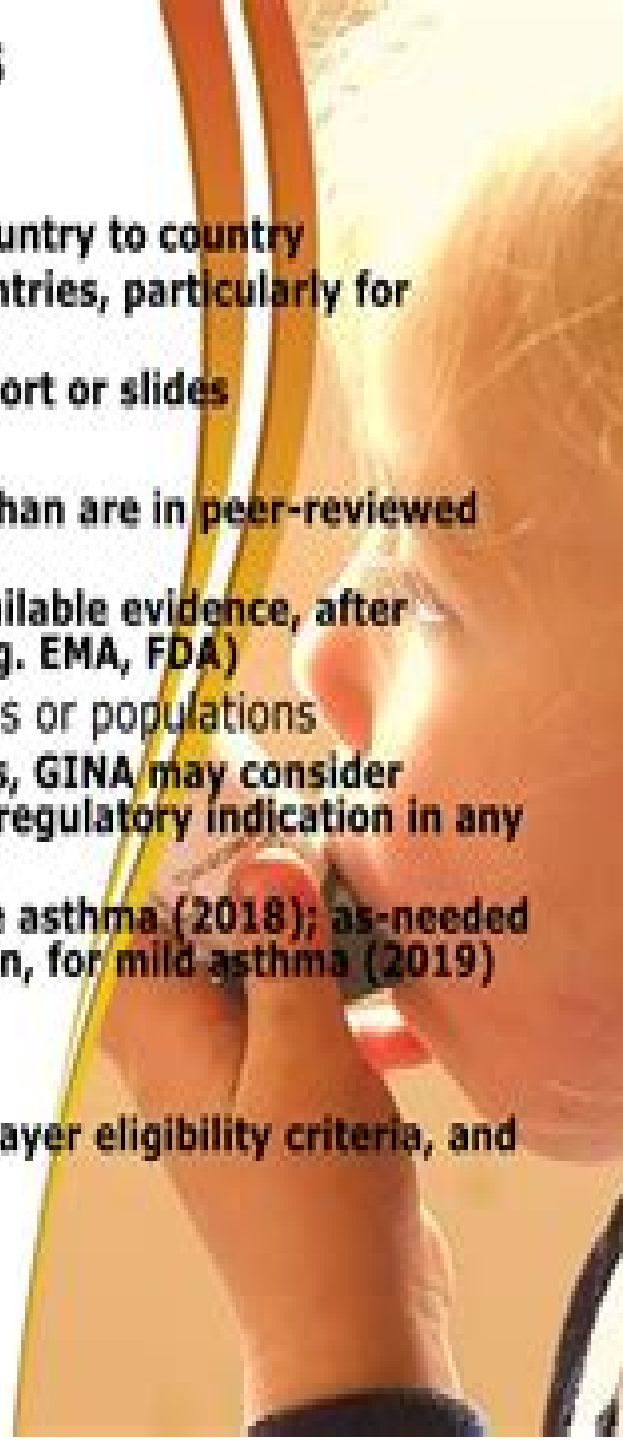


GINA methodology – additional details

- The GINA report is a global strategy document
 - **Regulatory approvals and submissions differ from country to country**
 - **Many recommendations are 'off-label' in various countries, particularly for paediatrics**
 - **The term 'off-label' is no longer used in the GINA report or slides**
- For new therapies
 - **Regulatory agencies often receive more safety data than are in peer-reviewed literature**
 - **GINA makes recommendations based on the best available evidence, after approval by at least one major regulatory agency (e.g. EMA, FDA)**
- For existing medications with evidence for new regimens or populations
 - **If satisfied with evidence for safety and effectiveness, GINA may consider making recommendations that are not covered by a regulatory indication in any country at the time**
 - **Examples: long-term macrolides for moderate-severe asthma (2018); as-needed ICS-formoterol, or taking ICS whenever SABA is taken, for mild asthma (2019)**
- When assessing and treating patients
 - **Use your own professional judgment**
 - **Take into account local and national guidelines and payer eligibility criteria, and licensed drug doses**



Bronchial Asthma Gina Guidelines 23

Mike Jess



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