



European Commission

Enterprise & Industry
Directorate-General

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INN Naming for Biosimilars

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Purpose of INN

- **Classification, Nomenclature**

“to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.”



Biological Complexity v INNs

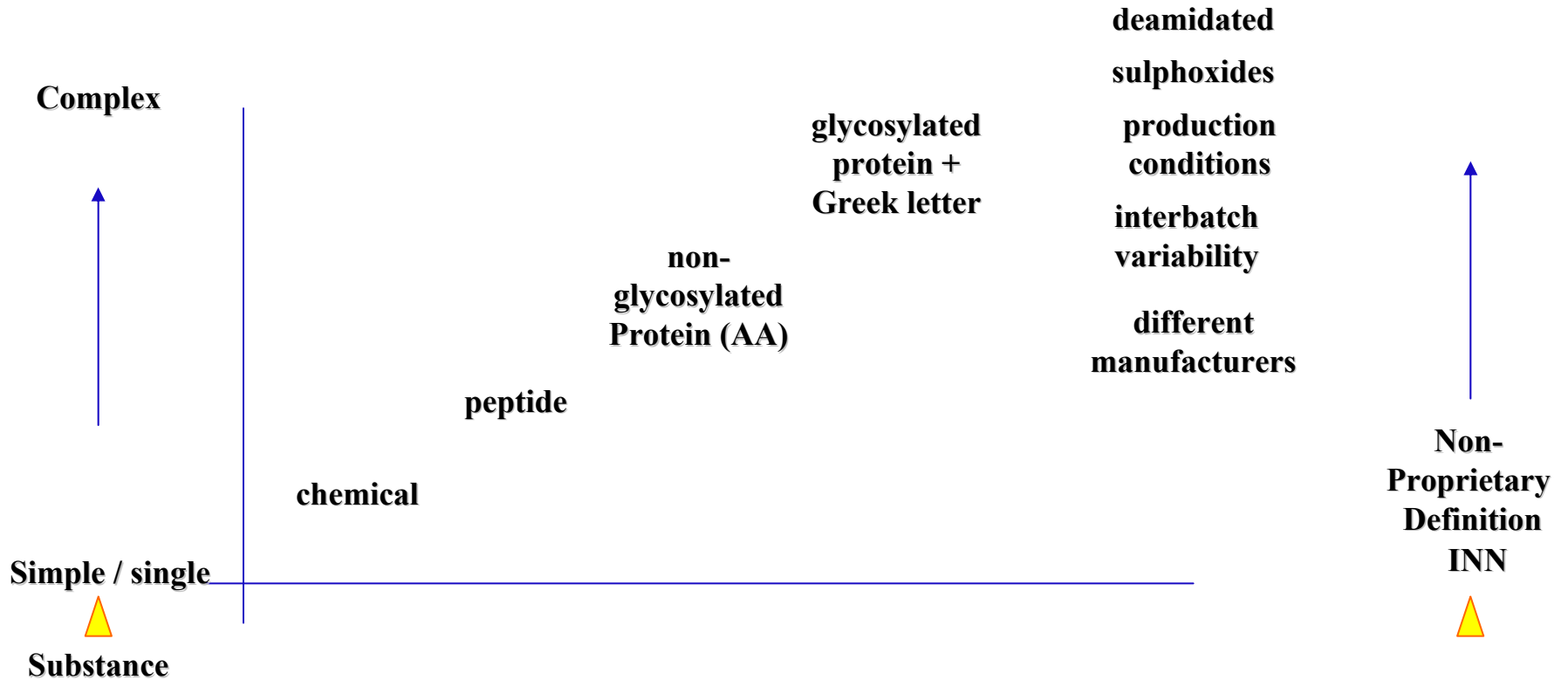
- **INNs can perform range of functions for chemicals**
- **Difficulties arise for complex active substances, e.g. vaccines**
- **Biologicals range in complexity and variability exists within a given product**



Current WHO Policy

- **INNs for glycosylated rDNA proteins**
 - **Core name based on Amino Acid sequence**
 - **Add Greek letter: “Differences” in glycosylation**
- **Difficult to define “Differences”**
 - **Also consider other sources of variability: e.g. manufacturing processes, batch-to-batch.**

Post-translation modifications



EU Perspective: INNs – Biotech. Proteins

- **For complex biologicals - may not be able to identify each individual substance**
- **INN contributes to, but is not a replacement for regulatory systems:**
 - **e.g. pharmacovigilance / traceability (NB applies to Finished Product – not active substance)**
- **INN classification at required level of detail**

FDA position

It would be the U.S. FDA's preference that INNs continue to be granted based only on molecular characteristics and pharmacological class of the active ingredient(s).

(...)

Concerns about inappropriate substitutions that can create safety issues may be beyond the scope of the INN program to address through nomenclature alone, and may be better addressed by specific steps taken by individual regulatory authorities to ensure appropriate prescribing."



CONCLUSIONS



Conclusions

- **Biologicals in general are complex**
- **Preserve logic and objectives of INN system**
- **INN classification at required level of detail**