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Cosmetics Products

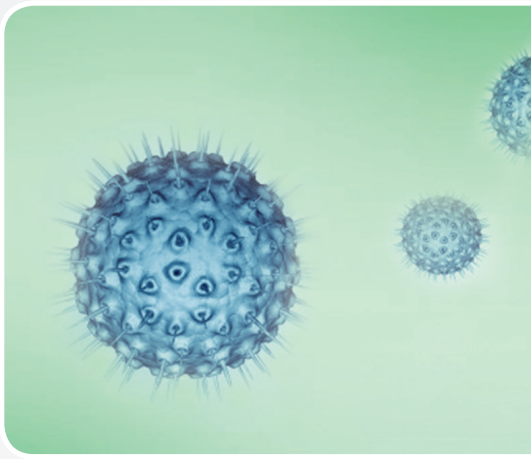
- Notification of distributors/manufacturers and notification of cosmetic products in the EU database CPNP
- Consultation and evaluation of product documentation and mandatory information
- Cooperation in the maintenance of up-to-date product information
- Advice and consultation concerning the labelling of cosmetic products
- Continuous support and updates regarding to EU legislation

Medical Devices

- Notification of medical devices and submission of documents to local authorities
- Classification of medical devices in accordance with European regulations
- Preparation, review and updating of technical documentation
- Recommendation and consultation in the area of product labelling
- Updating of information in accordance with current EU legislation

Veterinary Products

- Marketing authorisation of veterinary medicinal products (VMPs) and approval of veterinary products (VPs) through national procedure (NP) in the Czech Republic. Support and service during the process of marketing authorisation of VMPs and approval of VPs.
- Support for MRP, DCP and CP procedures.
- Preparation and checking of product information and documentation on the basis of documents supplied and legislation requirements
- Maintenance of up-to-date product information in accordance with legislation
- Contact with the national competent authority on the basis of documents supplied
- Consultation on mandatory labelling texts



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Medicinal Products

- Compilation and evaluation of the partner file, support in creating Module 1
- Creating eCTD files
- Negotiations with authorities, EU procedure management
- Lifecycle management for approved products (Renewal, Variation, Sunset clause…)
- **MA Holding** – full responsibility of MAH according to EU requirements and/or national regulations
- Contractual setup (marketing and distribution agreements))
- Establishment and maintenance of PIS
- Establishment and maintenance of system for safety and quality issues (rapid alerts, products recalls)
- Setting up of Product Information System (web services, contacts, inclusion into call centre, information compilation, training)
- 24/7/365 service (according to the local requirements)
- **Text management** (PIL, SPC, Labelling, Mockups)
- Harmonization of texts with EU reference product (generics)
- Translation of texts into all languages
- Braille requirements

Vigilance service

Medicinal Products, Veterinary Products, Medical Devices, Cosmetic products

Establishing Vigilance system

- Creation and running of the vigilance systems according to valid EU requirements
- Compulsory regular vigilance training of staff.

Vigilance system maintenance

- Complex services provided by Qualified Person
- Setting up of procedures with partners and authorities
- Non-stop services for the receipt of AE signals
- Verification and reviewing of serious unexpected events (SUE)
- Management of adverse effects of products reported by consumers, health professionals or authorities
- Data entry of adverse reactions in databases
- Submission of serious adverse events to the competent authorities
- Periodic literature search to identify safety information and adverse events
- Periodic Safety Update Reports (PSURs)/DLP harmonisation, if available

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