The Coalition for Affordable T-DM1
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1 October 2015

The Rt. Hon. Jeremy Hunt MP
Secretary of State for Health
Department of Health
Richmond House
79 Whitehall
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Via Email: mb-sofs@dh.gsi.gov.uk
Via Fax: 44 20 7210 5952

CC:
The Rt. Hon Oliver Letwin MP
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The Rt. Hon. Sajid Javid MP
Secretary of State for Business, Innovation and Skills
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Via Email: sajid.javid.mp@parliament.uk

Re: Notice of intent to request for non-exclusive compulsory licence on patents to expand access to T-DM1

Dear The Right Honourable Jeremy Hunt MP:

On behalf of the Coalition for Affordable T-DM1, we write to provide notice that we will be requesting the Government of the United Kingdom of Great Britain and Northern Ireland authorise the domestic manufacture and/or importation, use and sale of biosimilar versions of trastuzumab emtansine (T-DM1) used in the treatment of breast cancer, to be supplied to the government for use and sale in the UK.

The request will fall under the Crown Use provisions of Section 55 of the UK Patents Act 1977 (as amended), as well as other laws and regulations in the UK and the European Union.

T-DM1, also known as trastuzumab emtansine in Europe, is a combination of two drugs to treat cancer. It is an antibody-drug conjugate consisting of the monoclonal antibody trastuzumab (a drug marketed separately by Roche as Herceptin) linked to the cytotoxic agent DM1, a product Roche licenced from ImmunoGen. T-DM1, as a single agent, is approved as a cancer medicine to treat patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.

Sold by Roche under the trade name Kadcyla, the medicine is expensive and unaffordable to patients in the UK. The cost of T-DM1, from Roche, is £5,908 (including VAT) for each 3-week cycle, for a patient with a body weight of 75 kg.[1] For a year of treatment, this is £102,405, or roughly 3.9 times the 2014 per capita income of £26,350.

The National Institute for Health and Care Excellence (NICE) has not recommended T-DM1 for NHS reimbursement, “despite evidence of its benefits to patients” and issued three press releases criticizing the manufacturer's price.[2] T-DM1 has been reimbursed for some patients in England, through the Cancer Fund, but the reimbursements will be cut off for new patients, beginning November 4, 2015.[3]

We request that the Government of the United Kingdom of Great Britain and Northern Ireland permit third parties to supply the government with inexpensive biosimilar versions of T-DM1, under an open non-discriminatory and non-exclusive compulsory licence, subject to

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[1] Decision and Summary of Rationale, Cancer Drug Fund decision summaries. September 4, 2015. http://www.england.nhs.uk/wp-content/uploads/2015/09/cdf-decision-summ-trastuzumab-emtansine-2ndline-her2-mbc.pdf.

[2]http://www.nice.org.uk/news/press-and-media/breast-cancer-drug-costing-tens-of-thousands-of-pounds-more-than-other-treatments-unaffordable-for-nhs
23 April 2014, Breast cancer drug costing tens of thousands of pounds more than other treatments 'unaffordable' for NHS: A breast cancer treatment that can cost more than £90,000 per patient is not effective enough to justify the price the NHS is being asked to pay, NICE Press Release.

http://www.nice.org.uk/news/press-and-media/kadcyla-nice-disappointed-by-manufacturers-decision
07 August 2014, "Kadcyla: NICE disappointed by manufacturer’s decision. The National Institute for Health and Care Excellence (NICE) is very disappointed that Roche, the manufacturer of Kadcyla (trastuzumab emtansine) has decided not to offer its new treatment at a price that would enable it to be available for routine use in the NHS." NICE Press Release.

http://www.nice.org.uk/news/article/pressure-grows-on-roche-to-lower-breast-cancer-drug-price
08 August 2014, Pressure grows on Roche to lower breast cancer drug price
Leading cancer charities have joined NICE in calling on Roche to lower the price for its advanced breast cancer drug Kadcyla (trastuzumab emtansine).

