

Abridged Application as Simplification in OTC Registration

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AGENDA

1

OTC Products

2

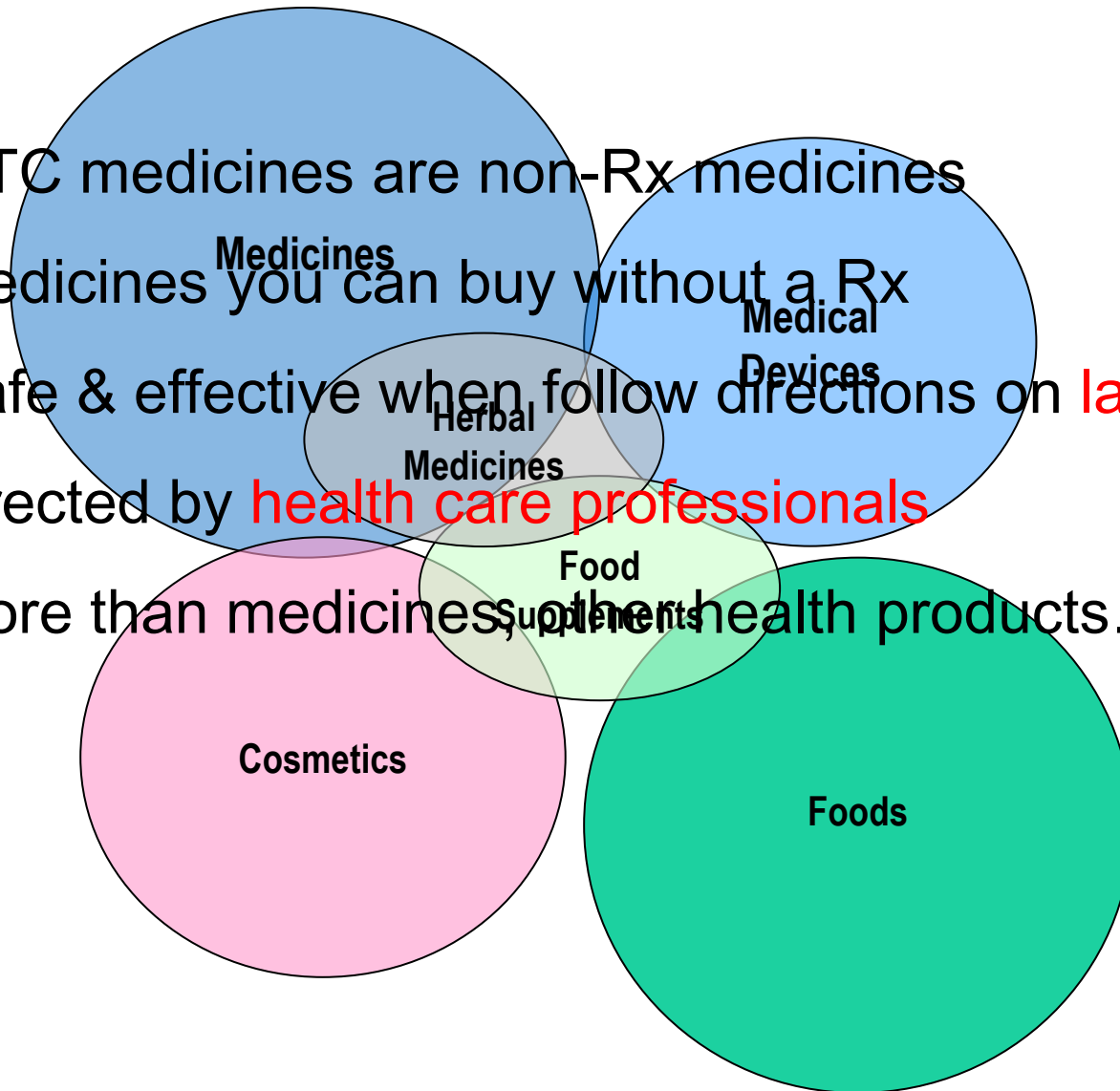
Registration Processes

3

Abridged Registration

1). Classification of OTC Products

- OTC medicines are non-Rx medicines
- Medicines you can buy without a Rx
- Safe & effective when follow directions on **label** & as directed by **health care professionals**
- More than medicines, other health products.....



2). Typical Registration Processes

- New registrations (NDA/ANDA)
- Rx→OTC switches
- New pack, new delivery innovations, line-extension
- Variations
- Unique to India – Ayurvedic registration
- Bibliographic submission
- Clone registrations
- Listing/Monograph
- Orange Book
- Other exemptions

3). Abridged Route as Simplification

- Full Evaluation
 - needing pharmaceuticals, pre-clinical & clinical
- Abridged Application
 - prior approval by at least one DRA at submission
 - often also generic drug
- Advantages:
 - PK & PD studies not needed
 - clinical data not needed or could be waived
 - for generic – BA/BE could be waived, eg. BCS
 - faster & more economical



3). Abridged Route – Enhancing Success

Current non-Rx medicines from at least:

- AU TGA – drugs substances listed in Sch 2 & 3 of SUSMP, or
- Health Can.– medicinal products classified under Sch II, III or U, or
- US FDA – products registered under OTC Monograph (21 CFR Chap.1.), or
- UK MHRA – medicinal products classified under P or GSL.

