



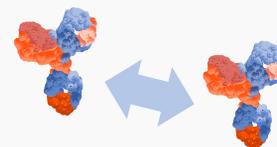
# Monoclonal antibody biosimilars in the treatment of solid tumours: Perspectives for pharmacists

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## What are biosimilar medicines?

- Owing to expiration of the original patent, many approved biologics are now available as '**biosimilars**'<sup>1</sup>
- MAb biosimilars show high **similarity** to their **reference biologic**<sup>1</sup>



## What 'similarity' do biosimilars show?

When compared with the reference biologic, MAb biosimilars have:<sup>1,2</sup>



## What does this mean for pharmacy practice?

- ✓ Confidence – **no clinically meaningful difference** between biosimilar and reference<sup>1,2</sup>
- ✓ **Interchangeability** and **switching** between brands<sup>1,2</sup>
- ✓ **Extrapolation** – pharmacies can stock one brand for all approved indications<sup>1,2</sup>



## Interchangeability, switching and substitution

### INTERCHANGEABILITY



**Exchanging** one medicine for another expected to have the same clinical effect<sup>1</sup>



- **Regulatory approval** of MAb biosimilars requires evidence of **similar immunogenicity** to reference biologic<sup>1</sup>
- **Interchangeability of biosimilars** supported by **178** clinical studies of brand switching (March 2020)<sup>3</sup>

### SWITCHING



**Physician** prescribes one medicine instead of another with the same therapeutic intent<sup>1</sup>



Physician

- European regulators have **approved brand switching**<sup>4</sup>

### SUBSTITUTION



One medicine is dispensed instead of another in the **pharmacy**, without consulting the prescriber<sup>1</sup>



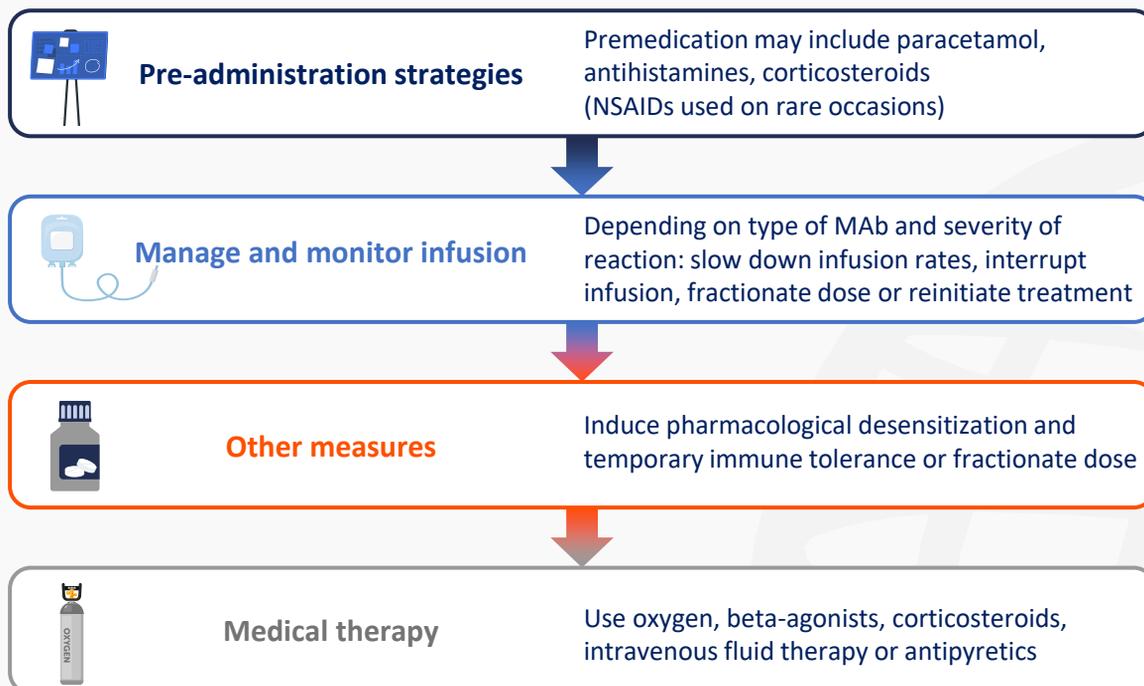
Pharmacist



## Practical aspects of administering MAb biosimilars

- Infusion-related reactions are the most common side effect when administering MABs and are usually manageable

