Scientific & Regulatory Affairs Committees 2012-2014

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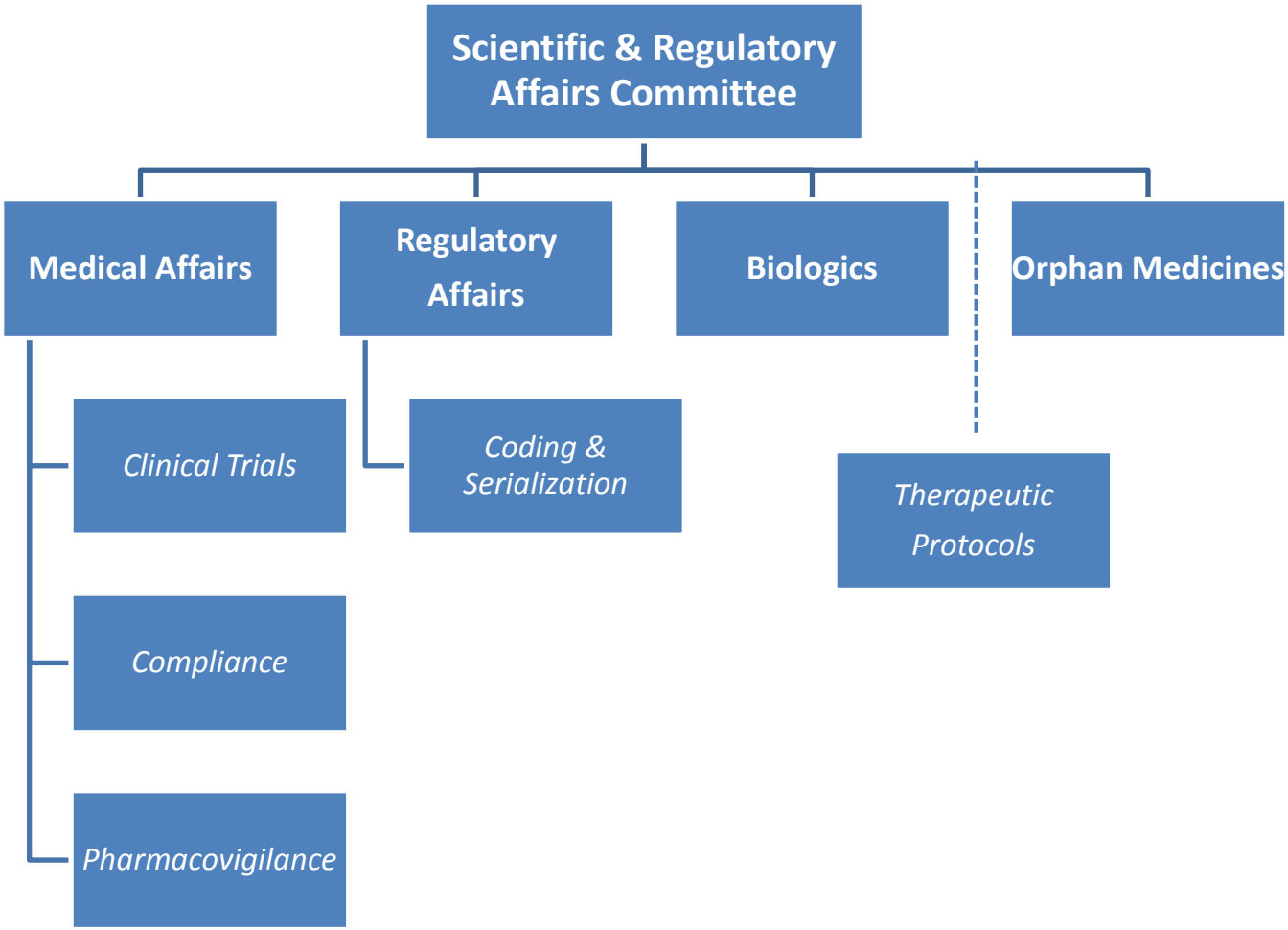
Scientific & Regulatory Affairs Committee



