



**HISTORY OF A MEDICINE**

# **TRASTUZUMAB ACCESS IN SOUTH AFRICA**

**Trastuzumab is a lifesaving  
treatment for women diagnosed  
with HER2+ breast cancer**

22 November 2019



**CANCER  
ALLIANCE**

Collective South African Voices for Cancer



# TIMELINE OF ACCESS TO TRASTUZUMAB IN SOUTH AFRICA

People are dying because big pharmaceutical companies like Roche are doing everything possible to exploit any loopholes which enable the sale of life-saving medicine for obscene profits. This timeline of Trastuzumab—a breast cancer medicine developed through public and private funding many decades ago—tells the story of the long and ongoing push by ordinary people, doctors and activists for a world in which we value life more than profit.

<b>1979</b>	The promise of Trastuzumab begins in 1979 when pioneering cancer researcher Robert Weinberg identifies the gene—now known as HER-2—which is involved in the development of multiple cancers, including what would later become known as HER2+ breast cancer. Around the same time, Genentech—the company that eventually brings Trastuzumab to market under the brand name Herceptin—was a fledgeling yet dynamic biotechnology firm in San Francisco in the United States.	<b>Book review:</b> <a href="#">HER-2: The Making of Herceptin, a Revolutionary Treatment for Breast Cancer</a> <b>Film:</b> <a href="#">Living Proof</a> <b>Fact sheet:</b> <a href="#">Breast cancer &amp; HER2+ breast cancer—with a look at Trastuzumab access in South Africa</a>
<b>1989</b>	The mother of a senior Genentech vice president is diagnosed with breast cancer. He convinces his colleagues that possible pharmaceutical interventions for HER2+ breast cancer are worth further research and development investment.	
<b>1990s</b>	Genentech and the University of California, Los Angeles (UCLA) develops Trastuzumab jointly, beginning the first clinical trial in 1992. Positive early results drive demand, leading to trial participant selection through a lottery. Public funding plays an important role in the research and development of the medicine, yet multiple patents on Trastuzumab (brand name Herceptin®) are granted to Genentech.	
<b>1998</b>	The registration of Trastuzumab (brand name Herceptin®) for the treatment of HER2+ breast cancer is fast-tracked and quickly approved by the FDA in the USA because of its efficacy.	
<b>2001</b>	Trastuzumab (brand name Herceptin®) is registered as treatment of HER2+ breast cancer in South Africa.	
<b>2004</b>	Exemplary cancer support volunteer Ann Steyn is one of the first women in South Africa to receive Trastuzumab through trial access. She later serves as Reach to Recovery International president.	<b>Interview:</b> <a href="#">Ann Steyn</a> <b>Website:</b> <a href="#">Reach to Recovery International</a>



