

## **DRUG ACCESS APARTHEID**

### **SLIDE 1**

THE WORD APARTHEID HAS BEEN ASSOCIATED WITH SA SINCE THE EARLY 60'S  
NOW 60 YEARS LATER WE STILL HAVE THE SAME CONTEXT TWO SETS OF RULES:

ONE GROUP BENEFITS AND THE OTHER PAYS THE PRICE FOR THE OTHER  
GROUPS BENEFITS

ONE DRUG TWO COUNTRIES

ONE SET OF RULES AND PRICES FOR UNITED STATES AND DEVELOPED NATIONS  
AND ANOTHER SET OF RULES AND PRICES FOR LMIC AND A PROFIT MODEL  
THAT IS AT THE COST OF SOME PEOPLES HEALTH.

SO, WE'VE SHIFTED FROM A SITUATION WHERE APARTHEID WAS THE LAW OF  
OUR LAND TO A NEW REALITY WHERE IT IS THE LAW OF THE INTERNATIONAL  
MARKET PLACE

WHAT HAS NOT CHANGED IS THAT ONE GROUPS ALWAYS WINS AND ONE  
DISENFRANCHISED GROUP WILL PAY THE PRICE...IN THIS CASE SOMETIMES WITH  
THEIR LIVES.

### **SLIDE 2**

HEALTH ACCESS IN SA REMAINS INEQUITABLE AND IS CERTAINLY IS ONE OF THE  
MOST INEQUITABLE HEALTH SYSTEMS GLOBALLY.

IF YOU ARE LUCKY ENOUGH TO BE AMONG THE 16 % OF SOUTH AFRICANS  
WHO ARE TREATED FOR THEIR CANCER YOU WILL HAVE ACCESS TO 84% OF  
THE COUNTRIES CANCER HEALTH CARE PROVIDERS.ON THE OTHER HAND IF  
YOU ARE IN PART OF THE **84% OF SOUTH AFRICANS WHO ACCESS** PUBLIC  
HEALTH PROVIDED CANCER SERVICES YOU ARE SERVED BY ONLY **16% OF THE  
COUNTRIES CANCER HEALTH CARE PROFESSIONALS.**

### **SLIDE 3**

CLEARLY THIS IS NOT EQUITY! OR CONSISTANT WITH NELSON MANDELA'S BELIEF  
THAT HEALTH IS NOT A MATTER OF INCOME BUT IT IS A BASIC HUMAN RIGHT.  
WITH ONE LOOK AT THESE NUMBERS WE ARE CONFRONTED WITH THE REALITY  
OF HEALTH CARE APARTHEID - THE VALUE OF LIFE AN WHAT WE ARE WILLING  
TO INVEST IN IT, DEPENDS ON WHERE YOU ACCESS YOUR CARE. IT IS FAR FROM  
EQUAL.

### **SLIDE 4**

SO, WHAT IS THE SITUATION IN SA FOR CANCER MEDICINES. WE, THE CANCER  
ALLIANCE, AN ALLIANCE OF 29 CANCER NON-PROFIT ORGANISATIONS,  
RESEARCHED 24 CANCER MEDICINE PATENTS AND FOUND THE FOLLOWING;

### **SLIDE 5**

IN TERMS OF ACCESSIBILITY - 21 MEDICINES ARE AVAILABLE IN THE PRIVATE SECTOR BUT ONLY 7 OF THESE ARE AVAILABLE IN THE PUBLIC SECTOR. ALTHOUGH THE WORLD HEALTH ORGANISATION CLASSIFIED 10 OF THE 24 MEDICINES AS ESSENTIAL MEDICINES ONLY 5 ARE ON THE SA ESSENTIAL MEDICINES LIST. - FURTHER OF THESE 24 THERE IS GENERIC AVAILABILITY FOR 16 MEDICINES IN INDIA, 4 IN THE USA AND ONLY 1 SA. WHY IS THAT?

