ACCADEMIC YEAR 2023/2024

General information		
Academic subject	**DRUG LEGISLATION, PHARMACOVIGILANCE AND TOXICOLOGY**	
Degree course	Animal Sciences L38	
Academic Year	II year	
European Credit Transfer and Accumulation System (ECTS)	6	
Language	Italian	
Academic calendar (starting and ending date)	II Semester: 26/02/2024 - 14/06/2024	
Attendance	Mandatory	

Professor/ Lecturer		
Name and Surname	Claudia Zizzadoro; Olimpia Lai	
E-mail	claudia.zizzadoro@uniba.it; olimpia.lai@uniba.it	
Telephone	+39 080 4679922; +39 080 4679924	
Department and address	Campus di Medicina Veterinaria, S.P. 62 per Casamassima km. 3, Valenzano (BA)	
Virtual headquarters	Piattaforma Microsoft Teams se richiesto (Codice Teams: mj6qar3)	
Tutoring (time and day)	Mercoledì: 15:00-17:00; Giovedì: 11:30-13:30 (Claudia Zizzadoro) Martedì: 13:00-15:00; Mercoledì: 13:00-15:00 (Olimpia Lai) previo appuntamento concordato via email	

Syllabus	
Learning Objectives	The teaching aims to explain the health, ecological and ethical problems that arise from use, misuse, abuse and non-use of drugs in the professional contexts for which the students are being trained. The ultimate purpose is to make the students understand the origin of the current legislation on drugs for food-producing and non-food-producing animals, the role that the rules dictated by existing law play in the management of the risk for drug-related problems, and hence the importance of respecting such rules. The teaching also aims to make the students understand the hazards arising from potential exposure of food-producing and non-food-producing animals to toxic substances of natural and anthropogenic origin, as well as the importance of adopting strategies to avoid or reduce such exposure in order to protect health and welfare of the various animal species, animal wildlife, and health of the consumer of foodstuffs of animal origin.
Course prerequisites	Students should possess knowledge and competence regarding the anatomy, histology, cytology, physiology, immunology, pathology and pathophysiology of higher animals. Furthermore, knowledge and competence regarding structural and functional characteristics of the most common pathogens of higher animals (bacteria and parasites) are required, along with knowledge and competence in chemistry and biochemistry. Finally, knowledge and competence regarding farming practices and sanitary management of food-producing and non-food-producing animals would be opportune, along with a good confidence with the reading of texts in English.
Contents	***Drug legislation and Pharmacovigilance*** • Introduction to the subject. Definition of drug. Difference between "classic drugs" and "chemotherapeutic agents". Applications of drugs in the professional contexts addressed by this Course of Study and resulting problems.

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	• Fundamentals of General and Clinical Pharmacology ☐ Primary pharmacodynamics of "classic drugs": mechanisms responsible for the primary (desired) pharmacological effects; quali-quantitative aspects of drug receptor action and causes of variability. Primary pharmacodynamics of "chemotherapeutic agents": selective toxicity; mechanisms responsible for the drug anti-pathogen effect; quali-quantitative aspects of drug anti-pathogen activity and causes of variability. ☐ Drug administration: major routes of drug administration; drug formulations and pharmaceutical kinetics. ☐ Pharmacokinetics: basic principles of drug movement relative to the animal body; drug absorption, distribution, metabolism and excretion (quali-quantitative aspects and causes of variability). ☐ Secondary (side and toxic) effects of "classic drugs" and "chemotherapeutic agents": mechanisms responsible for their production (secondary pharmacodynamics), conditions favouring their occurrence and causes of variability. ☐ Other possible undesirable consequences of drugs for the animals subjected to pharmacological treatment: hypersensitivity and idiosyncratic reactions, dismicrobism and biotropic phenomena. ☐ Drug administration protocol and its relationship with clinical efficacy, tolerability and toxicity of locally and systemically acting drugs. Therapeutic window. Medication leaflets. Variability of the clinical response to drugs. Indexes of drug safety (therapeutic index and drug's safety margin). ☐ Dangerousness of exposure to drugs used in food-producing and non-food-producing animals for human and environmental health: professional risks, drug residue toxicity and withdrawal time, environmental impact, selection of acquired drug resistance, technological dismicrobism • Main national and european laws that regulate the use of pharmacologically active substances in food-producing and non-food-producing animals, as well as in animal feed production ***Toxicology*** • General part ☐ Definition of toxic substance. ☐ Dose-response relationship: determination of toxicity and dose-response curves. ☐ Toxicity tests. ☐ General toxicity: short-, medium- and long-term toxicity. ☐ Special toxicity: teratogenesis, mutagenesis, carcinogenesis. ☐ Toxic dose: minimum toxic dose, maximim toxic dose, lethal dose 50. ☐ Fate of xenobiotic compounds in living organisms: routes of exposure, toxicokinetics, metabolism. ☐ Bioaccumulation and Biomagnification. ☐ Factors influencing toxicity. • Special part ☐ Pesticides: herbicides, insecticides, rodenticides. ☐ Heavy metals: mercury, lead, cadmium, fluorine.

