United States Department of the Interior

NATIONAL PARK SERVICE
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DIRECTOR'S ORDER #77-4: USE OF PHARMACEUTICALS FOR WILDLIFE

Approved: SHAWN BENGE Digitally signed by SHAWN BENGE Date: 2021.03.26 16:42:02 -04'00'

Deputy Director, Operations
Exercising the Delegated Authority of the Director, National Park Service

Effective Date: 3/26/21

Duration: This Order will remain in effect until rescinded or superseded.

Contents:

1. BACKGROUND

Natural resource management and research programs conducted in national parks may require administration of pharmaceuticals to wildlife (See *Management Policies* (2006), section 4.4.2). Pharmaceuticals commonly used in wildlife programs include immobilization drugs (e.g., anesthetics, sedatives, neuroleptanalgesics), antibiotics, vaccines, contraceptives, anti-parasitic drugs, and euthanasia agents. For the purposes of this Director's Order (Order) only, the term "wildlife" means animals that are wild in their place of origin, as well as other wild-living or feral animals.[1] Many of these species cannot be safely restrained or handled without the use of pharmaceuticals. Pharmaceuticals are also used to treat, prevent, or manage non-native diseases or diseases resulting from human intervention, diseases that threaten at-risk species, animal diseases that threaten human health, or otherwise to meet established park objectives. Contraceptives may be applied as a form of reproductive intervention to manage wildlife populations. Euthanasia agents may be administered when these techniques meet approved National Park Service (NPS) management objectives.

[1] Administration of pharmaceuticals to NPS-owned domesticated animals should be by, or under the supervision of, a licensed veterinarian in the standard course of veterinary practice.

Most of the pharmaceuticals used for wildlife are federally regulated to help safeguard human and animal health. NPS staff must possess adequate knowledge and experience in the use of pharmaceuticals for wildlife to provide an adequate standard for professional care, and to assure human safety.

The use of vaccines and other veterinary biologics is regulated primarily by the Center for Veterinary Biologics, Animal and Plant Health Inspection Service, U.S. Department of Agriculture; one exception is that contraceptive vaccines, as well as other contraceptive formulations used in free-ranging wildlife, are regulated by the Environmental Protection Agency (EPA). The use of other pharmaceutical agents in animals (i.e., animal drugs) falls under the jurisdiction of the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act and the Food and Drug Administration Modernization Act of 1997. Additional guidance is contained in the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994. These laws and their implementing regulations govern the prescription of animal drugs and the extra-label use of drugs. Extra-label (or off-label) use of drugs refers to the administration of an approved human or animal drug in a manner not in accordance with label directions. Extra-label use of drugs for wildlife is often necessary because the drugs are not licensed specifically for use in these species.

Further, many of the drugs used for wildlife, particularly for field anesthesia, are controlled substances whose use is restricted by the Drug Enforcement Administration (DEA). Controlled substances are narcotics and other dangerous drugs that are classified into five groups based on their potential for abuse and ability to cause psychic or physical dependence. A high degree of proficiency is required to safely and effectively administer these drugs. The Controlled Substances Act, as amended, requires an individual or agency to possess a DEA registration to purchase these controlled substances, and details requirements that govern recordkeeping and storage of controlled substances.

Finally, some pharmaceuticals, particularly new injectable immobilization drugs and contraceptives, are available for use prior to licensing to collect data that will be used in their registration. These products are regulated by FDA as Investigational New Animal Drugs (INADs) or by EPA under an Experimental Use Permit (EUP). Use of INADs and EUPs requires specialized authorization from the drug's sponsor (i.e., that entity seeking drug approval), for application under a research protocol.

The care and use of animals in research is governed by the Animal Welfare Act. If pharmaceuticals are administered as part of a research project, requirements of the Animal Welfare Act, including protocol review and approval by an Institutional Animal Care and Use Committee (IACUC), will apply. Management and routine monitoring activities are not regulated under the Animal Welfare Act; however, other standards and professional wildlife societies' guidelines do apply.

2. PURPOSE AND SCOPE

The purpose of this Order and the accompanying Reference Manual 77-4 (RM 77-4) is to establish NPS operational policies and procedures for compliance with existing Federal laws, regulations, and guidelines governing the use of pharmaceutical agents for wildlife in national parks. The section on "Chemical Immobilization and Sterilization Agents" from chapter 5 (specifically, pp. 5.69—5.71) of NPS-77, Natural Resources Management Guideline (Release No. 1, May 15, 1991), and a memorandum dated March 7, 1994, regarding "Service-wide Procedures for the Acquisition, Storage, and Use of Wildlife Immobilization and Anesthetic Drugs," are superseded and replaced by this Order and RM 77-4.