### Management of infusion-related reactions<sup>5</sup>



## Transportation, storage and handling of MABs<sup>6</sup>

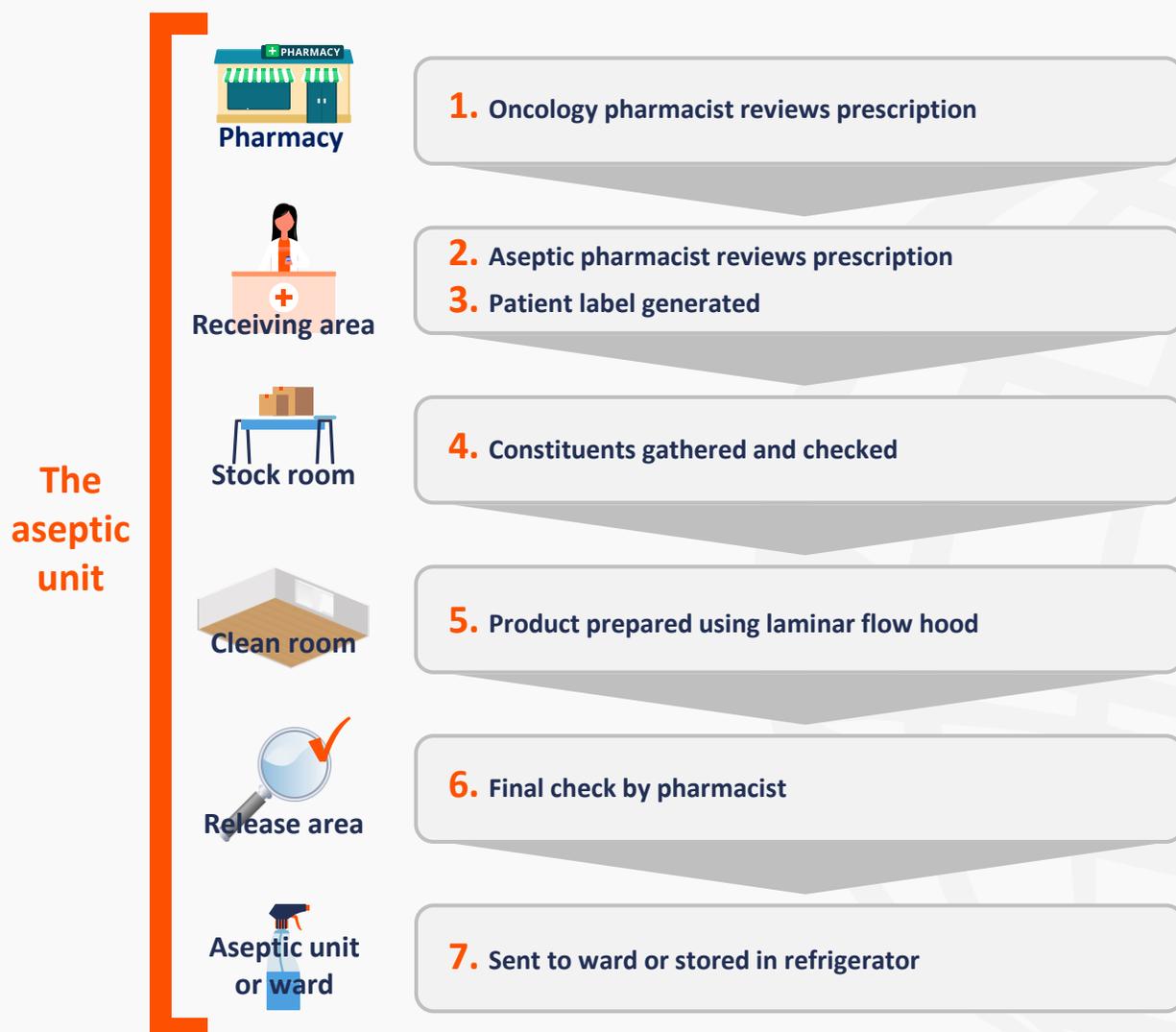
- Stress factors, e.g. temperature changes may degrade or denature MAB protein structure leading to instability and loss of efficacy
- Correct transportation and storage of MABs is key for maintaining their stability



## Preparation of MAb biologics for parenteral administration in patients with solid tumours

- The aseptic technique is used to ensure sterility and safety of the reconstituted product<sup>7</sup>

### The aseptic preparation pathway



Validity checks at each step to ensure traceability and safety<sup>6,8</sup>

- Reduce risks of microbial contamination
- Reduce risks of errors in preparation
- Ensure that the prepared medicines are appropriate for the patient
- Reduce levels of degradation of MAb product





## Abbreviations:

<b>MAb</b>	monoclonal antibody
<b>NSAID</b>	non-steroidal anti-inflammatory drug

## References:

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