Unpacking biosimilar pricing policies
Country examples promoting the use of biosimilar medicines toward affordable access
Achieving UHC requires people having access to safe, effective, quality, and affordable essential medicines and vaccines for all.

**WHO ‘Triple billion’ goals**

- **Healthier populations**
  - 1 billion more people enjoying better health and well-being
- **Universal health coverage**
  - 1 billion more people better protected from health emergencies
- **Health Emergency**
  - 1 billion more people benefitting from universal health coverage

**Sustainable Development Goals**

3.8 Achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all (2016-2030).
Resolution WHA72.8 (2019): improving market transparency

Requests WHO to continue supporting Member States in ensuring rapid and timely adoption of generic and biosimilar products

Availability: Presence of medicines in national formulary available to patients for free or for a fixed fee

Affordability
- for the health system – Proportion of spending on medicines compared to existing expenditure on medicines or other health products and services
- for individual patients – The number of days’ wages needed to pay for the cost of treatment

Transparency: The disclosure and dissemination of information to relevant parties to ensure accountability. For example, price transparency refers to disclosure of the net transaction prices of cancer medicines between the sellers (e.g., manufacturers, service providers) and the payers/buyers (governments, consumers) (cf. list prices in pricing catalogue or on invoice prior to applying discounts).

In September 2020, WHO Guideline on country pharmaceutical pricing policies was published

Ten pricing policies

1. External reference pricing
2. Internal reference pricing
3. Value-based pricing
4. Mark-up regulation across the pharmaceutical supply and distribution chain
5. Promoting price transparency
6. Tendering and negotiation
7. Promoting the use of quality-assured generic and biosimilar medicines
8. Pooled procurement
9. Cost-plus pricing for setting the price of pharmaceutical products
10. Tax exemptions or tax reductions for pharmaceutical products

https://www.who.int/publications/i/item/9789240011878
Credit: WHO AAP team
**Strong recommendations**

Promoting the use of quality-assured generic and biosimilar medicines

A. WHO recommends that countries enable early market entry of generic and biosimilar medicines through legislative and administrative measures, with a view to encouraging early submission of regulatory applications, allowing for prompt and effective review, and ensuring these products are safe, efficacious and quality-assured.

B. WHO recommends that countries use multiple pricing policies to achieve low prices for generic and biosimilar medicines that are informed by the cost of production. These policies may include: internal reference pricing, mark-up regulation, direct price controls, tendering, promoting price transparency and lower patient copayments.

C. To maximize uptake of generic and biosimilar medicines, WHO recommends that countries should implement, and enforce as appropriate, a suite of policies [...]
## Setting Prices

**Cost based:** factors of production  
**Value based:** (Anticipated) outcomes and preferences  
**Reference pricing:** benchmarking  
**Tender and negotiation:** best price (subject to other considerations)

## Managing prices

**Regulation of mark-ups / remuneration:** structure  
**Regulate price increase:** Frequency and magnitude  
**Revise prices:** changing market conditions or therapeutic landscape

## Unique considerations for biosimilars (and generics)

**Price setting:** in relationship to the originator/reference

**INN prescribing:** Requirements to prescribe medicines by its active ingredient name instead of the brand name

**Substitution:** Dispensing another equivalent and interchangeable medicine at the pharmacy level without consulting the prescriber

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**Combination of pricing approaches is often needed**
Today's discussion on unpacking biosimilar pricing policies
Country examples promoting the use of biosimilar medicines toward affordable access

Discussants:

Dorthe Bartels  Amgros, Denmark
Myriam Khrouf  Ministry of Health, Tunisia
Javier Guzman  Center for Global Development (formerly Invima, Colombia)

Key questions:

• Have you seen evidence of significant impact on access/utilization after entry of biosimilars? How has this affected expenditures?
• What policies have been put in place to enhance price competition? Have these been successful?
• How have practitioners been educated about appropriate substitution of generic and biosimilar medicines, and/or price advantages?
• When generic and biosimilar medicines enter the market, are prices appropriate?
DENMARK’S BIOSIMILARS STRATEGY

Dorthe Bartels
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Denmark:
Dorthe Bartels
Negotiator and Strategic Advisor
dbs@amgros.dk

Experience and Career:
- Current role: Strategic Advisor, Negotiator and Head of the Biosimilar task force in Amgros
- Previous Head of Procurement and Lead of Tender Department, Amgros I/S (2008-2016)
- Worked at Amgros since April 2008 with pharmaceutical industry experience from several companies (Roche, Pfizer, Ferring, and Nycomed)

Education:
- Master of Science (Pharmacy), School of Pharmaceutical Science, Faculty of Health and Medical Science, Copenhagen
- MBA (Marketing), Copenhagen Business school, Denmark
DENMARK – A UNIQUE MARKET AND A UNIQUE SET-UP

- **Public hospitals set-up:**
  - Politically managed regions responsible for public healthcare and funded through national taxes
  - **No patient** co-payment for hospital services, including pharmaceuticals.