Additional Supports:

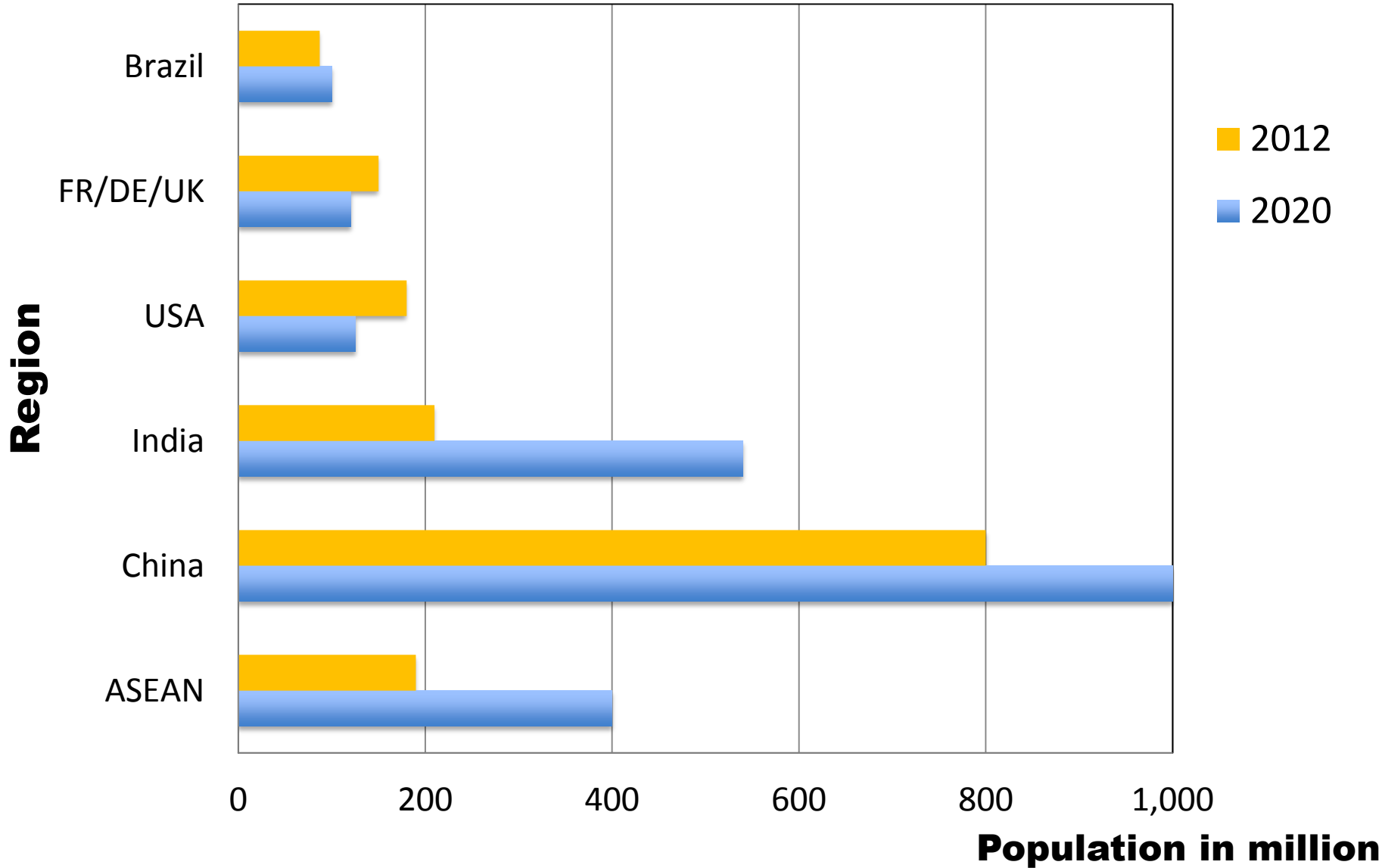
Well-documented active substance following standard texts:

- Martindale: The Complete Drug Reference..
- Handbook of Non-prescription Drugs
- Remington's Pharmaceutical Sciences.
- AHFS Drug Information.

*** Hold a pre-submission consultation with your DRA on possibilities/options**

Asia Grows Wealthier

• Middle-class population:



Source: Nielsen Estimates | Global Middle Class defined as \$16 to \$100 per day in 2005 PPP

Thank You Very Much!