

Medical Devices

Registration and notification

- Registration of the distributor/importer/ manufacturer according to national requirements
- Notification of products
- Check of the completeness and quality of documentation. translation

Classification of the borderline products

- Assessment of the product
- Recommendation of options for placing of the product on the market



Consultation and evaluation of product documentation and mandatory information

- Consultation and review of mandatory information, use promotional claims
- Consultation during the preparation of labelling

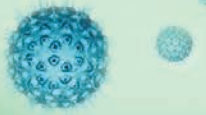
Pricing & Reimbursement services (SK, CZ)

- Completeness and quality check
- Documents preparation and submission
- Contact person for authority.

Vigilance system

- Set-up the system for monitoring safety
- Training of the staff
- Service of the responsible and contact person
- Verification and assessment of serious undesirable effects (SUE)
- Reporting





Cosmetic products and Food Supplements

Registration Products and Food Supplements

- Registration of the subjects, notification of products
- Review of data completeness and quality
- Maintenance and update
- Monitoring of legislation and reporting



Classification borderline products according to the European regulation

- Assessment of the product
- Recommendation of options for placing of the product on the market

Consultation and evaluation of product documentation and mandatory information

- Consultation and review of mandatory information, use promotional claims
- Consultation during the preparation of labelling

Vigilance system

- Set-up the system for monitoring safety
- Training of the staff
- Service of the responsible and contact person
- Verification and assessment of serious undesirable effects (SUE)
- Reporting