- **NATIONAL Guidelines and tenders (since 2010)**
  - Danish Medicines Council develops **national guidelines** for therapeutic areas
  - Amgros makes **national calls for tenders** (ATC-code 5 level), and the hospitals follow the tender and the decision.
  - The 5 regions implement the guidelines and tender results at the hospitals

5.7 Million inhabitants

Biosimilar – 28. september 2021
SUCCESS WITH INTRODUCTION OF BIOSIMILARS IN DENMARK !!

- Worked with biosimilars since 2009 and established “biosimilar task force” in 2012

- The biosimilar task force has been an important part of the success by:
  - **Training** of nurses, doctors and patient since 2013
  - **Planning, Dialogue and Involvement** of doctors, specialist groups and drug committees
  - Initiated development of **Guidelines, biosimilar statement**, educational material, and implementation

- Planning (timely to patent expiration) national tenders and a strong set-up for implementation of tender results and guidelines at the Danish hospital

Europe: Infliximab biosimilar market share in treatment days

Europe: Etanercept biosimilar market share in treatment days

Source: IQVIA MIDAS MTH March 2018
Denmark welcomed biosimilar adalimumab November 2018

- 90% MS in week 3
- 2 players: Hyrimoz and Imraldi (40 mg)
- This saved the Regions about US $ 50 million in the first year

Source: IQVIA European Thought Leadership; IQVIA MIDAS MTH May 2019

Biosimilar – 28. september 2021
PLANNING, DIALOGUE AND INVOLVEMENT ARE THE KEY TO SUCCESS

- Specialist groups/
  Danish Medicines Council
- Biosimilar Task force
- Amgros / tendering
- Drug committees /
  pharmacists
- Doctors /
  specialists /
  nurses
- Patients

* Complex stakeholder involvement
* Multiple clinical decision makers and influencers
FUTURE!

• Continued with biosimilar implementation set-up with:
  - Involvement
  - Guidelines
  - Education and patient materialeg
  - Tendering and close follow-up

• Next biosimilar introduction
  - Ranibizumab (Lucentis) summer 22
  - 100 biologic medicines will lose exclusivity (from 2024-2029)
Biosimilar Pricing Policies: examples from countries

Pr. Myriam Khrouf
Drug and Pharmacy Unit
National Regulatory Authority

PV Center

National Drug Control Lab

Drug and Pharmacy Unit

Pharma Inspection

Technical supervision of PCT

A unique Market

PCT makes national call for tenders, and the hospital follow the result of tender and the decision
Medicine Distribution System

- Tunisian Central Pharmacy Monopoly of Drug Importation
- Local Manufacturers
  - Wholesalers
    - Private Clinics
    - Private Officines
- Public Health Institutions
  - National Essential Medicine List
- Polycliniques CNSS
  - Specific medicines

DIRECTION DE LA PHARMACIE ET DU MÉDICAMENT
UPM Missions

**Pharmaceutical Industry**
- Licencing
- Ministerial Order for Pharmaceutical responsibility
- Agreement of modifications

**Medicines**
- Registration
- Clinical Trials approval
- Promotion Control
- Import and Export Authorization

**Medical devices and Health Products**
- Import Technical Control
- Medical devices, Food Supplements, Cosmetics, infant formulas

**Pharmacies and Wholesalers of pharmaceuticals**
- Licencing
- Waiting lists in order to create a community pharmacy
- Transfers, replacement ...

