The Max Foundation

Dignity and hope in the face of cancer

Humanitarian Donation Programs in the era of Targeted Therapies

Prepared for PQMD

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Program Overview

1. In 2001 the FDA approved the first targeted therapy for a cancer diagnosis (Glivec was approved for the treatment of chronic myeloid leukemia)
2. The Max Foundation entered into a partnership with Novartis to provide humanitarian donations of Glivec to properly diagnosed CML patients in 80 low and middle income countries
3. Glivec is an oral therapy that must be taken daily on a continued, long term basis
4. The role of The Max Foundation is to identify each patient and their treating physician, verify that they meet the program criteria, and liaise with the company to deliver drug to the HCP for that specific patient on 3 months intervals

Program Highlights

- This PPP resulted in a new access model, commonly referred to as a Patient Access Program (PAP) that has become the standard for access programs for oncology targeted therapies
- The direct to patient donation approach avoids stockpiling of donated drug as well as protects again product diversion
- The Max Foundation has developed a strong process of safety reporting that could become the standard for other programs
- The Max Foundation has also developed a Patient Assistance Tracking System (PATS), a smart web engine that propels the life-cycle of each patient in the program
- PATS includes a safety reporting tool that promotes high quality adverse event reports

Impact, results achieved

- Since 2001, more than 49,000 patients in 80 countries have benefited from this partnership, and
- More than 2,300,000 monthly doses of Glivec have been approved and delivered for donation, under the care of 1,500 HCPs
- The Max Foundation has an average of 10,000 touch points with patients every month (120,000 contacts a year)
- The current number of active donation recipients in 31,000 plus

Impact, results achieved

- In 14 years on ongoing donation of drug, no product diversion has been reported or identified

- The donor company delivers product to each institution on periodic basis as per Max Foundation program approvals and re-approvals. Drug delivered meets the same industry standards as commercial product

- A great deal of healthcare infrastructure has been developed in these countries around this donation program, including diagnostics and monitoring technology and HCP trainings

Lessons Learned, Scalability

- Safety: It is possible to safely treat patients with long term targeted therapies in LMIC
- Commitment: once a patient is on donated life saving product that requires long term therapy, donors must understand the responsibility to ensure continuation of treatment
- Support: concomitant high touch programs at the local level ensure the support that patients and HCPs need
- AE reporting: it is possible to comply with current health authorities regulations and protect the safety of patients
- Expertise: new areas of expertise are needed from international donation organizations to implement this kind of program

Thank you!