REGULATORY STATUS OF COMPOUNDED TREATMENTS, BY COUNTRY

Note: This is our understanding of regulatory status of non-FDA-approved compounded treatments such as calcium chloride sterilization in various countries, based on input from two regulatory consultants, one regarding the U.S. and E.U. and one international, as of 9/2012. It is to give a general idea of regulatory requirements, as a starting point for your own research and information-gathering. Do not rely on it; consult authorities in your country and/or state.

Countries without a strong veterinary regulatory structure:

In general, in countries without a strong veterinary regulatory structure, a veterinarian should make a decision whether or not to use a treatment based on the **greatest good** for the animal and the community, after acquiring as much information as possible about benefits and risks. For example, a veterinarian may decide that although 1 out of 200 dogs in a surgical spay program will be lost to anesthesia complications and 5 out of 100 will develop an infection at the incision site requiring treatment, the benefits to the dogs' overall lifespan and to the community in general make the treatment worth doing; or that although 1-2 cases of Vaccine Associated Sarcoma (VAS) may occur per 10,000 rabies and feline leukemia vaccinations, the benefits to the animal and community or guardian outweigh the risk.

Veterinary drug regulation capacities vary widely. In 2003, even for medicines for humans, the WHO estimated that less than 20% of WHO Member States were thought to have a well developed drug regulation system, and those that did were mostly industrialised countries. Of the remaining Member States, about 50% implemented drug regulation at varying levels of development and operational capacity. The other 30% either had no drug regulatory authority (DRA) in place, or had only a very limited capacity that barely functioned. Countries which do not have a strong veterinary regulatory pathway may include Nigeria, Trinidad and Tobago, Bangladesh, Fiji, Ghana, Iraq, Kenya, Nepal, Tanzania, and Sierra Leone.

Information about your country's regulatory status may be sought by doing an online search of your country name and "veterinary drug regulations compounding," by consulting colleagues, by seeking the guidance of a paid regulatory expert, from documents such as "The Role of Official Bodies in the International Regulation of Veterinary Biologicals" and "Background and objectives of the VICH considerations regarding wider international harmonisation" produced by the World Organisation for Animal Health and its collaborating center on veterinary medical products in Fougeres, France (http://www.oie.int/our-scientific-expertise/veterinary-products/), and possibly from the International Journal of Compounding Pharmacists. The Alliance for Contraception in Cats & Dogs may be able to put practitioners in contact with an appropriate regulatory consultant familiar with international veterinary law.

Countries with a strong veterinary regulatory structure:

In general, in countries with a strong regulatory structure, veterinarian use a non-regulator-approved, compounded treatment such as calcium chloride may be permissible if conditions such as the following are true:

- there is no regulatory body-approved veterinary drug for the same indication
- the veterinarian can provide justification and precedence for its use in the peer-reviewed literature
- the injection solution is sterile-filled by a reputable compounding pharmacy
- there is a valid veterinarian-client-patient relationship
- the veterinarian keeps records of patient outcome

In considering use of calcium chloride, veterinarians in countries with strong regulatory structures should also consider any additional regulations of their local jurisdiction (e.g. state) and the

expectations of their veterinary board, along with the greatest good for the animal and the community. Examples of jurisdictions with a strong veterinary regulatory structure include the European Union, Canada, China, South Africa, Australia, and Japan.

Special situation: Countries where an approved injectable sterilant is already on the market
In these countries as of 9/2012, an injectable male dog sterilant is already on the market and approved for use in dogs, eliminating the need for a compounded and non-standardized alternative for that purpose. The approved, standardized product should be used.
Brazil (Infertile®)
Mexico (Esterilsol™)
Bolivia (Esterilsol™)
Panama (Esterilsol™)

Special situation: The United States

The United States generally falls under the "strong regulatory structure" category above. However, Zeuterin™ (Esterilsol™) zinc gluconate injection is scheduled to come to the United States market as an FDA-approved dog sterilant in late 2012, after successful use in Mexico and Central America, at which time there will no longer be a need for a compounded product for dogs and the approved product should be used. (Use in cats is different, as there is no FDA-approved nonsurgical neutering agent/sterilant with an indication for use in cats.) Although the FDA is generally loathe to interfere with an individual veterinarian's practice of veterinary medicine unless drug residue in food animals is involved or it receives complaints of bad outcomes, United States veterinary law generally provides for compounding only when there is no commercially-available drug available for the indication—partially to protect companies which have spent many years developing products, and partly to ensure the greatest standardization, safety, and oversight of drugs reaching the public.
Information about the U.S. regulatory structure can be found at the FDA website:
http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm
And by searching "veterinary compounding regulation."

For informational purposes only; animal population management stakeholders should read all information available, including all published studies, in order to make an informed decision about whether use is consistent with the greatest good, and permitted by regulation, in their context. Rev. 9/2012

PARSEMUS FOUNDATION
Committed to innovative and/or neglected medical research,
with a focus on animal sterilants, contraceptive development, and breast cancer.
P. O. Box 2246, Berkeley, CA 94702 • (415) 839-6304 • www.ParsemusFoundation.org