Price is related to the MA
Marketing authorization process for generics and Biosimilars

1. DUP (MoH) Application submission
2. Administrative Informations (Module 1)
3. LNCM (Module 3: Quality Aspects)
4. Assessment and Testing
5. Experts: Specialized Scientific Commission: Safety and Efficacy data
6. Technical Committee for Proprietary Medicinal Products
7. Minister of Health
8. MAA
9. 1st Generic / Biosimilars
Security and efficacy assessment

**Experts / Specialized Scientific Commissions (SSC)**

- Approximately **200** Experts appointed by The Minister of Health from different relevant specialties
- **10** Specialized Scientific Commissions
- The SSC met 2-3 times each year
Specialized Commissions

1. Rhumatology, Urology, Néphrology and Radiology
2. Gynécology, Gastroentérology, Endocrinology, Métabolisme and Nutrition
3. Neurology et Psychiatry
4. Ophtalmology, Dermatology, ORL et Phytothérapy
5. Pneumology, Allergology, Intensive care and Cardiology
6. Antiinfective, and vaccines
7. Hématology
8. Oncology
9. Biosimilars
10. Radiopharmaceutics
Commission of assessment of biosimilars

<table>
<thead>
<tr>
<th>Transversal Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians from different specialities which use biosimilars: Oncology, hematology, cardiology, endocrinology...</td>
</tr>
<tr>
<td>Transversals specialists: pharmacologues, épidémiologists, immunologists</td>
</tr>
</tbody>
</table>

Initiated development of guidelines
Involvement of doctors, specialist group and drug committee

**Article 4 (nouveau)** - Pour les différentes classes thérapeutiques, des commissions spécialisées seront constituées. Les membres de ses commissions sont nommés par décision du ministre de la santé parmi les spécialistes des disciplines de santé.

Les membres des commissions spécialisées ne doivent avoir aucun intérêt personnel direct ou indirect dans des établissements liés à la fabrication, la distribution ou la promotion des produits pharmaceutiques et de façon générale tout intérêt dans la commercialisation des médicaments sur lesquels ils sont appelés à donner leurs avis. Ils doivent déclamer sur l’honneur selon un modèle établi à cet effet par le ministère de la santé, leur engagement de respecter scrupuleusement les termes de la charte d’éthique fixée par décision du ministre de la santé.

Les commissions spécialisées étudient les dossiers en tenant compte notamment de l’intérêt thérapeutique et des effets indésirables constatés ainsi que du rapport coût - efficacité.

Le président, le rapporteur ou un membre d’une commission spécialisée, peut être invité pour présenter au comité technique les conclusions de sa commission.

A cet effet, ne sont proposés à l’enregistrement que les médicaments qui sont présumés apporter une amélioration du service médical rendu et une économie sur le coût de la santé, et ce, notamment par rapport aux produits de même visée thérapeutique et similaires commercialisées.

Les conclusions des commissions spécialisées sont consignées dans des procès-verbaux.
Tunisian guidelines for registration of drugs: Generics, Biosimilars...
Technical Committee for Proprietary Medicinal Products (MA committee)

Committee composition:
◦ Experts representatives of different specialties
◦ representatives of relevant governmental structures (NMCL, DIP, CNPV, Central Pharmacy of Tunisia, National Health Insurance Fund/Ministry of Social Affairs, Ministry of Trade)
◦ College of pharmacists and physicians

Global assessment
◦ Quality report (NMCL)
◦ SSC opinion
◦ Price négociations

Approval or rejection of the MAA
Multiple price setting

Reference pricing by doing a benchmark at the introduction of the product

Internal reference pricing. When the drug have already therapeutic similars

Biosimilar : Tendering when we have two Marketing autorisation
Drug price is not free in Tunisia but needs homologation

Prix des médicaments:

Lois:

Loi n°91-64 du 29 juillet 1991, relative à la concurrence et aux prix. [Voir détails]

Loi n°95-42 du 24 avril 1995, modifiant et complétant la loi n°91-64 du 29 juillet 1991 relative à la concurrence et aux prix. [Voir détails]

Loi n°99-41 du 10 mai 1999, modifiant et complétant la loi n°91-64 du 29 juillet 91 relative à la concurrence et aux prix. [Voir détails]

Décrets:

Décret n°91-1996 du 23 décembre 1991, relatif aux produits et services exclus du régime de la liberté des prix et aux modalités de leur encadrement. [Voir détails]

Décret n°95-1142 du 20 juin 1995, modifiant et complétant le décret n°91-1996 du 23 décembre 1991 relatif aux produits et services exclus du régime de la liberté des prix et aux modalités de leur encadrement. [Voir détails]

Arrêtés:


Circulaires:

Circulaire n°137/92 du 29 février 1992, relative aux prix des médicaments et produits et accessoires à vente exclusive en pharmacie.