<b>2006</b>	Determined private sector patient Samantha Galliet successfully litigates for coverage for the cost of Trastuzumab by her medical insurer Discovery Health. She becomes known as “the woman who took on Discovery”.	Interview: <a href="#">Mail &amp; Guardian</a> Podcast: <a href="#">Jacaranda FM</a>
<b>2002-2009</b>	Relentless activism and legal challenges by the Treatment Action Campaign (TAC) and the AIDS Law Project (now SECTION27) culminates in access to affordable generic antiretroviral treatment (ART) for all people living with HIV in South Africa. The cost of HIV treatment is cut by more than 90%, making it possible for the government to set up the largest publicly funded ART programme in the world.	Article: <a href="#">The campaign for access to medicines for HIV in South Africa</a> Website: <a href="#">TAC</a> Website: <a href="#">SECTION27</a>
<b>2009</b>	Swiss pharmaceutical company Roche buys Genentech for \$46.8 billion. Genentech subsequently operates as a subsidiary of Roche.	
	Nonki Rampoporo from Sasolburg is diagnosed with HER2+ breast cancer in Sasolburg. Her medical scheme Bonitas declines treatment cover for Trastuzumab. She can't pay most of her treatment bills, leaving her in financial debt.	
<b>2011</b>	In the Northern Cape, public sector oncologists successfully motivate for the budget to put public sector HER2+ patients at Kimberley Hospital on Trastuzumab treatment. Treatment remains inaccessible to public sector patients in other provinces.	
<b>2012</b>	The Union for International Cancer Control applies to the World Health Organization (WHO) for Trastuzumab to be included on the model list of essential medicines.	
<b>2013</b>	<b>The South African Companies and Intellectual Properties Commission (CIPC) grants two further patents to Roche for Trastuzumab because it is not listed by the National Department of Health as an essential medicine. These patents will be valid until the year 2033 and can potentially block biosimilar products until then, leaving patients at the mercy of big pharma's exorbitant pricing.</b>	Patent listing: <a href="#">ZA201109459B</a> Patent listing: <a href="#">ZA201207815B</a> List: <a href="#">Other low- and middle-income countries patents on Trastuzumab</a>
<b>2013</b>	The Department of Defence provides Trastuzumab treatment to patients at military hospitals. Treatment at public hospitals remains unavailable.	
<b>2014</b>	Claudette Moore is diagnosed with HER2+ early-stage breast cancer. She is a public sector patient at Charlotte Maxeke Johannesburg Academic Hospital—where Trastuzumab treatment is not available. She volunteers at the Breast Health Foundation and becomes involved with the Advocates for Breast Cancer, Cancer Alliance and Fix the Patent Laws advocacy campaigns. “That is how I found out that there is a life-saving treatment available for my type of cancer,” she says.	
	Another determined private sector patient, Veroney Judd-Stevens, challenges the refusal of her medical insurer Bonitas to cover her prescribed 12-month course of Trastuzumab. The Council for Medical Schemes initially rules that Bonitas should cover the full 12-month course for all scheme members, but this ruling is overturned on appeal.	Article: <a href="#">Judd-Stevens wins treatment</a> Article: <a href="#">Bonitas wins appeal</a>
<b>2015</b>	<b>Almost two decades after its development, Trastuzumab remains inaccessible to the majority of women in South Africa. The treatment is mostly unavailable in the public sector and in the private sector, not all medical schemes cover it. Despite limited access, Roche rake in fat profits from Trastuzumab in South Africa because they retain their monopoly on it and can charge a ridiculously high price. Trastuzumab is the second most expensive private sector medicine in 2014 and 2015—earning Roche over R100 million a year.</b>	
	June: The World Health Organization finally adds Trastuzumab to its list of essential medicines.	



**2016**

**The Cancer Alliance joins the Fix the Patent Laws coalition, which brings together various health NGOs in SA in the fight against weak patent laws for lifesaving medicines. The coalition models its advocacy on the success of HIV treatment activism in the 2000s, and now really ramps up pressure on government and Roche.**

**Website:** [Fix the Patent Laws](#)



Herceptin® IV is available in the private sector at R424,116 per recommended treatment of 18 cycles over one year. Public hospitals in SA pay R190,242 for one year of treatment with Herclon® (another Roche brand name for Trastuzumab).

**3 February:** The Fix the Patent Laws coalition releases an advocacy video about Trastuzumab in South Africa. The video features women with HER2+ breast cancer who are unable to access the medicine, including public sector patient Tobeka Daki. It also highlights that granted patents could prevent more affordable biosimilars until 2033—more than a decade after patent protection has already expired in the EU, US and other countries.

**Watch:** [South Africa: Access to critical breast cancer drug Trastuzumab limited by patent laws](#)

**17 March:** Cancer Alliance activists Tobeka Daki and Babalwa Malgas testify at the Johannesburg Dialogue of the United Nations High-Level Panel on Access to Medicines about their personal challenges in accessing the treatment that they need.

**Watch:** [Tobeka Daki at the UN High-Level Panel in Johannesburg](#)

**31 March:** The Fix the Patent Laws coalition, led by Tobeka Daki, pickets outside Roche's Johannesburg offices. They call on Roche to drop the exorbitant price of Trastuzumab.

**Watch:** [Activists demand Roche drops the cost of vital breast cancer medicine](#)

**10 May:** During his budget speech in Parliament, Health Minister Aaron Motsoaledi highlights the excessive cost of cancer medicines—including Trastuzumab—saying that “today we have no option but to call for HIV and AIDS-like solidarity of all the progressive forces to force significant decreases in the price of these medicines.”

