EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public webpage on summary of product characteristics (SmPC)

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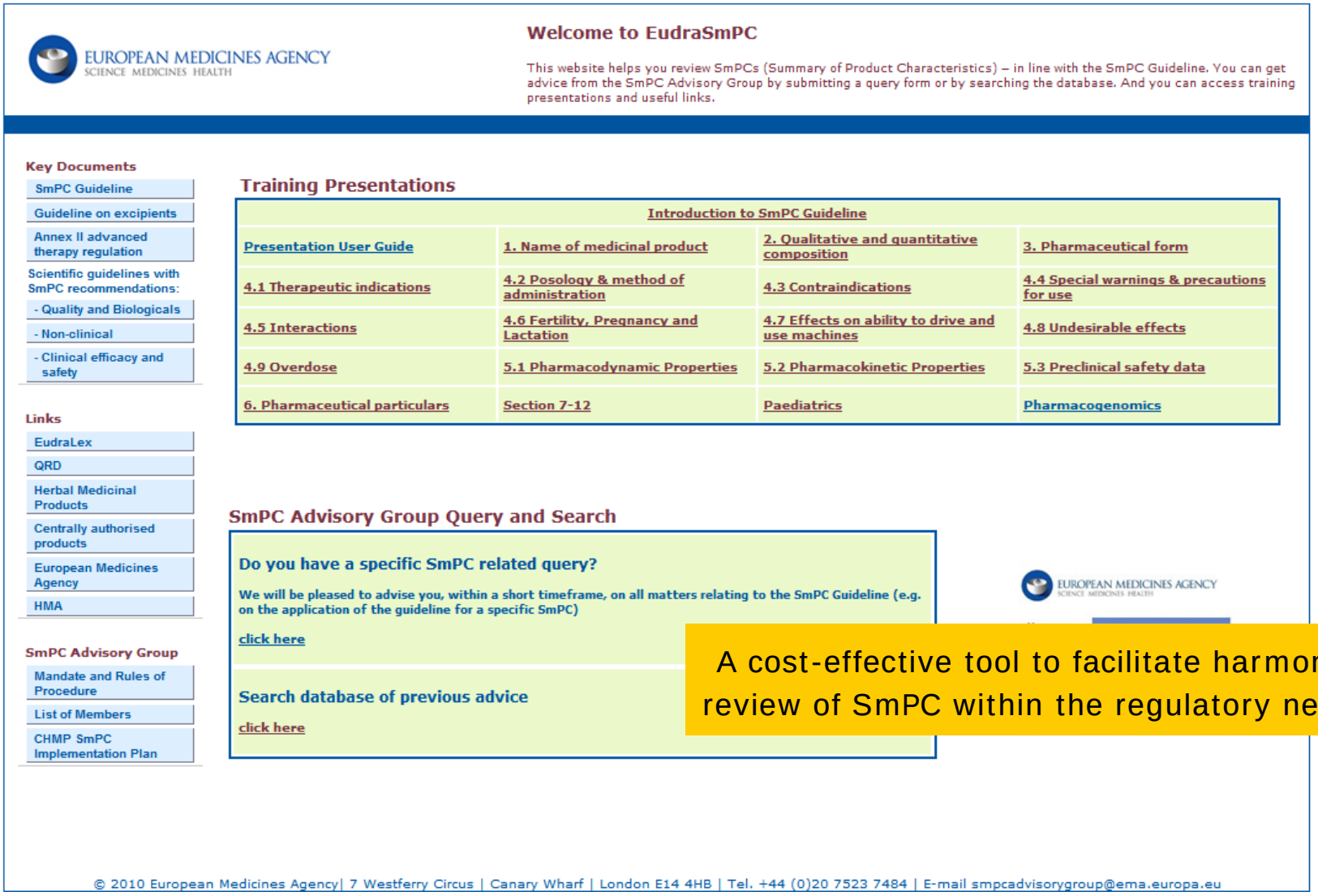
Background

- Information on benefit-risk of medicines: patients', consumers' and healthcare professionals' expectations (10/07/2009)
  - To optimise regulatory information
    - SmPC Guideline implementation plan
    - Revision of the template of package leaflet
    - EPAR usability project
  - To inform about the role of the regulatory authorities

    (e.g. where to find information on benefits and risks, where data come from)
- Involvement of Patients and Healthcare Professionals Organisations in the review of SmPC and package leaflet

SmPC implementation plan



A cost-effective tool to facilitate harmonised review of SmPC within the regulatory network

Why a public access to the webpage?

- Share training material with pharmaceutical industry
- Support Healthcare Professional or Patients Organisations' involvement in the review of SmPC or Package leaflet
- Increase HCPs' knowledge on SmPC
- Contribute to public awareness of regulatory information

Future public webpage

- Same content as EudraSmPC webpage except Query&Answer system which supports regulatory review process.
  - Update of training presentations + on-demand webinars

- New presentations:
  - "SmPC: what is it and what does it contain?"
    - A draft presentation is being circulated for your input
  - Future presentations
    - *Package Leaflet*
    - *Elderly population and SmPC information*
    - *Other suggestions?*