Circulaire n°60/92 du 10 juillet 1992, relative aux prix de vente des produits pharmaceutiques.
## Rules of Generic fixation price

<table>
<thead>
<tr>
<th>Innovators</th>
<th>Benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Comparison with the therapeutic similar in Tunisia</strong></td>
</tr>
</tbody>
</table>

| 1\textsuperscript{st} Generique | 30 % reduction / Price of innovator |
| 2\textsuperscript{nd} Generique | 5 % de reduction / Price du 1\textsuperscript{st} generic |
| 3\textsuperscript{rd} Generique | 5 % reduction / Price of the 2\textsuperscript{nd} generic |

Benchmark at the first introduction of the drug
### Rules of Biosimilar price fixation

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<tbody>
<tr>
<td></td>
<td>Comparison with the therapeutic similar in Tunisia</td>
</tr>
</tbody>
</table>

| Biosimilars | 2 Marketing authorisation : National Tenders |
Subsitution : as we have a national tender, once a biosimilar is retained in a tender, at the pharmacy level they will dispense the equivalent without consulting the prescriber.
Less than half price of innovator
# Hospital experience

<table>
<thead>
<tr>
<th></th>
<th>22 juin 2017 to 21 septembre 2017 HERCEPTIN</th>
<th>22 juin 2018 to 21 septembre 2018 HERTRAZ</th>
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</thead>
<tbody>
<tr>
<td>Number of units</td>
<td>2958</td>
<td>3685</td>
</tr>
<tr>
<td>Global cost</td>
<td>6 MD 044</td>
<td>2 MD 546</td>
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</table>
Metastatic Breast cancer MARS 2018

<table>
<thead>
<tr>
<th>Année</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nombre total de bénéficiaires de Trastuzumab</td>
<td>837</td>
<td>786</td>
<td>772 (fin septembre)</td>
</tr>
<tr>
<td>Nombre de bénéficiaires de Trastuzumab au stade métastatiques</td>
<td>76 **</td>
<td>54 **</td>
<td>168</td>
</tr>
</tbody>
</table>

**Source : décision de dérogations et de recours judiciaire unité de médicaments spécifiques district Nord.**

**Données de la CNAM**
## Authorized biosimilars (09/ 2021)

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Authorization date</th>
<th>Brand Name</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatropin</td>
<td>2005</td>
<td>GENOTONORM</td>
<td>BELGIUM</td>
</tr>
<tr>
<td></td>
<td>2009</td>
<td>HHT</td>
<td>ARGENTINA</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td>OMNITROPE</td>
<td>AUSTRIA</td>
</tr>
<tr>
<td>Epoetin alfa</td>
<td>2002</td>
<td>HEMAX</td>
<td>ARGENTINA</td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td>EPOTIN</td>
<td>UAE</td>
</tr>
<tr>
<td></td>
<td>2008</td>
<td>EPOMAX</td>
<td>TUNISIA</td>
</tr>
<tr>
<td></td>
<td>2010</td>
<td>IOR EPOCIM</td>
<td>CUBA</td>
</tr>
<tr>
<td>Infliximab</td>
<td>2017</td>
<td>REMSIMA</td>
<td>JORDAN</td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>2018</td>
<td>HERTRAZ</td>
<td>INDIA</td>
</tr>
<tr>
<td>Human Insulin</td>
<td>2012</td>
<td>JUSLINE</td>
<td>UAE</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>GENSULIN</td>
<td>POLAND</td>
</tr>
<tr>
<td>Enoxaparine</td>
<td>2007</td>
<td>ENOXA</td>
<td>TUNISIA</td>
</tr>
<tr>
<td></td>
<td>2015</td>
<td>ENOXAMED</td>
<td>TUNISIA</td>
</tr>
<tr>
<td>Filgrastim</td>
<td>2011</td>
<td>NEUTROMAX</td>
<td>ARGENTINA</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td>ZARZIO</td>
<td>GERMANY</td>
</tr>
<tr>
<td></td>
<td>2016</td>
<td>NIVESTIM</td>
<td>UK</td>
</tr>
<tr>
<td></td>
<td>2017</td>
<td>ACCOFIL</td>
<td>UK</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>2021</td>
<td>ABEVMY</td>
<td>INDIA</td>
</tr>
</tbody>
</table>
Coming soon (2022)