#### **SLIDE 6**

MAINLY PATENTS AND COST. IN SA WE DO NOT ALLOW FOR PATENT EXAMINATION - IT IS A MERE DEPOSITORY SYSTEM. SECONDARY PATENTS ARE THEREFOR AT THE ORDER OF THE DAY. THIS HAS SERIOUS IMPLICATIONS FOR ACCESS TO MEDICINE. THERE IS A DISCONNECT BETWEEN THE PATENT LAW AND HEALTH REGULATORY SYSTEM THAT FURTHER EXACERBATES ACCESS.

IN TERMS OF AFFORDABILITY WE FOUND THAT 15 OF THE MEDICINES ARE AVAILABLE IN INDIA FOR LESS THAN 50% OF THE PRICE OFFERED TO THE SA PRIVATE SECTOR - AND REMEMBER THAT'S ONLY SERVING 16% OF THE POPULATION!

LET ME SHARE TWO CLASSICAL EXAMPLES:

#### **SLIDE 7**

TRASTUZUMAB IS LISTED AS A LIFESAVING MEDICINE FOR HER2+ BREAST CANCER (EARLY AND METASTATIC) BY THE WORLD HEALTH ORGANISATION. ROCHE'S PATENT FOR THIS EXPIRES EARLY 2019 IN US HOWEVER IN PATENT THEY HOLD IN SA COULD POTENTIALLY BLOCK GENERIC ACCESS TILL 2032.

ORIGINATOR HERCEPTIN IS AVAILABLE @ \$33 000 FOR ONE YEAR'S TREATMENT WHILST THE CLONE HOWEVER, MEANING THE SAME DRUG JUST ANOTHER PACKAGE WAS MADE AVAILABLE TO THE SA PUBLIC SECTOR UNDER A STATE TENDER FOR \$9000 FOR ONE YEARS TREATMENT - THE ONLY DIFFERENCE BETWEEN THE TWO PRODUCTS IS A BOX THAT IS APPERENTLY COSTS \$24000. IS THAT NOT INSANE? BUT WAIT THERE IS MORE! THE ESTIMATED BIOGENIC COST IS OF THE DRUG IS ONLY \$ 243 - OR \$8757 LESS THAN THE CHEAPER CLONE OPTION. AND ON BIOGENERICS - THERE ARE SEVRAL THAT ARE APPROVED BY REPUTABLE REGULATORY OFFICES AROUND THE WORLD AND ARE AVAILABLE - BUT NOT IN SA. WHY ... OUR REGULATORY SYSTEM IS NOT TUNED INTO THE REAL NEEDS OF THE PEOPLE.

I HAD THE PLEASURE OF LISTENING TO SEVERAN SCHWAN CEO OF ROCHE IN 2015 IN COPENHAGEN AND IN HIS MIND THE MODEL THAT SERVES MANKIND BEST. IS THE MODEL WHERE THE ORIGINATOR COMPANY HAS 10 YEARS FOR R&D AND 10 YEAR'S EXCLUSIVITIES TO EARN BACK ON THE INVESTMENT. THAT SEEM PERFECTLY REASONABLE. AFTER THAT IT'S TIME FOR GENERICS AND BIOSIMILAR TO COME INTO THE MARKET. TO QUOTE HIM DIRECTLY "THE BIGGEST GIFT TO SOCIETY IS TO ALLOW GENERICS TO COME INTO MARKET @ LOWER PRICE. IMPORTANT MEDICINES WILL THEN BE AVAILABLE BROADLY

FOREVER AND AT A LOWER COST!" INSPIRING INDEED! BUT IN THE SA THE REALITY IS THAT HIS COMPANY WILL CONTINUE TO PROFIT YEARS AFTER THEY HAVE REALISED THE RETURN ON THEIR INVESTMENT. PART OF THE BLAME IS THE SA PATENT LAW THAT IS ARCHAIC, BUT MR SCHWEN ISN'T YOUR COMPANY THAT CONTINUES TO ACCEPTS PROFITS ALSO COMPLICIT?