Medical Affairs Committee

Clinical Studies

- **Interventional Studies**
  - –SFEE positions re clinical research communicated to MoH & Proposal with changes in GG390/21.02.13
  - – Collaboration labs SFEE - EPLO & stakeholders: MoH, Ministry of Finance, Ministry of Development
    - EOF, YPE, Hospitals, Researchers, Academia etc
  - – Study on clinical research investment from NSPH 2012 VS. 2010: presented in ISPOR 2014
  - – SFEE Event in NSPH about CTs, in May 2014 with the participation of all stakeholders
  - – Increased publicity & acceptance within government officials
- **Non-Interventional Studies**
  - – Proposal on institutional & legislative framework required
- **«Delon» Registry**
  - – Access to the public for non-interventional studies : 56 studies uploaded

Training

- **Patient Education Programs**
  - – Proposal for adaptation within the code of ethics of SfEE of responsibilities and practices for patient education programs
- **Continuous Education Program SFEE - DEREE**
  - – Clinical Research
  - – Pharmacovigilance
  - – GCP for researchers
  - – Patient Centricity
  - – Medical Affairs

Medical Affairs Committee

Suggested Priorities for 2015

- **Clinical Studies**
  - Event on International Clinical Studies Day, May 2015
  - Evaluate Investment of Pharma Industry in Clinical Studies through an independent body (Medicines, diagnostic tests, research expenses, fees for professionals involved such as CROs, physicians etc.)
  - Preparation on the Implementation of the New European Regulation (working committees with stakeholders; Action plan for attracting Clinical studies and investment)
- **Therapeutic Protocols**
  - Workshop on the establishment of a transparent institutional framework on TPs.
- **Biologics**
  - Collaboration with the respective working team for an Educational Workshop on Biologics

Regulatory Affairs Committee

- Agreement over the method of implementation of **Regulation 712** in order to accelerate the use of variations before the issuance of the official decision.
- **Public access** to the approved **SPC_PIL** through an online database set up by EOF – Q1 2015
- Preparation of proposal for **fees reduction** based on payment per active substance/brand and not per SKU – 2015
- **Coding & Serialization** project
  - update re counterfeit medicines; Follow-up with partners to keep members & authorities updated on the progress of the project.
  - The project will be implemented in Greece **by 2023;** monitoring system through authenticity tags already in place. However, pharma companies **supplying products to the EU** have to comply by **2017**.

Orphan Drugs Committee

- Updated **Position paper** re policy framework necessary for P&R approval of orphan drugs.
- **Stakeholder call plan execution** to sensitize authorities on rare diseases & access problems patients face to incorporate our position in the **National Action Plan for Rare Diseases.**
  - President of Committee of National Action Plan for Rare Diseases
  - General manager of KEELPNO & Scientific Coordinator
  - EOPYY President & Director of Pharmaceutical Services
- Collaboration with Mrs. Michelakaki for the update of **Orphanet with national data**
- **Press Conference** re barriers in access of orphan drugs during the **World Rare Disease Day** (Prof. Bouros & General Secretary of Public Health Mr. Avgerinos)

Biologics Committee

- Rx of biologics based on brand name (GG3057/18.11.12)
- Collaboration with authorities to ensure that biosimilars and biologics are **not interchangeable** resulting in EOPYY circular 36/88/13 & GG64/16.01.14.
- Advisory Board of all stakeholders (physicians, hospital pharmacists, MoH, EOPYY, EPY/YPE, EOF) on biologics differentiation and added value that could result in **a consensus paper;** proposed to take place in 2015
- **Day Conference on Biologics** with the support of pharma industry & MoH hospice to provide a holistic view on biologics (regulatory, clinical and economic perspective) within Q2 2015

Thank you