**19 July:** Led by Tobeka Daki and the Treatment Action Campaign, international activists attending the International AIDS Conference in South Africa storm Roche's display booth demanding affordable access to Trastuzumab in South Africa and elsewhere.

**Watch:** [Protest at the International AIDS Conference 2016](#)

**27 September:** Tobeka Daki leads a march to the Department of Trade and Industry, calling on the department to urgently end delays in finalising reform of South Africa's patent laws which would improve medicine affordability.

**Watch:** [Protest at the Department of Trade and Industry](#)

Nonki Rampopororo faces a recurrence of her HER2+ breast cancer. Her new medical scheme Sasolmed approves Trastuzumab and all other treatment for her. A success story for one woman that could have had a very different outcome!

**1 November:** Ann Steyn, one of the first women to get Trastuzumab in South Africa, is elected as a board member of the Union for International Cancer Control. “I would not be alive today if it was not for Trastuzumab,” she says.

**Website:** [Union for International Cancer Control](#)

**14 November: Tobeka Daki dies in her home, leaving behind her two elderly parents and two sons. Messages of condolences come from people around the world who were touched by her struggle to access Trastuzumab.**

**15 November:** The Cancer Alliance submits a motivation for Trastuzumab in the public sector to the Department of Health. The submission calls for the department to use all available options to secure an affordable price—as well as an adequate budget for treatment and early detection.

**Read:** [Cancer Alliance motivation for the provision of Trastuzumab in SA's public sector](#)

**22 November:** Members of the Fix the Patent Laws coalition meet with Roche. Roche confirms that they have offered a lower Trastuzumab price for public sector tender, but refuses to disclose the price or confirm that they will not use ongoing patents to block cheaper products.

**2017**

Broad access to Trastuzumab in the public sector remains uncertain as the Department of Health delays finalising a tender for its procurement.

**7 February:** The Fix the Patent Laws coalition pickets Roche's Johannesburg office as part of a global day of action. Women with HER2+ breast cancer join the action, remembering the recent passing of powerhouse activist Tobeka Daki who died after she could not get access to Trastuzumab treatment.

Read: [Demands for Roche to drop price of breast cancer drug](#)

**27 March:** Mylan applies to the South African Health Products Regulatory Authority (SAHPRA) to make a Trastuzumab biosimilar available.

**10 April: The National Department of Health and all provincial departments adopt the Breast Cancer Control Policy. This detailed policy was initiated in 2014 after lobbying by Cancer Alliance member Advocates for Breast Cancer and makes provision for the treatment of HER2+ breast cancer. Various cancer NGOs also contribute to the development of the policy.**

Read: [The Breast Cancer Control Policy](#)



**June:** The South African Competition Commission announces an investigation into Roche and two other pharmaceutical companies for price-fixing on certain cancer drugs, including Trastuzumab.

Article: [People have died because of this](#)

**23 June: Veroney Judd-Stevens dies at her home in Pietermaritzburg after being denied lifesaving Trastuzumab treatment.**

**July:** Trastuzumab is added to the Essential Medicines List of the National Department of Health, two years after the World Health Organization added it to their list of essential medicines.

**July:** The National Department of Health signs contract with Roche for the supply of HERCLON® (another Roche brand name for Trastuzumab) at R117,569 per recommended 18 cycles each patient should receive. The Western Cape Department of Health indicates that it is still an unfunded mandate and they cannot afford to procure it.

**December: Roche reports a global accrued revenue from Trastuzumab of US\$ 88.2 billion.**

Read WHO report: [Pricing of cancer medicines and its impacts](#)

**2018**

**March:** 47-year-old Margaret Boshoff is diagnosed with HER2+ breast cancer and is denied treatment cover by her medical scheme Bestmed. She cannot afford an upgrade to a plan that would cover Trastuzumab.

**July:** The Cancer Alliance (CA) writes to SAHPRA to request the approval of the Mylan biosimilar. The applications system is not transparent, and CA cannot get any information on the application.

**21 August:** The Cancer Alliance writes to the Council of Medical Schemes and all medical schemes to alert them to the inclusion of Trastuzumab in the Breast Cancer Control Policy—which makes the medicine a prescribed minimum benefit (PMB). Some react positively and some argue that it cannot be regarded as PMB as it is still not available in all public hospitals.