As is the case with all components of the NPS Directives System, this Order is intended only to improve the internal management of the NPS and it is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its departments, agencies, instrumentalities or entities, its officers or employees, or any other person.

3. AUTHORITY TO ISSUE THIS DIRECTOR'S ORDER

The authority to issue this Order and the associated Reference Manual is contained in 54 USC 100101(a) *et seq.* (the National Park Service Organic Act and related laws), and the delegations of authority contained in Part 245 of the Department of the Interior Manual.

Legal and regulatory requirements include:

- Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Modernization Act of 1997 (21 USC 301 et seq.).
- Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 (Pub. L. 103-396), codified primarily to 21 USC 360b (New Animal Drugs); see regulations at 21 CFR part 511 (New Animal Drugs for Investigational Use) and 21 CFR part 530 (Extralabel Drug Use in Animals).
- Controlled Substances Act (21 USC 801 et seq.); see regulations published at 21 CFR part 1301 (Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances).
- Animal Welfare Act (7 USC 2131—2159); regulations published at 9 CFR 1.1 to 12.10.
AND
- Federal Insecticide, Fungicide and Rodenticide Act (7 USC 136—136y); see regulations at 40 CFR part 172 (Experimental Use Permits).

4. POLICY, REQUIREMENTS, AND RESPONSIBILITIES

This Order sets forth the policy, requirements, and responsibilities for administration or application of pharmaceuticals to wildlife within national parks.

4.1 Policy

The administration of pharmaceuticals to wildlife is a necessary component of some management and research activities conducted in the NPS. It is our policy to administer pharmaceuticals to wildlife in a manner that is safe for humans; safe for animals (unless lethal outcome is the objective); adheres to humane standards; and is in accordance with NPS wildlife management policies and objectives. Regardless of registration agency of drugs and vaccines, pharmaceuticals applied to wildlife in national parks will be under the supervision of a licensed veterinarian. To implement this policy, NPS employees, agents, and cooperators will comply with all provisions of this Order.

4.2 Requirements

4.2.1 For the safe and responsible use of pharmaceuticals for wildlife, the NPS will:

A. Comply with FDA regulations on the use of drugs in animals.

1. Prescription Drugs. Nearly all drugs used for wildlife are prescription drugs. Veterinary prescription drugs are restricted to use by or on the order of a licensed veterinarian under a valid veterinarian-patient-client relationship. In the case of the NPS, this relationship triad consists of wildlife as the patient, a resource manager or scientist as the client, and NPS staff veterinarian or consulting veterinarian (e.g., qualified local practitioner, Federal or State agency veterinarian) as the veterinarian of record. This formal relationship establishes that a licensed veterinarian assumes the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client agrees to follow the instructions of the veterinarian. The veterinarian does not have to be onsite during use of the drugs, but he or she must be familiar with the species, herd, or local population, and if possible the individual animal treated. This requirement may be most efficiently and effectively met through the use of protocols approved by the veterinarian of record.

2. Extra-label Use of Drugs. If a labeled drug that fully meets the need is available for use, it must be used for food-producing animals (animals that may be harvested for human consumption) and is recommended for use in other species. However, most drugs administered to wildlife are applied on an extra-label basis. AMDUCA specifies additional requirements for the extra-label use of drugs. These include:

a. Well-defined records that are maintained for two years:
(1) The established name of the drug and its active ingredient.
(2) The condition treated (e.g., capture for radio collaring).
(3) The species treated.
(4) The dosage administered.
(5) The duration of treatment.
(6) The number of animals treated.
(7) The specified withdrawal time for drugs used in food-producing animals as advised by the prescribing veterinarian.

b. Labeling requirements:
(1) Name and address of prescribing veterinarian.
(2) Established name of drug.
(3) Directions for use.
(4) Cautionary statements.
(5) Withdrawal time for human consumption of food products from treated animals.

c. *Exclusion of the treated animal from the human food chain until the drug withdrawal time is met*. Food-producing animals that receive pharmaceuticals must be identified (e.g., with an eartag or radio-collar) to notify individuals that may harvest or otherwise collect the animals not to consume meat until the specified drug withdrawal time has elapsed. Coordination with State wildlife management agencies is encouraged to meet this requirement.

