EUROPEAN GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms

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EGA Vision 2020

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

EGA Vision 2020

EGA VISION

PATIENTS

QUALITY

VALUE

SUSTAINABILITY

PARTNERSHIP

Modified Release Products- Benefit for Patients

- **Benefit for patients to use high quality modified release medicines**
  - Better adherence to therapies
  - More patient-friendly pharmaceutical forms

Reassurance of High Quality Standards

- Guideline contributes to harmonised developmement and assessment of modified release pharmaceutical forms

High Value for Health Care System

- **Modified release products with well known active substance provide**
  - more affordable and
  - modern alternative of treatment to patients

Sustainability and Development of the Industry

- **Significant move of the generic industry into development of modified release forms**
- **Opportunity to access non-EU markets**
- **Single development program as a key success element**
  - Convergence across regions in clinical program

Partnership to assure Harmonised Implementation

- **Cooperation between authorities and industry is essential to achieve harmonised implementation in practice**
  - Facilitating development of modified release forms and
  - Increasing the predictability of the assessment outcome

- **Workshop as a great discussion platform to achieve those objectives**
- **Special acknowledgment for the EMA hosting the workshop**
  - Educational role in disseminating the information