EUROPEAN GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

European Biosimilars Group
EGA sector group

EGA-EBG Considerations on WHO's BQ Proposal

Suzette Kox, Senior Director International, European Biosimilars Group

WHO INN Open Session with Stakeholders

Geneva, 13 Oct. 2105

PATIENTS
Increasing patient access

QUALITY
Quality, safety and efficacy

VALUE
Investors in innovation

SUSTAINABILITY
160.000 jobs across Europe

PARTNERSHIP
Key partners for public health

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To provide sustainable access to high quality medicines for all European patients

EGA VISION

PATIENTS

QUALITY

VALUE

SUSTAINABILITY

PARTNERSHIP

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Thanks!

EGA continues to appreciate the WHO INN's Office's efforts to counteract the proliferation of divergent schemes for biologics around the world

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Outline

- **Introduction**
  - science supporting same INN
  - Intent of the INN
  - Existing identifiers
- **EGA-EBG position on WHO BQ proposal** *(June 2015 version)*
- **Summary recommendations**

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Regulatory science supports “comparable” / “highly similar” biologics share INNs

- If products pre- and post-manufacturing change are comparable, they retain the same INN
- Biosimilars are systematically developed to be highly similar to their reference products (EMA states similarity = comparability)
- State-of-the art analytical technologies in both comparability and similarity exercises allow detailed characterization and a sound regulatory science judgment
- Regulatory Authorities in “highly regulated markets” determine if sufficient comparability/similarity has been demonstrated
- If comparability/similarity is demonstrated no new INN is required
- This consistent scientific principle should continue to apply to all biologics including biosimilars
- Drug substances from different manufacturers should therefore be entitled to get the same INN if the substances are found to be comparable/highly similar

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The INN applies to the active substance; was never intended to identify products on its own

The intent of the INN

is …

- The identification of drug substance, not of the drug product
- To have a common nomenclature, ie, a means of classifying and cataloguing pharmacological classes

is Not …

- The sole means of identification of a medicinal product or its impurities
- A statement of therapeutic equivalence of a medicinal product
- A tracking and tracing tool for the use of a medicine

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Clarity is needed on which issues the BQ can address and who will use it

- The following arguments were brought in support of the BQ:
  - traceability, adverse reaction reporting, prescribing
- All of these needs are better fulfilled either with a trade name or by the combination of the INN + company name
- Unless the following point are clear, no change should be introduced
  - what the need is, and,
  - whether or not the proposed change effectively and safely addresses this need

So what need is being addressed with the BQ?

Which countries will use it?

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Many identifiers are already available today

- Trade name
- INN + company name
- 2D bar code (e.g. EU FMD unique identifier)
- ISO IDMP (identification of medicinal product) standards
- National drug code (NDC)
- Lot number …

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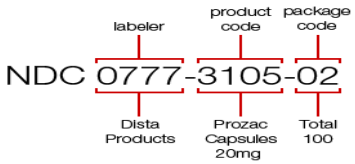

Do we really have a lack of identifiers?

Does another identifier really add value?

Or would it just increase complexity and confusion?

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Example of a powerful unique identifier: EU Falsified Medicines Directive (FMD)

- Data-Matrix code, developed to ISO-standards
- Key data elements:
  - Making each product unique:
    - Product code (GTIN/NTIN or PPN)
    - Randomized unique serial number
  - Facilitating Pharmaco-vigilance:
    - Expiry date
    - Lot number
  - National health number (where necessary)

Product #:	09876543210982
Lot:	A1C2E3G4I5
Expiry:	140531
S/N:	12345AZRQF1234567890

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ISO standards established for identification, under active implementation in the EU

- Worldwide system for internationally harmonized data definitions to establish unique identifiers for medicinal products to be used during their entire life-cycle for
  - approved medicinal products and
  - investigational medicinal products
- Driven by regulatory and pharmacovigilance requirements originally developed by ICH
- Fundamental research to establish a lasting framework of internationally accepted and relevant standards
- Allows exchange of medicinal product information in a robust and reliable manner
  - Why are these ISO standards not rolled out internationally?

ISO FDIS 11615 Health Informatics

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ISO standards established for identification
ISO IDMP 11238 – Defining Substances

- Unique ID for each substance, non-sequential, robust, non-semantic
- Substances are defined based on what they are
  - Not on how they are made or used
- Materials that are defined as the same substance are not necessarily bioequivalent or pharmaceutical equivalents

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The WHO BQ Proposal is not supported in its current form

- The BQ should NOT be implemented in countries where identification can be facilitated by other means
  (e.g. brand name, INN + company name)
- BQ should be **connected to company**
  - The company should define which of its units will be in charge of representing its "Global Group of Affiliated Companies" towards the WHO regarding the BQ globally **to maintain one global BQ per product**

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A random identifier is especially challenging

- Any identifier which has a somewhat ambiguous meaning can cause confusion
- A random identifier of consonants is much harder to remember:
  - yzxw, dpqb ...
- The likelihood is high a random identifier will be
  - Misspelled or, even more likely,
  - Not recorded at all.

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Any new identifier system must be tested systematically to ensure it does not do more harm than good

- Consequently, any new identifier system must be tested:
  - By an independent, renowned institution
  - In comparison to the system today (trade name or INN + company)
  - To demonstrate it actually does improve identification and reduce safety risks
  - With all key stakeholders (physicians, pharmacists, patients, drug safety officers, etc.)

**In the interest of patient safety,
no decision can be made on implementation
prior to systematic testing and
discussion with all stakeholders**

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Call for a moratorium and increased international dialogue

- WHO BQ proposal should not be implemented before a vast majority of regulators agrees
  - It is needed on their territory and,
  - It will be used;
- Given the recently published FDA draft guidance on nonproprietary naming of biological products which mimics to some extent the WHO BQ,

NEW

We call for a moratorium regarding the WHO BQ proposal and for further international exchange and dialogue

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Summary

- EGA-EBG does not support the WHO Proposal in its current form
- Clarification is needed on which issue(s) the BQ could actually address
- Traceability requires strong systems, training and consequent follow-up rather than additional identifiers
- Any new identifier bears safety risks and must be tested with all stakeholders
- We call for a moratorium regarding the WHO proposal and for further international exchange and dialogue
- EGA remains supportive of the use of trade names or INN + company name

EGA appreciates the efforts of the WHO INN office to maintain a globally unified naming system and is looking forward to contributing to further discussions!

THANK YOU FOR YOUR ATTENTION

QUESTIONS?

Acronyms

- BQ Biological Qualifier
- EBG European Biosimilars Group
- EGA European Generic and Biosimilar medicines Association
- EU European Union
- INN International Nonproprietary Name
- PV Pharmacovigilance
- WHO World Health Organization