3. Compounding Animal Drugs. Compounding is defined as any manipulation to produce a drug form or provide a dosage other than that provided for in the directions for use (e.g., freeze-drying a drug for reconstitution at a higher concentration). Compounding by licensed veterinarians and pharmacies (acting on a valid prescription) is allowed under certain circumstances. The NPS will comply with FDA regulations on compounding, and specifically will not use drugs compounded by sources other than a veterinarian or pharmacist within the confines of a legitimate practice.

B. Comply with agency regulations and the sponsor's instructions on use of Investigational New Animal Drugs and Experimental Use Permits.

Records on the use of INADs and EUPs will be submitted to the sponsor of the investigation, and all other reporting requirements of FDA (as set out in 21 CFR part 511) or EPA will be met.

C. Promote humane use of pharmaceuticals for wildlife.

The NPS will comply with the Animal Welfare Act, including the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, as required when pharmaceuticals are applied to animals used in regulated activities. For the use of pharmaceuticals in animals for management and routine monitoring activities, the NPS will comply with acceptable humane standards as described in RM 77-4.

D. Ensure appropriate disposition of carcasses of wildlife that have received pharmaceuticals.

Exclusion of carcasses from the human food chain is addressed above in section 4.2.1.A(2)(c). Further, the prescribing veterinarian should provide instructions that must be followed to reduce or eliminate potential food-chain effects to other animals. Adherence to labeled environmental warnings (e.g., on pentobarbital-containing euthanasia agents to prevent secondary poisoning of scavenger species) is required.

E. Require training and qualification for individuals who perform remote delivery of pharmaceuticals.

Department of the Interior and NPS firearms or other remote delivery systems[2] policies will be followed as applicable if firearms or other remote delivery systems are used to deliver pharmaceuticals. Employees must receive training and qualify with each type of firearm or other remote delivery system used. In the absence of specific Service-wide guidance, superintendents (or regional or Washington office supervisors for their respective staffs) are delegated authority to establish qualification training for the use of remote delivery systems. Managers, in consultation with the firearms officer, will establish training requirements based on specific needs and uses to ensure that employees are properly qualified to safely use remote delivery systems. Superintendents must require, and may offer, equivalent training for NPS cooperators (e.g., State or other Federal agency staff, academic staff, et al.) who use remote delivery systems in national parks.

F. Authorize only well-qualified individuals to administer pharmaceuticals.

Parks, or in rare incidences regional or Washington offices, with a need to administer pharmaceuticals to wildlife will appoint a park practitioner. Pharmaceuticals are regulated because of their toxicity or other potential for harmful effects. Through compliance with FDA regulations and establishment of a valid veterinarian-patient-client relationship, adequate information to safely and effectively administer pharmaceuticals should be provided by the veterinarian to the park practitioner.

4.2.2 In addition to the above, for the safe and responsible use of immobilization drugs or controlled substances for wildlife, the NPS will:

A. Comply with DEA regulations on use of controlled substances.

Parks with a need to acquire or store immobilization drugs or controlled substances, or to administer them to wildlife, will ensure that the appointed park practitioner has substantial classroom and field experience with wildlife pharmaceuticals. Park practitioners may obtain controlled substances under a prescription from an individual holding an appropriate DEA license (e.g., an NPS or local veterinarian) and should register directly with the DEA to possesses these substances. DEA registration of NPS non-medical personnel is for wildlife management and research activities only. Although non-veterinarians registered by the DEA may legally acquire and possess controlled substances, they may not administer these drugs in national parks without a valid veterinarian-patient-client relationship. Security and storage requirements for controlled substances will be in compliance with 21 CFR 1301.71 to 1301.76; recordkeeping will be in compliance with the DEA requirements under 21 CFR part 1304, and the requirements under 21 CFR part 1305 regarding DEA Official Order Forms.

[2] Remote delivery devices are mechanical devices capable of delivering drugs to an animal from a distance usually by means of a ballistic projectile such as a dart.

B. Require certification of individuals to administer immobilization drugs or controlled substances to wildlife.

Many wildlife immobilization drugs and controlled substances are potentially lethal to humans if accidental exposure occurs. Further, controlled substances and techniques used for field anesthesia pose a concern for animal welfare. Therefore, all NPS employees, agents, or cooperators who use immobilization drugs or controlled substances for wildlife management, monitoring, or research purposes must be fully qualified in accordance with requirements described in RM 77-4. Qualification will be assessed through completion of training programs and demonstration of appropriate knowledge, experience, and skills in wildlife anesthesia and administration of controlled substances (e.g., pharmacology, human safety, animal safety and humane standards, regulations and legal requirements, techniques of field anesthesia, euthanasia). Superintendents, and regional or Washington office supervisors, must ensure appropriate training, experience, and veterinary oversight of their staffs who administer immobilization drugs and controlled substances to wildlife. Approval may be granted by superintendents to NPS cooperators based on documentation from the cooperating entity that NPS requirements are adequately met.

