Max Access Solutions
Product Donation Guidelines
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SECTION 1: BACKGROUND

The Max Foundation is an international non-governmental organization (INGO) that believes everyone deserves access to cancer treatment – no matter who they are or where they live. Our mission is to increase global access to treatment, care, and support for people living with cancer.

Max Access Solutions is our innovative, patient-centered model for delivering cancer treatment to those in need. Through Max Access Solutions, we receive donations of lifesaving cancer medicines from pharmaceutical companies and channel them to people facing cancer in countries where those medicines are not locally available. This work is made possible through partnership with our network of vetted health care providers (HCPs), who initiate treatment requests and manage the treatment of patients receiving medication through our programs. We work through a third party logistics provider (3PL) who, as our agent, receives product on our behalf directly from manufacturers and delivers it to partner HCPs and clinics. Max Access Solutions is meant to bridge access to treatment in underserved countries, with a focus on low- and middle-income countries (LMICs), until local access channels can be put in place.

The Max Foundation has extensive experience managing patient access programs for oncology products. The Max Access Solutions: Product Donation Guidelines are the result of the best practices and expertise we have developed over time. These guidelines are reviewed and updated periodically and shared externally with donor companies, local health authorities, and other relevant stakeholders. They are meant to provide a foundation for the development of internal procedures for product requests under Max Access Solutions. The guidelines further aim to align with World Health Organization (WHO) international guidelines for product donation\(^1\), as well as Partnership for Quality Medical Donations (PQMD) standards for international product donations\(^2\).
SECTION 2: GOVERNANCE

Governance

1. As an INGO and non-profit organization in the State of Washington, The Max Foundation is governed by a Board of Directors
   1.1. The Board of Directors maintain a set of bylaws;
   1.2. Bylaws are reviewed and updated on a regular basis, as determined to be adequate by the Board of Directors;
   1.3. Each member of the Board of Directors completes a conflict of interest form to ensure participation on the Board does not present a conflict

Finance

2. The Max Foundation complies with Generally Accepted Accounting Principles (GAAP) and
   2.1. Files an IRS 990 tax return in the US;
   2.2. Generates a financial statement that is audited annually

3. Product donated to the organization is valued based on a third-party source, IQVIA, fair value data, which reflects wholesale prices available in multiple relevant international markets. The values are recorded, by drug, based on the estimated fair value in the relevant international market of highest volume

4. All product donations are recorded as revenue and expensed based on product value, inventory, and record of end-use transfer

Gifts-in-Kind Policies

5. The Max Foundation accepts product donations in furtherance of the organization’s mission and for which there is a specific programmatic need

6. The Max Foundation requests product from donors to fulfill the needs of verified requests on behalf of patients and only accepts products of confirmed quality and with adequate shelf life of at least 18 months at time of product donation

7. Product is distributed in eligible countries, with focus on LMICs, through a third party logistics provider (3PL)
   7.1. A 3PL is selected following a bidding process and review by the Chief Executive Officer and Board of Directors;
7.2. The Max Foundation, with its 3PL, monitors key performance indicators as agreed upon contractually

8. The Max Foundation aims to ship product with at least 12 months of shelf life at time of importation into a recipient country with a minimum of 9 months of shelf life on an exceptional basis, assuming that shipments aim to support six months of treatment needs

Organizational Evaluation

9. The Max Foundation is guided by the organization’s strategic plan when developing criteria to evaluate the effectiveness of programs that integrate gift-in-kind

Information Systems

10. The Max Foundation utilizes a proprietary, web-based, customer relationship management system, referred to as Patient Access Tracking System (PATS), that tracks the treatment life cycle of each individual patient and integrates physician-driven treatment decisions with business processes and supply chain operations

Local Partners Assessment

Country and Regional Assessment

11. The Max Foundation considers both the World Bank’s country income classifications, as well as the lack of local access programs or commercial activities for each specific product, when assessing country eligibility for product donations

12. Eligible countries are selected jointly with the Donor company donating product to The Max Foundation

13. In cases where country eligibility is determined by the World Bank country income classifications, if an eligible country moves into a higher income group outside the low and low-middle income classification and remains in the higher income group for at least one year, The Max Foundation and the Donor company will consider removing the country from the list of eligible countries

Clinic or Institution Assessment

14. Potential clinics and institution partners are assessed based on four criteria:

14.1. Capacity to treat the type of cancer for which a product is indicated

14.2. Capacity to handle importation and dispensation of each eligible product

14.3. Authority to handle pharmaceutical products in accordance with local regulations as per European Union Good Distribution Practices (EU GDP)

14.4. Referral from a current partner institution
Physician Assessment

15. The Max Foundation reviews the medical licenses of new HCPs to ensure that they are authorized to prescribe donated product in the country in which they practice.

16. The Max Foundation enters into collaboration agreements with HCPs to:

   16.1. Ensure that patient care is managed in accordance with the Max Access Solutions Product Donation Guidelines, including prescribing and managing treatment in accordance with the product label, and reporting adverse events as per local health regulations.

   16.2. Ensure that product is maintained in accordance with donation guidelines, including storage, dispensation, and as needed, destruction of unused product.