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	☐ Persistent organic pollutants (POPs): dioxins, polychlorinated biphenyls (PCBs), *polycyclic aromatic hydrocarbons* (PAHs). ☐ Mycotoxins. ☐ Algal biotoxins. ☐ Toxic plants. ☐ Radionuclides. • Residue Toxicity ☐ Definition of residue. ☐ Classification of residues. ☐ Factors influencing residue formation in food-producing animals. ☐ Toxicological risk assessment of residues. ☐ Bioavailability and relay toxicity of residues. ☐ Main national and european laws dealing with residues. ☐ Concept of Residue Acceptability and Definition of Maximum Residue Level (MRL). ☐ Concept of Residue Tolerance in relation to environmental contaminants. ☐ Newly formed residues ***Practical lessons*** • pharmaceutical calculations • analysis and discussion of medicinal leaflets • reporting adverse drug reactions for pharmacovigilance • access to official websites in order to report an adverse drug reaction or to fill in the Pharmacological treatment register or animal transport documents
Books and bibliography	• Anderson M. "Bill's Clinical Pharmacology and Therapeutics for Veterinary Technicians". Elsevier (Health Science Division), 5th Edition (2023) • Belloli C., Carli S., Ormas P. "Farmacologia veterinaria". II Ed. Idelson-Gnocchi (2021) • Gupta R.C. "Veterinary Toxicology, Second Edition: Basic and Clinical Principles". Academic Press, 2nd Edition (2012) • Plumlee "Clinical veterinary toxicology". Mosby Inc. Ed. (2004) • Mengozzi & Soldani "Tossicologia veterinaria". Ed. Idelson-Gnocchi (2010)
Additional materials	Material provided by the teachers, consisting of the PDF version of the power point presentations shown during the lectures (made accessible online via Google Drive or Teams, immediately after the end of the teaching course)

Work schedule			
Total	Lectures	Hands on (Laboratory, working groups, seminars, field trips)	Out-of-class study hours/ Self-study hours
Hours			
150	***40***	***10***	***100***
ECTS			
6	***5***	***1***	

Teaching strategy	
	Lectures will be hold in a classroom, using power point presentations and/or videos as a support. Students will be stimulated to actively contribute to the discussion of the various topics, and possible curiosities and/or questions arisen from them will be taken as the starting point for further in depth discussions.

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	Practical lessons will also take place in a classroom (using, where needed, internet connection) and will consist of various activities including written exercises, group discussions, simulations. During the practical lessons, the theoretical concepts will be problematized and contextualized with situations from real everyday professional life, with the aim to make the students' learning process as meaningful as possible, and to allow students to grow familiar with practical aspects of drug manipulation and management that will be part of their job in the future.
Expected learning outcomes	
Knowledge and understanding on:	By the end of the lectures, the student is expected to have acquired knowledge and understanding of the following topics: ○ basic principles of the interaction between drugs and living organisms that are treated with such drugs (food-producing and non-food-producing animals) or that are exposed to such drugs (workers and consumers of foodstuffs of animal origin, as well as micro- and macro-organisms with pathogenic, ecological or technological roles); ○ factors that influence the quali-quantitative aspects of drug-organism interaction and its effects; ○ main national and european laws that regulate the use of drugs in food-producing and non-food-producing animals, as well as in animal feed production; ○ specific drug-related responsibilities assigned by legislation to professional figures that are formed by this Bachelor degree course; ○ origin and toxic potential of the various natural and anthropogenic xenobiotics of toxicological interest; ○ basic principles of toxicodynamics, toxicokinetics, antidote therapy and decontamination; ○ principles that regulate the movement of pollutants along the trophic chain.
Applying knowledge and understanding on:	By the end of the lectures, the knowledge and understanding of the student is expected to turn into: ○ conscious, responsible and virtuous approach to the activities linked to the professional practice that include drugs as potential chemical hazards (e.g. implementation of some of the pharmacological treatments prescribed by veterinarians and monitoring of the animal response to treatment; production of animal feed containing drugs or pharmacologically active additives; trade of foodstuffs obtained from pharmacologically treated animals; storage and manipulation of the medications that are to be administered to animals or added to feed; disposal of unused or expired medications); ○ conscious, responsible and vituous approach to situations linked to the professional practice that imply or may imply exposure of food-producing and non-food-producing animals to natural and/or anthropogenic toxic xenobiotics, or contamination of the trophic chain and of foodstuffs of animal origin.
Soft skills	By the end of the lectures, the student is expected to have acquired the following skills: • *Making informed judgments and choices* ○ understand the main information reported in the leaflet of pharmaceutical products and turn them into correct management and handling of these products when treating the animals (food-producing and non-food-producing animals) or preparing medicated feed;