<table>
<thead>
<tr>
<th>GENERIC NAME</th>
<th>BRAND NAME</th>
<th>APPLICANT</th>
<th>COUNTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSULIN GALRGINE</td>
<td>GLARGEN</td>
<td>MEDIS</td>
<td>TUNISIA</td>
</tr>
<tr>
<td></td>
<td>SEMGLEE</td>
<td>MYLAN</td>
<td>FRANCE</td>
</tr>
<tr>
<td>ADALIMUMAB</td>
<td>AMGEVITA</td>
<td>AMGEN EUROPE</td>
<td>NETHERLAND</td>
</tr>
<tr>
<td></td>
<td>HULIO</td>
<td>MYLAN</td>
<td>FRANCE</td>
</tr>
<tr>
<td>ETANERCEPT</td>
<td>ERELZI</td>
<td>SANDOZ</td>
<td>AUSTRIA</td>
</tr>
<tr>
<td>TRASTUZUMAB</td>
<td>HERZUMA</td>
<td>HIKMA</td>
<td>JORDAN</td>
</tr>
<tr>
<td>PEGFILGRASTIM</td>
<td>FULPHILA</td>
<td>MYLAN</td>
<td>USA</td>
</tr>
<tr>
<td>RITUXIMAB</td>
<td>RIXATHON</td>
<td>SANDOZ</td>
<td>AUSTRIA</td>
</tr>
<tr>
<td></td>
<td>TRUXIMA</td>
<td>HIKMA</td>
<td>JORDAN</td>
</tr>
<tr>
<td></td>
<td>REDDITUX</td>
<td>DR REDDY'S</td>
<td>INDIA</td>
</tr>
</tbody>
</table>
Perception of hematologists and oncologists about the biosimilars: A prospective Tunisian study based on a survey

Selma Hadoussa ¹ ², Mehdi Bouhlel ¹ ², Mohamed A Soussi ¹ ², Chema Drira ¹ ², Myriam Hadoussa ³, Myriam R Khrouf ¹ ²

❖ Target Population:
➢ 107 oncologists and hematologists
➢ Public and private sector

The majority of oncologist and hematologist (96%) have revealed a lack of information about biosimilar.
Conclusion
Biosimilar are as safe, efficacious and quality assured than innovators
Challenges !!!

The introduction of biosimilar needs:

- A robust pharmacovigilance system
- Lot of trust
- An important work in training and information is needed before the introduction
THANK YOU FOR YOUR ATTENTION

WELCOME TO TUNISIA

myriam.khrouf@tunisia.gov.tn
Unpacking biosimilar pricing policies: The Colombian case
1. Population: 50.8m
2. Life expectancy: 77 years
3. Upper Middle-Income Country
4. GNI per capita: US$ 5780
5. GNI per capita PPP: US$14,280
6. High Human Development (HDI ranking: 83)
7. Health Care Coverage: ~97%

Sources: World Development Indicators database, Human Development Report 2020
The problem - low health expenditure

Source: OECD Health Statistics 2019, WHO Global Health Expenditure Database
The problem - financial sustainability

Revenue

COL$ 48,0 b (~US$12.5b)

- Otros
- Aportes de la Nación (incluye compensación de regalías)
- Desahorro Fonpet para RS
- Excedentes financieros, reintegros
- Rentas cedidas
- Sistema General de Participaciones
- Cajas de Compensación Familiar
- Cotizaciones

Expenditure

COL$ 49,5 b (~US$12.9b)

- Otros
- Atención en Salud, transporte primario, indemnizaciones y auxilio funerario a víctimas.
- NO PBS y tutelas
- Salud Pública y Promoción y Prevención
- Régimen Contributivo
- Régimen Subsidiado

Source: MHCP, ADRES, FUT
The problem- technological pressure

Expenditure on health technologies outside the health benefits package (COL MM)

Source: ADRES May 2018
The solution: overview pricing policies

Transparency
- E-prescribing
  - Sunshine Act

Policies on demand side
- Standard treatment guidelines

Price regulation
- IRP, Reimbursement Ceiling
- Value based pricing
- Biosimilars