   16.3. Verify that the HCP has reviewed, understands and takes responsibility for prescribing a product according to its label.

17. Endorsement from a current partner HCP from that country is required.

18. HCPs are verified through this process and enlisted into a Max Global Network of approved HCPs.

Patient Assessment

19. The Max Foundation ensures the right patient receives the right treatment at the right time by individually screening all requests on behalf of new patients to ensure eligibility.

20. Only approved HCPs are able to submit requests on behalf of a patient. The request must confirm the disease and diagnosis date as well as specific indication for which the physician is prescribing a product.

21. The Max Foundation requests copies of the prescription and confirmatory diagnostic test as possible.

22. Socio-economic information provided by the HCP on behalf of the patient are the basis for financial eligibility screening.

Patient Verification

23. Patient identity and country of residence is confirmed through the collection of relevant documentation.

24. Continuation of treatment is verified at least annually via direct contact with the patient, confirmation of dispensation from the institution dispensing log, physician confirmation, or institution appointment ledger.

Medical Eligibility

25. Each patient is confirmed to be under the care of a verified HCP in the Max Global Network of approved HCPs.

26. For initial approval of product donation, The Max Foundation follows product label indication(s).
26.1. If the product is registered locally, The Max Foundation follows the local product label as a reference document

26.2. If the product is not registered locally, The Max Foundation follows the product label of the country where Max receives the product donation

27. For ongoing approval of product donation, The Max Foundation confirms treatment continuation with the HCP

Financial Eligibility

28. The Max Foundation reviews the insurance status of patients to determine their ability to access product through social security, health insurance, reimbursement, or other access scheme

28.1. Patients who have access to the product through insurance or similar means are not eligible for product donation under Max Access Solutions

28.2. Every effort is made to help patients sign up for and navigate existing channels of access, as applicable

29. The Max Foundation performs a financial review of patients and their ability to afford the product in countries where product is commercially available

29.1. To determine financial eligibility, the patient’s annual household income is compared against the annual, local purchase price of the product; should the purchase price constitute more than 5% of the total household income, the patient is eligible for product donation

29.2. In countries where government issued ration or below poverty level (BPL) cards are available, patients holding these cards are eligible for product donation and no further review is needed

Privacy & Consent

30. Each patient under consideration for a product donation receives a consent form regarding the use of patient information and program expectations

30.1. By signing the consent form, the patient permits collection of confidential patient information, and if approved for product donation, agrees to abide by program rules

31. The Max Foundation does not share patient names or individual patient information with Donor companies

31.1. Aggregate data is reported periodically to Donor companies and to the public at large

Adverse Event Reporting, Special Scenarios, &/or Product Complaints

32. The Max Foundation monitors the safety of patients receiving donated product and notifies donor companies of any adverse event, special scenario, and/or product complaint which come to the attention of any team member, agent, or subcontractor involved in the Max Access Solutions program for as long as donated product is available
33. The Max Foundation reports all adverse events, special scenarios, and product complaints directly to the Donor company within one business day and no more than three calendar days in the event of weekends or national holidays.

34. All team members involved in the administration of a Max Access Solutions program complete safety reporting training at program start and on an annual basis thereafter.

35. HCPs in the Max Global Network of approved HCPs are responsible for reporting adverse events as per local health regulations.

36. All adverse events, special scenarios, product complaint reports, and related source documents are maintained indefinitely.

37. Any adverse event, special scenario, and product complaint reported to the Donor company are reconciled internally.

**Case Closure**

38. Product donation is discontinued on a patient-by-patient basis in the event of death and loss of contact, change in ability to access and financial eligibility, and/or for reasons specified by the HCP.

39. If a representative of The Max Foundation is unable to perform annual verification with a patient or HCP to confirm ongoing treatment, product donation is discontinued on a patient-by-patient basis.
SECTION 3: DEFINITIONS

**Adverse event** – Any untoward medical occurrence in a patient or clinical investigation subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.

**Clinic or Institution** – Refers to a hospital, brokerage, pharmacy, other dispenser, or warehouse in which product is received once it clears customs and is dispensed to an intermediary or end user.

**Donor company** – The pharmaceutical company or manufacturer that donates product to The Max Foundation for distribution to end users.

**Gift-in-kind** – Also referred to as in-kind product donations.

**Max Access Solutions** – The Max Foundation’s innovative, patient-centered model for delivering cancer treatment to those in need with a focus on low- and middle-income countries.

**PATS** – The Max Foundation’s proprietary, web-based, customer relationship management system used to tracks the treatment life cycle of each individual patient and integrate physician-driven treatment decisions with business processes and supply chain operations.

**Product** – Refers to pharmaceuticals, such as targeted oral chemotherapy, and/or biotechnical devices that are used to treat patients or enable health care providers to make treatment decisions.

**Product complaint** – Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medicinal product (including packaging and labeling) after it is released for distribution.

**Special scenario** – Includes exposure during pregnancy, exposure during breastfeeding, lack of efficacy, disease progression, interactions, medication errors, overdose, abuse or misuse, off-label use, and occupational exposure.

**Third party logistics provider (3PL)** – a partnering organization that manages product throughout the supply chain until product reaches its ship-to recipient.

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