[3] Decision and Summary of Rationale, Cancer Drug Fund decision summaries. September 4, 2015. http://www.england.nhs.uk/wp-content/uploads/2015/09/cdf-decision-summ-trastuzumab-emtansine-2ndline-her2-mbc.pdf. Sarah Boseley, Life-extending cancer drugs to be axed by NHS. NHS England de-lists costly Kadcyla drug, among 16 others, in wake of ‘overspent’ Cancer Drugs Fund. September 3, 2015; Andrew Ward Cancer drugs cut as UK budget clampdown bites, FT, September 4, 2015.

the payment of remuneration to patent holders, and other conditions to protect the legitimate interests of patent owners. We also propose other actions to facilitate the entry into the UK market of affordable biosimilar versions of T-DM1. In this memorandum, we outline the rationale for the request, the challenges for obtaining biosimilar versions of the medicine, and strategies for addressing those challenges. Taken together, we present the Government with a range of options which reflect different levels of ambition, risk and commitment from the government to obtain affordable versions of T-DM1, and expand access to this important cancer drug.

The least ambitious strategy would be to announce the granting of compulsory licences on relevant patents for T-DM1, under the Crown Use provisions in the UK law. The more ambitious strategies would include such actions as (1) challenging the test data exclusivity for T-DM1, allowing for faster and smaller clinical trials to support the registration of a biosimilar product, or earlier access to the biosimilar product through trials, (2) sharing the costs of biosimilar trials, in return for concessionary pricing of the biosimilar product (3) requiring Roche to disclose know-how regarding the manufacture of T-DM1, (4) sanctioning Roche for excessive prices, through fines levied by competition authorities, taxes on excessive prices, or by removing the exclusivity for other products sold by Roche, including other expensive cancer drugs for which generic versions are now available, and (5) expanding these measures to other drugs that are both medically important and excessively priced.

One company has already indicated a willingness to manufacture T-DM1 in the UK, if a compulsory licence on the patents is issued for local production.

These strategies will not directly address the current crisis in access to T-DM1 for those patients who are now unable to get reimbursement for the drug. However, any signal by the Government that it will undertake one or more measures will likely change the reaction by Roche to longstanding requests for lower prices for T-DM1, and make it easier to obtain lower and more affordable prices in the near term

The manufacturing, testing and regulatory approval of biosimilar products is both costly and time-consuming. The rationales for taking measures today are several. The future affordability of T-DM1 matters, for both patients and taxpayers, and every journey has to start somewhere. But perhaps more importantly, the measures described in our proposal, embraced in part or more extensively, would be a forward-looking model for addressing the challenges of ensuring universal access to medically important drugs, without putting patients at risk. We propose an approach that addresses the effects of a drug's monopoly, when prices are unreasonable and/or unaffordable as a result, and which creates a more sustainable model for innovation and access going forward, as the population of the UK ages, and medical science provides new hope for treating disease.

We intend to provide your office with proposals, with timelines, for addressing the challenges and strategies for overcoming those challenges, over the next two weeks.

Sincerely,

Members of the Coalition for Affordable T-DM1

Signing on behalf of organizations

Dzintars Gotham, *National Coordinator, Universities Allied for Essential Medicines UK*
Ellen ‘t Hoen LLM, *President* and Dr. Tido von Schoen-Angerer*, MD, MPH, Board Member Knowledge Ecology International Europe*
Manon Ress, *Knowledge Ecology International*
Philippa Saunders, *Union for Affordable Cancer Treatment*
Rufus Pollock, *Open Knowledge*
Sandeep P. Kishore, MD/PhD, President, and Jordan D. Jarvis, MSc, Executive Director, *Young Professionals Chronic Disease Network*

Signing as individuals

Dr. Andrew Hill, *PhD, University of Liverpool*
Chris Redd, *Peninsula College of Medicine and Dentistry*
Diarmaid McDonald, *Access to Medicines Campaigner*
Dr. Mohga Kamal-Yanni, *MPhil, MBE, Work on access to medicines*
Susannah Markandya, Barrister

To contact the coalition via email, send a note to TDM1@CANCERUNION.ORG

To contact the coalition via postal service:

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