



*Making Medicines Affordable*

# Generic Medicines Industry Experience with Art. 46

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# Experience with Art. 46 (1)

- Implementation: Similar messages as proposed for Art. 45
  - Alignment with other ongoing regulatory procedures (eg, referrals etc); one molecule being assessed on all aspects in parallel
    - Possibility to submit as grouped variation
  - Final wording and translation of relevant part of SmPC/PIL

# Experience with Art. 46 (2)

- We acknowledge that timelines for implementation of Art. 46 are within 60 days of publication of the PdAR.
- Experience with Art. 46 is limited given the number of PdARs that have been published but we anticipate that they will increase over time.



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**Thank you!**