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	○ differentiate between desirable and indesirable effects of drugs occurring in the treated animals; recognize possible unwanted effects arising in the workers that manipulate medicines or in the environment; report adverse drug reactions to health professionists; ○ predict the behaviour of a drug after administration or exposure, as well as how the intervention of certain factors may change drug behaviour and the biological response arising from it; ○ fill in and manage the documentation for assuring the traceability of the medicines and medicated feed that are used in animals (both food-producing and non-food-producing animals) and in the production of animal feed (for what falls in the competence of the professional figures formed by this Bachelor degree course); ○ predict and recognize the situations in which animal exposure to toxic xenobiotics of natural or anthropogenic origin may occur, identifying the most critical activities that are carried out in a geographic area (e.g. presence of factories, garbage dumps, agricultural activities, urban maintenance); ○ choose and implement the most appropriate remedial actions in case of animal exposure to toxic xenobiotics (to the extent of what the professional figures formed by this Bachelor degree course are allowed to do). • *Communicating knowledge and understanding* ○ communicate with veterinarians (e.g.: understand their instructions regarding drug administration, report effects observed in the treated or intoxicated animals, report the intervention of factors that may modify the response of animals to drugs and/or toxicants); ○ communicate with the farmer, the farmworkers and/or the animalkeepers (e.g. explain the meaning of the rules that govern the administration of drugs to animals, as well as the production of medicated feed, and the importance of applying them; acquire information that may help identify possible sources of animal intoxication) ○ communicate with inspectors during pharmacosurveillance inspections; ○ communicate with local authorities in case of environmental contamination that may put at risk wildlife species (particularly the protected ones); ○ communicate with colleagues (i.e. other technicians) in order to share professional experiences involving drugs or toxicants and/or to express personal opinions in a discussion about drugs, toxicants and their management strategies. • *Capacities to continue learning* ○ keep up with the continuous changes occurring in veterinary drug market and legislation (e.g. registration of new medicines, removal of some medicines from the market, abrogation of laws, adoption of new laws), as well as in the exposure of living organisms to toxicants of natural and anthropogenic origin (e.g. occurrence of ecological disasters, impact of climate change); ○ undertake more advanced study courses or training internships at public or private institutions (e.g. EFSA) to broaden or deepen personal knowledge of drugs, toxicants and their management

Assessment and feedback	
Methods of assessment	For both parts of the teaching (namely, "*Drug Legislation and Pharmacovigilance*" and "*Toxicology*"), the acquirement of the expected learning outcomes by the

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	students will be assessed by an oral examination focusing on at least three different topics of the program. During the "*Drug Legislation and Pharmacovigilance*" examination the ability to solve an exercise of pharmaceutical calculation will also be verified. Passing the "*Drug Legislation and Pharmacovigilance*" exam is prerequisite for admission to the "*Toxicology*" exam. Students can take the two orals on the same exam session or on different exam sessions. In the latter case, students must take the "*Toxicology*" exam within 3 months after passing the "*Drug Legislation and Pharmacovigilance*" exam. Otherwise, the first part of the exam should be repeated.
Evaluation criteria	During the examination procedure, students will have to demonstrate: • *Knowledge and understanding (Scored from 1 to 8 points)* ○ knowledge and understanding of the concepts and principles that regulate the interaction of xenobiotics (drugs and toxicants) with living organisms; ○ knowledge of the problems that can derive from the interaction of drugs and toxic substances with living organisms; ○ knowledge of the rules governing the use of drugs in animals (food-producing and non-food producing) and in the production of medicated feeds; ○ knowledge of the origin and mode of formation of the various toxic substances, as well as of the principles that regulate the movement of pollutants along the trophic chains. • *Applying knowledge and understanding (Scored from 1 to 8 points)* ○ understanding of how adherence to the rules dictated by the various regulations makes it possible to eliminate or mitigate the problems that may arise from the use of drugs in animals (food-producing and non-food producing) and in the production of medicated feed; ○ understanding of how it is possible to intervene to reduce the exposure of animals (food-producing and non-food producing) to toxic substances of natural or anthropic origin and/or to reduce the contamination of trophic chains or foodstuffs of animal origin. • *Autonomy of judgment (Scored from 1 to 3 points)* ○ ability to critically think about the study conducted, autonomously identifying and solving new problems, different from those analyzed during the lectures; ○ ability to autonomously formulate one's own opinion or reflection on issues inherent to general and applied pharmaco-toxicology. • *Communicating knowledge and understanding (Scored from 1 to 3 points)* ○ ability to summarize and fluently organize knowledge; ○ ability to effectively and consistently present one's reasonings to specialist and non-specialist interlocutors; ○ ability to use proper pharmaco-toxicological vocabulary competently • *Capacities to continue learning (Scored from 1 to 8 points)* ○ ability to answer the questions proposed in a non-mnemonic but reasoned way, establishing logical connections between concepts ○ ability to identify the connections between this course and the others attended over the years, also inherent to disciplines that are not strictly related to pharmacology and/or toxicology
Criteria for assessment and attribution of the final mark	For each part of the examination procedure (namely, "Drug Legislation and Pharmacovigilance" and "Toxicology"), a partial grade expressed out of thirty will be awarded (with 18/30 being the minimum passing grade) The highest grades will be attributed to students who demonstrate good skills in exposition, critical reasoning

	and propriety of language. The final grade (that will be put on record) will be calculated as the arithmetic mean of the two partial grades (rounded up).
Additional information	

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