Workshop 4
Pricing implications of policies on biosimilar cancer medicines
Purpose and agenda

To discuss the barriers and facilitating factors for enhancing the affordability of biological cancer medicines

10 An overview of biosimilar (cancer) medicines and their access  Malvika Vyas, ESMO Head of Public Policy

10 Industry’s perspective on access to biosimilar (cancer) medicines  Vivian Frittelli, CEO Generic & Biosimilar Medicines Southern Africa

05 A very short introduction on internal reference pricing  Kiu Tay-Teo, WHO Technical Officer

30 Small group discussion  All participants in small groups

10 Oral summary of discussion  Rapporteurs from small groups

25 Discussion and conclusions  All participants
What are the policies in your countries for the regulation, pricing, prescribing and use of biosimilar (cancer) medicines?

What are the supply and demand-side barriers to the uptake and affordable pricing of biosimilar (cancer) medicines?

What could be done to mitigate these barriers, thereby improving access to biosimilar products at affordable prices?
Pricing approaches
GOVERNMENTS’ PRICING APPROACHES

Setting prices

Cost based: factors of production
What to include and how?

Tender and negotiation: best price
Market dynamics?

Reference pricing: benchmarking
To what?

Value based: (Anticipated) outcomes and preferences
What to include and how?

Managing prices

Regulation of mark-ups / remuneration: structure
To whom and at what level?

Regulate price increase: Frequency and magnitude
Restriction

Revise prices: changing market conditions or therapeutic landscape
When and how?
**AUSTRALIA**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
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<tbody>
<tr>
<td>Total population (2017)</td>
<td>24.6 million</td>
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<tr>
<td>Total expenditure on health per capita (Intl $, 2014)</td>
<td>$4,357</td>
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<td>Total expenditure on health as % of GDP (2014)</td>
<td>9.4%</td>
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<tr>
<td>Total pharmaceutical spending as % of health expenditure (2016)</td>
<td>14.5%</td>
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**Pathway 1:** Second brand listed

**Pathway 2:** Second brand listed

### Pricing rules for single and multiple source products

- **Mark-ups regulations for single source products, including biologicals**:
  - 5% at 5 years
  - 10% at 10 years
  - 5% at 15 years

- **Internal reference pricing for multiple source products**:
  - 25% when second brand is introduced

- **Market based pricing for multiple source products**:
  - According to disclosed price
**Pricing rules for biosimilar products**

### Biosimilar products

1. 1st biosimilar: **38%** on the price of reference product
2. 2nd biosimilar: **15%** on the price of the 1\textsuperscript{st} biosimilar
3. 3rd biosimilar: **10%** on the price of the 2\textsuperscript{nd} biosimilar

### Reference product

1. **30%** price 3 months after the first biosimilar
2. Match price of the cheapest biosimilar after the entry of the third biosimilar product