Increased competition

Risk transfer
- Prospective payments

Improving coverage and value for money
The solution: overview pricing policies


- National Pharmaceutical Policy
- Regulation to Register Biosimilar Medicines
- Value-Based Pricing
- Priority Registration Procedures
- Sunshine Act
- Prospective Payments
- Standard Treatment Guidelines
- E-prescribing
- Reimbursement Ceilings
- International Reference Pricing
- Sunnshine Act

Javier Guzman | 09/2021 | CGDev.org
# International Reference Pricing

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<tr>
<th>Ex-factory price</th>
<th>Distributor Price</th>
<th>Hospital Price</th>
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</thead>
<tbody>
<tr>
<td>Suggested</td>
<td>Distributing/</td>
<td></td>
</tr>
<tr>
<td>distribution</td>
<td>dispensing</td>
<td></td>
</tr>
<tr>
<td>margin 7%</td>
<td>margin Freely</td>
<td>margin 7%</td>
</tr>
<tr>
<td></td>
<td>chosen</td>
<td>If price ≤ ~US$300</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.5% If price &gt; ~US$300</td>
</tr>
</tbody>
</table>

Source: MSPS modified by Johnattan García
<table>
<thead>
<tr>
<th>Country</th>
<th>Reference Pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>GERMANY</td>
<td>Higher price</td>
</tr>
<tr>
<td>CANADA</td>
<td></td>
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<tr>
<td>UNITED STATES</td>
<td></td>
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<tr>
<td>CHILE</td>
<td></td>
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<tr>
<td>COLOMBIA (BEFORE IPR)</td>
<td></td>
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<tr>
<td>AUSTRALIA</td>
<td></td>
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<td>PANAMA</td>
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<td>ECUADOR</td>
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<tr>
<td>UNITED KINGDOM</td>
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<td>BRAZIL</td>
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<tr>
<td>NORWAY</td>
<td></td>
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<tr>
<td>URUGUAY</td>
<td>25th percentile</td>
</tr>
<tr>
<td>COLOMBIA (AFTER IPR)</td>
<td></td>
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<tr>
<td>MEXICO</td>
<td></td>
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<tr>
<td>PORTUGAL</td>
<td>Lower price</td>
</tr>
<tr>
<td>SPAIN</td>
<td></td>
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</table>

Source: MSPS modified by Johnattan García
Regulation to register biosimilar medicines

2. Regular comparability

3. Abbreviated comparability

FDA, 2016
Essential biotherapeutic products

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<tr>
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</thead>
<tbody>
<tr>
<td>Etanercept</td>
<td></td>
<td></td>
<td>-13%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Rituximab</td>
<td></td>
<td></td>
<td>-41%</td>
<td></td>
<td></td>
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<tr>
<td>Trastuzumab</td>
<td></td>
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<td>-29%</td>
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<tr>
<td>Infliximab</td>
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<td></td>
<td>-39%</td>
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<tr>
<td>Adalimumab</td>
<td></td>
<td></td>
<td>-25%</td>
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<tr>
<td>Bevacizumab</td>
<td></td>
<td></td>
<td>-24%</td>
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<td>Ranibizumab</td>
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<td>Golimumab</td>
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<tr>
<td>Pertuzumab</td>
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</table>

Registration Date of:
- Green: Innovator
- Yellow: 1st competitor
- Orange: 2nd competitor
- Red: 3rd competitor
- Pink: 4th competitor
- Pink: 5th competitor

Policies:
- %: IRP, reduction in price (%) following IRP
- Δ: Included in the health benefits package
Biologics and biosimilars in Colombia

Adalimumab (units)

Adalimumab (price)

Trastuzumab (units)

Trastuzumab (price)
Biologics and biosimilars in Colombia

Rituximab (units)

Rituximab (precio)

Infliximab (units)

Infliximab (precio)
Reflections

- Biotherapeutics strain the financial sustainability of health care systems in middle income countries
- The promise of competition has not materialized in Colombia yet
- WHO plays a key role in supporting countries to facilitate early market entry of biosimilars
- There is no silver bullet but there can’t be an endless toolkit
- Important to fully implement and evaluate any pricing policy deployed
- Pricing policies might have unintended effects and often have high transaction costs
Think of pharmaceutical expenditure as a balloon

(Contiades et al. 2007)
Thanks!
Discussion: Unpacking biosimilar pricing policies
October webinar

TBC What pricing information is publicly available to improve price transparency?