Progress Report on Neglected Tropical Disease Drug Donation Programs



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ABSTRACT

Purpose: Neglected tropical diseases (NTDs) impose a significant burden on public health, particularly in developing nations. Many can be treated costeffectively with drugs donated or offered at or below marginal cost. In 2012, the World Health Organization published an NTD roadmap that outlined a strategy for the prevention, control, and eradication of 17 NTDs by 2020. Inspired by this roadmap, executives from 13 pharmaceutical companies, government agencies, and other interested parties signed the London Declaration on Neglected Tropical Diseases in January 2012. In this paper, we will assess progress in meeting commitments on drug donations laid out in the London Declaration.

Methods: We conducted Medline and LexisNexis searches of peer-reviewed publications and trade journals, as well as product development partnership and government reports. Subsequently, we designed a survey instrument and surveyed 10 company signatories (companies with drug donation programs) to the London Declaration to determine current donations and pledges.

Findings: Nine of 10 companies with donation programs responded to the survey. The respondents reported substantial progress in meeting the goals laid out in the London Declaration. Survey respondents maintained 17 drug donation programs across 10 disease categories. In 2014, companies donated >1 billion treatments, with a dollar value of nearly \$1.5 billion. However, not all donated products were distributed to patients in need. In addition, 4 of the 17 programs were slated to end before 2020, three of the 17 programs did not report explicit program objectives, and 7 of 17 did not measure the impact

of programs in terms of numbers of patients treated. None of our survey respondents reported on whether the programs were leading to a reduction in disease prevalence.

Implications: Donations are a necessary but insufficient condition for patient access to neglected disease drugs. Additional resources must be allocated to ensure delivery of donated products to patients. In addition, drug donation programs should provide explicit descriptions of program objectives, measurements of the impacts of their programs, and extension of all donation commitments through 2020. To achieve this, multiple stakeholders with a vested interest in reducing the burden of neglected diseases must collaborate in a multipronged approach toward NTD elimination. (*Clin Ther.* 2016;38:1193–1204) © 2016 Elsevier HS Journals, Inc. All rights reserved.

Key words: drug donation programs, London Declaration on Neglected Tropical Diseases, neglected tropical diseases, patient access.

INTRODUCTION

Neglected tropical diseases (NTDs) are a group of diseases that are predominant in the poorest parts of the world. According to the World Health Organization (WHO), there are currently 17 NTDs prevalent in 149 countries, affecting >1.4 billion people. NTDs cause an estimated 35,000 deaths per day worldwide.

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In spite of significant burden of disease, lack of commercial prospects hindered development of new products. Trouiller et al² reported that only 16 of 1,393 new chemical identities marketed between 1975 and 1999 targeted NTDs. Additionally, Trouiller et al found that in 1999, <\$100 million was invested in neglected disease drug development.

The dearth of neglected disease drugs led to a search for innovative ways to fund and coordinate drug development programs. Beginning in the late 1990s, new initiatives included the establishment of product development partnerships, such as the Medicines for Malaria Venture, Drugs for Neglected Diseases, and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.³ Philanthropies, such as the Bill and Melinda Gates Foundation, have further contributed to an increase in funding of neglected disease drug development. The pharmaceutical industry has also been allocating more resources, either in conjunction with product development partnerships or on its own.

Currently, >\$3 billion is spent annually on research and development targeting neglected diseases.⁴ Three billion dollars is still a relatively small amount compared with research and development expenditures on nonneglected diseases. Nevertheless, increased funding has resulted in progress in development of new neglected disease products. Cohen et al⁵ identified 43 new approvals of NTD products in the period 2000 to 2013. Approvals included 3 new molecular entities, 7 vaccines, 9 new indications for existing drugs, 17 fixed-dose combination products, and 7 new formulations.

In the debate on NTDs, patient access has often taken a back seat. To effectively combat neglected diseases, both new drug development and patient access to existing products must be tackled simultaneously. Here, we consider one critical contributor to access to be pharmaceutical company donation programs aimed at patients suffering from NTDs. Our study objective is to assess the progress made by industry endorsers of the 2012 London Declaration on Neglected Tropical Diseases, which aimed to sustain, expand, and extend drug access programs to control schistosomiasis, onchocerciasis, soil-transmitted helminths, Chagas, and leishmaniasis, among other NTDs.⁶ In 2012, WHO published Accelerating Work to Overcome the Global Impact of Neglected Tropical Disease: A Roadmap for Implementation, in which the industry committed

to supplying the necessary drugs to eradicate by 2020 guinea worm disease, lymphatic filariasis, leprosy, human African trypanosomiasis, and blinding trachoma. The Inspired by this roadmap, executives from 13 pharmaceutical companies; the governments of the United States, United Kingdom, and United Arab Emirates; the Bill and Melinda Gates Foundation; the World Bank; and other global health organizations signed the London Declaration on Neglected Tropical Diseases in January 2012, pledging to eliminate or control 10 NTDs by 2020 through donations, with WHO serving as a conduit.

Our paper reports on the fulfillment of company commitments to drug donation programs. Here, we aim to identify the numbers and names of drugs being donated, regions, nations, and organizations to which medications are being donated, diseases being targeted by the donated medicines, duration of donation programs, stated objectives of donation programs, and the measured impact of the program (eg, numbers of people treated or the degree to which disease incidence has been reduced).

Brief History of NTD Donation Programs

Donation programs facilitate procurement and delivery of pharmaceutical treatments for patients who would otherwise not be able to afford them. Some programs include drugs donated by drug companies for individual use (eg, pentamidine indicated for human African trypanosomiasis), while others include drugs donated by drug companies are for mass drug administration (eg, ivermectin indicated for lymphatic filariasis).

Programs come in many shapes and sizes. Some are sponsored by the pharmaceutical industry. Other programs are philanthropy and government-based. Here, our focus is company-based programs. The oldest such program is Merck's donation of ivermectin,* which was established in 1987 to help eradicate onchocerciasis. In 1998, the program expanded to include donations of ivermectin for treatment of lymphatic filariasis wherever onchocerciasis and lymphatic filariasis are co-endemic. The same year, GlaxoSmithKline pledged to provide albendazole to treat lymphatic filariasis. Also, in 1998, Pfizer began donating azithromycin to help eliminate trachoma.

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