OUR NEXT CASE IS LENALIDOMIDE - I AM SURE THAT WE ALL REMEMBER THALIDOMIDE OF THE LATE 50'S AND EARLY SIXTIES. THE DRUG THAT WAS GIVEN TO PREGANT WOMEN FOR MORNING SICKNESS ONLY TO DISCOVER IT CAUSES BIRTH DEFORMITIES. SUBSEQUENTLY IT WAS DISCOVERED THAT THIS ONE MOLECULE STRUCTURE MEDICINE (THEREFOR SO EASY TO MANUFACTURE THAT YOU CAN DO IT IN OUR OWN KITCHEN) ALSO CAN BE USED FOR THE TREATMENT OF MULTIPLE MYELOMA.

CELEGENE REGISTERED A PATENT IN 2005 AND HAVE MADE SUBSEQUENT DEALS WITH NATCO AN INDIAN GENERIC MANUFACTURER TO HAVE MARKET EXCLUSIVITY UNTIL 2021. THIS IS WHILSTS THERE ARE OTHER SAFE, EFFECTIVE AND QUALITY GENERICS ALREADY AVAILABLE GLOBALLY. SO, WHAT HAPPENED IN SA.?

#### **SLIDE 8**

THE ORIGINATOR COMPANY, ROCHE IN 2017 ALONE REGISTERED US\$ 88.2 BILLION IN ACCRUED SALES GLOBALLY - THE QUESTIONS REMAINS WHY NOT LOWER THE PRICE. NO, IT'S FINALLY ABOUT THE SHAREHOLDERS AND NOT ABOUT PATIENTS. IT IS ALSO INTERESTING TO SEE THE PRICE OF THIS ESSENTIAL MEDICINE AGAINST THE COST OF A BIOSIMILAR.

SHOWN HERE ON THE SLIDE IS THE 2018 PRICES IN SOUTH AFRICA IN US\$. ROCHE DEVELOPED THEIR ORIGINATOR IV PRODUCT, BRANDED HERCEPTIN® AND SIMULTANEOUSLY DEVELOPED THEIR OWN CLONE HERCLON®. IN THE SOUTH AFRICAN CONTEXT, HERCEPTIN IS ONLY AVAILABLE IN THE PRIVATE SECTOR, WHILST THE CLONE, IS ONLY AVAILABLE IN THE PUBLIC SECTOR. ESSENTIALLY NO DIFFERENCE BETWEEN THE TWO MEDICINES NOT EVEN THE PAMPHLET INSERT - THE ONLY DIFFERENCE WAS THE COST! ONE COULD THEN ASK THE QUESTION WHETHER IT IS ETHICAL TO HAVE SUCH AS DIFFERENCE IN PRICE BETWEEN THE TWO PRODUCTS?

#### **SLIDE 9**

THE PRICES FOR TRASTUZUMAB SHOWN HERE ARE THE 2019. NOTE THE DIFFERENCE IN PRICE NOW. THE REASON FOR THAT IS THE ADVENT OF BIOSIMILAR ENTRY IN GLOBALLY AND SOUTH AFRICA. ROCHE HAD A GLOBAL DEAL WITH MYLAN THAT THEY WILL NOT BLOCK BIOSIMILAR ENTRY IN THE MARKET. THEY WERE NOT WILLING TO CONFIRM THIS FOR SOUTH AFRICA AND IF THEY INSISTED ON ENFORCING THE PATENT IT WOULD BE VALID TILL 2033. THE FURTHER MARKETING STRATEGY OF ROCHE WAS TO LAUNCH THEIR SUBCUTANEOUS (SUBCUT) PRODUCT IN THE MARKET. THIS PRODUCT IN ESSENCE IS EASIER TO MANAGE FOR THE TREATMENT FACILITY AS IT DOES NOT REQUIRE CHEMOTHERAPY ROOMS AND A SPECIALIST CHEMO NURSE. FOR THE PATIENT'S IT IS ALSO A BETTER TREATMENT AS IT IS MUCH QUICKER TO ADMINISTER AND

THERE DOES NOT REQUIRE YOU TO SPEND HOURS IN A CHEMO ROOM. THE SUBCUT PRODUCT IS THEREFORE CHEAPER THAN THE IV. THEY ALSO FILED FURTHER PATENTS ON THE SUBCUT - AND THESE ARE VALID TILL 2033. ROCHE IS NOW USING THE SAME STRATEGY FOR OTHER BIOLOGICS SUCH AS RUTIXIMAB ANOTHER BIOLOGIC WHERE FOR WHICH THE BIOSIMILARS ARE ALREADY APPROVED BY REGULATORY AUTHORITIES SUCH AS FDA  
IN MAY 2019, THE MYLAN BIOSIMILAR OGIVRI® WAS APPROVED BY THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA) AND THIS IS NOW AVAILABLE IN THE PRIVATE SECTOR MARKET AT 35% LESS THAN THE HERCEPTIN® SUBCUT.

