



UNIVERSITÀ DEGLI STUDI DI PALERMO

DEPARTMENT	Scienze e Tecnologie Biologiche, Chimiche e Farmaceutiche		
ACADEMIC YEAR	2023/2024		
BACHELOR'S DEGREE (BSC)	ANIMAL PHARMACEUTICALS AND NUTRACEUTICALS		
SUBJECT	REGULATIONS ON FOOD, HEALTH PRODUCTS AND VETERINARY DRUGS		
TYPE OF EDUCATIONAL ACTIVITY	B		
AMBIT	50150-Discipline Farmaceutiche e Tecnologiche		
CODE	22968		
SCIENTIFIC SECTOR(S)	CHIM/09		
HEAD PROFESSOR(S)	SCIALABBA CINZIA	Ricercatore a tempo determinato	Univ. di PALERMO
OTHER PROFESSOR(S)			
CREDITS	6		
INDIVIDUAL STUDY (Hrs)	102		
COURSE ACTIVITY (Hrs)	48		
PROPAEDEUTICAL SUBJECTS			
MUTUALIZATION			
YEAR	3		
TERM (SEMESTER)	1° semester		
ATTENDANCE	Not mandatory		
EVALUATION	Out of 30		
TEACHER OFFICE HOURS	SCIALABBA CINZIA Tuesday 11:00 13:00 Via Archirafi 30. Terzo Piano		

DOCENTE: Prof.ssa CINZIA SCIALABBA

PREREQUISITES	Knowledge of pharmaceutical technology
LEARNING OUTCOMES	<p>Knowledge and understanding: the student will have to demonstrate adequate knowledge and understanding of the EU and national veterinary pharmaceutical and feed legislation.</p> <p>Ability to apply knowledge and understanding: the student will have to demonstrate knowledge and concepts useful for understanding and interpreting the most recent Community and national legislation on feed legislation, health products and veterinary drugs.</p> <p>Making judgements: the student will have to demonstrate the ability to critically examine and argue the principle aspects of Animal Feed and Veterinary Pharmaceutical Legislation.</p> <p>Communication skills: the student will have to demonstrate the ability to communicate the acquired skills with appropriate terminology and to present the results of the studies even to a non-expert audience.</p> <p>Learning skills: the student will have to demonstrate that they possess the learning skills to independently increase their knowledge of EU legislation on feed safety and the marketing authorization of veterinary medicinal products.</p>
ASSESSMENT METHODS	<p>Learning will be evaluated through an oral examination and expressed in thirtieths. Oral examination aims to assess the student skills and disciplinary knowledge.</p> <p>The questions will be specifically designed to test the learning outcomes and to verify: a) the knowledge of topics; b) the ability to process the knowledge, c) the scientific language and presentation skills. The assessment has a final grade included in the following range: 30-30 with honours (excellent), corresponding to "excellent knowledge of topics, excellent use of language, good analytical skills, the student can implement his/her knowledge to solve the posed problems"; 26-29 (very good), corresponding to "good mastery of topics, very good use of language, the student can implement his/her knowledge in order to solve the posed problems"; 24-25 (good), corresponding to "basic knowledge of the main topics, fair use of language, with moderate capability to independently implement knowledge to solve the posed problems"; 21-23 (satisfactory), corresponding to "the student doesn't possess full mastery of the main topics but possesses knowledge of them, satisfactory use of language, poor ability to independently implement the acquired knowledge"; 18-20 (passing grade), corresponding to "poor basic knowledge of main topics and scarce technical language, very poor ability to independently implement the acquired knowledge"; unsatisfactory when the student doesn't possess an acceptable knowledge of the contents of the topics dealt with during the course.</p>
EDUCATIONAL OBJECTIVES	The objective of the course is the knowledge of the principles and legislation on hygiene feed, manufacturing chain, marketing, distribution of feed, additives, animal by-products, which can be used as feed, and medicated feed. The aim of the course is also the acquisition of the tools for understanding the regulatory framework for the production and marketing of health products and veterinary medicines, and their correct classification for regulatory purposes and to give knowledge concerning the registration and the use of a veterinary medicinal product.
TEACHING METHODS	In addition to the lectures using PowerPoint presentations, the course provides the use, after training and group exercises, of suitable computer media for the collection and analysis of Community and national laws as well as of the most significant doctrinal elements. The analysis of some important regulations will serve as a guide and as a model for the analysis and the normative texts interpretation.
SUGGESTED BIBLIOGRAPHY	<p>Compendio di diritto alimentare, Di Costato L. et al, CEDAM 2022</p> <p>Normative e regolamenti europei. Legislazione farmaceutiche , Paola Minghetti, Nona edizione CEA.</p> <p>Legislazione farmaceutica nella Pratica Professionale, G. Barberini L. Casettari</p> <p>www.salute.gov.it/portale/medicinaliVeterinari</p>

SYLLABUS

Hrs	Frontal teaching
6	European regulation on laying down requirements for feed hygiene. Authorisation for the production and placing on the market of feed and health veterinary products.
4	Marketing and labeling of health products for veterinary use
4	Good manufacturing standards for feed and health products (GMP).
4	Quality and safety of feed and healthy products for veterinary use.
6	National and European organizations working in the health field. Role of regulatory affairs in the pharmaceutical veterinary industry.
4	Veterinary Medicinal Products European Regulation
3	Classification of veterinary medicines.

SYLLABUS

Hrs	Frontal teaching
4	Marketing Authorisation (MA). Registration dossier
3	Veterinary Pharmacovigilance.
3	Prescribing and using of veterinary medicines. Electronic prescription.
3	Regulation of veterinary narcotics.
4	Guidelines on the prudent use of antimicrobials in veterinary medicine.