**August:** 31-year-old Justine McKinnon from Cape Town is diagnosed with HER 2+ breast cancer. Her medical scheme Discovery denies coverage for Trastuzumab on the plan she is on. With the support of family, she pays R76,300 out of her own pocket for four treatments. She upgrades her medical aid scheme plan in January 2019 and is covered for a further thirteen cycles.

**September:** 44-year-old Nomini Hlangwana from East London is diagnosed with HER2+ breast cancer and is denied coverage for Trastuzumab by her medical scheme FedHealth.

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**September:** Margaret Boshoff receives public sector treatment of her HER2+ breast cancer at Charlotte Maxeke Academic Hospital. Campaign for Cancer lodges a complaint against Boshoff's medical aid scheme Bestmed with the Council of Medical Schemes because they denied her treatment coverage earlier in 2018.

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**November:** The Council of Medical Schemes (CMS) initiates a process of revision of the prescribed minimum benefits for breast cancer. Cancer Alliance makes a submission to CMS on behalf of patients and testifies at the hearing.

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**December:** Herceptin® 600mg/5ml SC is reported in the Mediscor Review as the fifth most-prescribed product used in the private sector in SA. This is an increase from ranking 106 in 2017.

[Read: Mediscor Medicines Review 2018](#)

**2019**

**The access saga continues as Roche works throughout 2019 to undermine biosimilar access and squeeze every last bit of death-soaked profit out of Trastuzumab.**

- **Herclon®** is available in public hospitals at a cost of R117,569 for the recommended treatment of 18 cycles. The government pays for this, and some patients at some hospitals can get it. Roche calls this drug a biosimilar to their 'originator' drug Herceptin® to justify the much heftier price in the private sector for what is basically the same medicine.
  - **Herceptin® Trastuzumab (SC)** is available in the private sector at a cost of R239,590 for the recommended treatment of 18 cycles. More than 90% of private-sector patients are on this subcutaneous (SC) formulation because it is more convenient for patients than the longer treatment process for the IV (intravenous) version of the medicine. In November, Roche drops the cost to R163,800 per 18 cycles.
  - At the beginning of 2019, **Herceptin® Trastuzumab (IV)** is available in the private sector at a cost of R342,271 for the recommended treatment of 18 cycles. In November Roche drops the price to R153,000 to compete with Mylan's biosimilar—which sells for R155,733.
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**May:** Margaret Boshoff is denied Trastuzumab treatment at Charlotte Maxeke public hospital and referred back to the private sector. The Cancer Alliance lodges a second complaint to the Council of Medical Schemes.

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**4 June: The Mylan biosimilars (brand name Ogivri®) for Trastuzumab is finally approved by SAHPRA—more than 2 years after applying.**

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**10 July:** Margaret Boshoff wins her case against her medical aid scheme Bestmed and her Trastuzumab treatment is finally approved by the Council for Medical Schemes as a prescribed minimum benefit.

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**17 July:** Cancer Alliance submits motivation for the speedy approval of the other Trastuzumab biosimilars still awaiting approval at SAHPRA. The more biosimilars in the market place, the cheaper this important medicine will become. The motivation is also shared with the Minister of Health, Dr Zweli Mkhize.

[Read: Cancer Alliance Motivation for Prompt Registration of Trastuzumab Biosimilars in South Africa](#)

**11 September:** BestMed still refuses to cover Margaret Boshoff's treatment, despite the CMS ruling in July. The Cancer Alliance writes them to demand treatment on behalf of the patient.

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**September:** The Competition Commission investigation into price-fixing behaviour by (amongst others) Roche remains incomplete.

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**November:** Mylan announces their biosimilar, Ogivri® to be sold for R155,733 per recommended treatment of 18 cycles. Only the less comfortable intravenous (IV) version of the biosimilar will be available. Roche drops their IV price to beat Mylan's. Later in the month, Roche drops the price of Herceptin® SC to R163,800 per recommended treatment of 18 cycles, making it only marginally more expensive than the less comfortable IV treatment.

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