involved.

In the early phases of the program, there were a lot of challenges faced by Cipla and the WHO in terms of time required for review and approvals.

However, now the assessment procedures have been expedited and are now reviewed on an on-going basis, thus reducing the time for approval.



The Stavudine containing formulations of Cipla, which were originally the first line treatment and are still prescribed for paediatric use are now being replaced with newer formulation, which have also been pre-qualified by the WHO, like Duovir-N, Trioday, Viraday, Qvir, Odivir



The path ahead

Following are the suggestions, which would further help in expediting the PQP approval process:-

Adoption of electronic filings / submissions by the WHO for speedy review and approval and thus avoid the submission of paper copies of the DMF / responses.

For generics, getting innovator samples for use as reference products (especially anti-malarials) are very difficult, during such times an alternate strategy should be adopted by the WHO, so that more suppliers can submit their dossiers for pre-qualification. This has been voiced in the previous meetings as well.



The WHO, through the PQP (Pre-qualified programme) has ensured availability of quality medicines to the patients globally.

Its mission has been successful and hence, it is now imperative that the Essential Medicines List- PQP be updated on a regular basis to include treatment of global ailments like Cancer, heart diseases, hypertension, diabetes, diarrhoea, dysentery, etc., which are prevalent in emerging markets like Africa and Asia.

This move shall make the costly treatment regimens such medicines and the treatment affordable to the masses.

We also look up to the WHO to recommend essential drugs as required for developing countries so that the generic manufacturers can focus their activities to cater to these requirements.



Chairman's quote :-

- ***Our Chairman and Managing Director states “What good are the essential medicines if they are not accessible at affordable prices?”***

Thank you for your attention.