C. Require protocols for the use of immobilization drugs or controlled substances for wildlife.

Prior to the use of immobilization drugs or controlled substances, the park practitioner will have in place an approved protocol for (1) the individual wildlife species, or (2) the project. For routine management activities (e.g., relocation, euthanasia) development of species-specific protocols is encouraged. In the case of research projects, an IACUC-approved study protocol is generally sufficient. Protocols will be developed by the park practitioner, or researcher, in consultation with the veterinarian of record. Protocols will be approved by the superintendent and by the veterinarian of record.

4.3 Responsibilities

A. Associate Director, Natural Resource Stewardship and Science

1. Issues, reviews, and revises as appropriate, RM 77-4, which may provide additional technical guidance, procedures, detailed explanation of program areas, and requirements.
2. Ensures that NPS veterinarians who have Service-wide responsibilities hold a State veterinary licensure in at least one State, and maintain, as required, DEA controlled substances registration.

B. Washington Office Division Chief

1. Ensures that programs planned or implemented by staff are conducted by trained employees possessing DEA controlled substances registration as necessary, using protocols approved by the veterinarian of record and superintendent of the park where pharmaceuticals will be used.
2. Appoints park practitioner for the Office, if needed.
3. In the absence of specific Service-wide guidance, establishes qualification training for the

use of remote delivery systems by Office staff.

C. Regional Director

Ensures that standards are uniformly applied to all parks within the region.

D. Regional Natural Resource Manager

1. Ensures that programs planned or implemented from the regional office are conducted by trained employees possessing necessary DEA controlled substance registration as appropriate, using protocols approved by the veterinarian of record and superintendent of the park where pharmaceuticals will be used.
2. Appoints regional park practitioner, if needed.
3. In the absence of specific Service-wide guidance, establishes qualification training for the use of remote delivery systems by regional office staff.

E. Superintendent

1. Ensures that this Order and RM 77-4 are incorporated programmatically into park operations.
2. Except where otherwise established, approves personnel to perform park duties based on the personnel having obtained relevant training.
3. Appoints the park practitioner.
4. Approves, or delegates approval of, protocols for the use of immobilization drugs or controlled substances for wildlife in the park.
5. Within existing budgets and priorities, ensures that funds are available commensurate with demands and needs for veterinary consultation and staff training.

F. Park Practitioner

1. Obtains training on the use of pharmaceuticals. Possesses substantial classroom and field experience if immobilization drugs and controlled substances are administered to wildlife.
2. Establishes, or delegates to resource manager, veterinarian-patient-client relationship for use of pharmaceuticals and adheres to all instruction from the prescribing veterinarian.
3. Obtains DEA controlled substances registration as required, and ensures that all controlled substance activities carried out are in compliance with DEA regulations and requirements.
4. Ensures appropriate protocols are in place prior to use of pharmaceuticals.
5. Maintains records on pharmaceuticals as required by regulations and policy, and provides copies to the veterinarian of record as requested.

G. Resource Manager

1. Plans and implements wildlife programs in a safe, effective, and humane manner, in part by developing protocols for the use of immobilization drugs or controlled substances for wildlife.
2. Obtains training for self and those under his/her supervision.
3. As requested, establishes veterinarian-patient-client relationship for use of pharmaceuticals.

H. National Park Service, Veterinary Medical Officer(s)

1. Advises the Associate Director on (a) the use of pharmaceuticals for wildlife in parks, and (b) policies regarding the same.
2. Provides technical assistance (consultation or on-site assistance) on the development of protocols and the use of pharmaceuticals for disease treatment and prevention, anesthesia, euthanasia, and other veterinary applications.
3. Provides training, or assists in identifying training opportunities, for NPS staff and cooperators to obtain required knowledge and experience for the use of pharmaceuticals, including immobilization drugs and controlled substances, for wildlife in national parks.
4. As requested by parks or regional or Washington offices, and as deemed appropriate and feasible by the veterinarian, serves as the veterinarian of record, or assists in developing a relationship with a consulting veterinarian.
5. In coordination with park staff, administers pharmaceuticals to wildlife as deemed necessary under the standard course of veterinary practice.

5. ADDITIONAL GUIDANCE

Until RM 77-4 is issued, any provisions of chapter 5 of NPS-77 (see section 2, above) not inconsistent with this Order will remain in effect.

----------End of Director's Order----------