### **SLIDES 9, 10, 11, 12**

THERE HAS BEEN LOADS OF ACTIVISM FOR TRASTUZUMAB ACCESS IN SOUTH AFRICA. THIS WAS A COLLECTIVE ACTION AND ALSO IMPORTANT THAT IT WAS A CONTINUOUS ACTION. WE WERE SUCCESSFUL IN DAMAGING THE ROCHE GLOBAL BRAND - THEY EVEN APPOINTED A COMPANY TO INVESTIGATE THEIR DAMAGE DONE BY THE ACTIVISM AND HOW THEY SHOULD RELATE TO THIS IN FUTURE.

THE WORK OF CANCER ALLIANCE ACCESS TO MEDICINE CAMPAIGN CAN BE FOLLOWED ON OUR WEBSITE [HTTPS://CANCERALLIANCE.CO.ZA/ACCESS-TO-MEDICINE/](https://canceralliance.co.za/access-to-medicine/)

WE HAVE DEDICATED FACT SHEETS ON THE MEDICINES THAT WE WORK ON LINKED WITH SOCIAL MEDIA MEMES AND DEDICATED PATIENT STORIES.

### **SLIDE 13**

ALLOW ME TO SHARE ANOTHER MEDICINE THAT WE ARE WORKING ON, NAMELY LENALIDOMIDE.

THIS MEDICINE WAS UNREGISTERED AND PATIENTS WERE ALLOWED TO IMPORT THE GENERIC PRODUCT UNDER A SECTION 21 LICENSE AT A COST OF \$408/MONTH.

### **SLIDE 14**

THEN CELEGENE CAME AND REGISTERED THE MEDICINE IN SA. IMMEDIATELY THE PATIENTS RIGHTS TO IMPORT THE GENERIC MEDICINE WAS CANCELLED AND THEY NOW HAVE ACCESS THE REGISTERED PRODUCT @ \$6126/MONTH! THAT IS A WHOPPING \$5718

MORE - WHO HAS THAT MONEY. CERTAINLY, NOT THE SA GOVERNMENT TO TREAT PATIENTS IN THE PUBLIC SECTOR WITH THIS AND PRIVATE SCHEMES CANNOT AFFORD THIS PRICE EITHER.

SO, WHO'S WINNING - CERTAINLY NOT THE PATIENT. IT IS THE PATENTS AND THE PHARMACEUTICAL COMPANY'S SHAREHOLDERS THAT ARE SLEEPING COMFORTABLE.

HOW LONG ARE WE GOING TO ACCEPT THE MODEL OF PROFIT PROJECTION AT THE COST OF LMIC'S??

**SLIDE 15**

AGAIN, WITH COLLECTIVE ACTION AS PART OF THE FIX THE PATENT LAW, CANCER ALLIANCE TOGETHER WITH TAC, SECTION 27 LAUNCHED AN ADVOCACY CAMPAIGN FOR AFFORDABLE ACCESS TO ESSENTIAL LIFESAVING TREATMENTS WE FOCUSED GLOBAL ATTENTION ON THE ISSUES AT THE 2019 FAIR PRICING FORUM.

**SLIDE 16**

COLLECTIVE ACTION IS WHAT BROUGHT APARTHEID DOWN - COLLECTIVE ACTION WILL ALSO BE BEHIND THE CHANGE IN PATENT LAW AND ACCESS SYSTEM.

THERE IS AN AFRICAN PROVERB - IF YOU WANT TO GO QUICKLY YOU GO ALONE, BUT IF YOU WANT TO GO FAR YOU GO TOGETHER.

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