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ORIGINAL ARTICLE

Encouraging reporting in the veterinary profession: Prospective study and analysis of the pharmacovigilance system in university settings☆

Promouvoir la déclaration dans la profession vétérinaire : étude prospective et analyse du système de pharmacovigilance vétérinaire en milieu universitaire

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Summary The French pharmacovigilance system is known as one of the world's most advanced monitoring systems for medicinal products. In this study, we tried to determine the actual number of adverse events occurring at the Toulouse National Veterinary School during dermatology consultations and follow-up. We also tried to highlight the practicality of e-reporting so as to suggest means of improvement to limit under-reporting. This study was carried out over two 10-week periods during the 2013—2014 school year. Ninety-six adverse events were detected, but only 75 of them were fit for reporting. This points out a major under-reporting in veterinary medicine, where only 0.1 notification is recorded per veterinarian per year. This work was also an opportunity to highlight the types of drugs, which are most involved in adverse effects, along

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with the types of reported adverse events. A difference with the official figures of Anses-ANMV is noted, but our conclusions must be related to the necessity of reporting when an adverse event is detected.

MOTS CLÉS
Pharmacovigilance ;
Médicament ;
Effet indésirable ;
Anses-ANMV ;
Dermatologie

Résumé Le système de pharmacovigilance français est connu pour être l'un des meilleurs moyens de surveillance des médicaments dans le monde. Dans cette étude, nous avons tenté de mettre en évidence le nombre réel d'évènements indésirables (EI) apparaissant dans les suivis de cas du service de dermatologie de l'École Nationale Vétérinaire de Toulouse (ENVT). Nous avons également tenté de relever la praticité de la télédéclaration pour proposer des voies d'amélioration afin de limiter la sous déclaration. Cette étude s'est déroulée sur deux périodes de dix semaines au cours de l'année 2013—2014. Quatre-vingt seize EI sont décelés mais seulement 75 sont déclarés, les autres étant incomplets. Cela dénote une sous-déclaration majeure en médecine vétérinaire pour laquelle seulement 0,1 déclaration est enregistrée par vétérinaire et par an. Par la même occasion, nous avons pu mettre en évidence les types de médicaments les plus concernés par les EI ainsi que les types d'EI déclarés. Il en ressort une différence avec les chiffres officiels de l'Anses-ANMV mais tout cela est à mettre en relation avec l'importance de la déclaration vis-à-vis d'un EI observé.

Introduction

Under-reporting is a recurring problem already well-known in human pharmacovigilance. Today, we globally evaluate this under-reporting at about 10%, i.e. only 10% of adverse events would be reported. Up to this day, no study allowed to quantify under-reporting in veterinary medicine in France. Indeed, many factors must be considered to assess it in the best possible way: we have among us canine, equine, bovine, swine and poultry veterinarians, general practitioners and specialists. All of these fields require a different approach.

According to the French Agency for Food, Environmental and Occupational Health and Safety-French Agency for Veterinary Medicinal Products (Anses-ANMV) 2012 annual report, the French veterinarian market represented about 2700 drugs for a total of around 16,750 veterinarians registered to the French ''Ordre National des Vétérinaires'' (organization in which all practitioners have to register) and about 130 Marketing Authorization Holders. During this year, the Anses-ANMV counted 2909 notifications from all origins. More than 90%, i.e. 2877 notifications, were transmitted by veterinarians. In theory, this amounts to 0.17 notifications per veterinarian in France in 2012. It represents a relatively weak progression of the number of notifications as compared to 2008, when it was estimated at about 0.16 [1]. In real terms, only about 1560 veterinarians report actively (2013 figures, source: Anses. They were 1286 in 2009).

Among reported adverse events, the Anses-ANMV differentiates between cases concerning vaccination against blue tongue and other cases, because the former are the result of an important awareness raising campaign. E-reporting was developed as a result of this campaign. In 2012, only 22 adverse events involved Blue tongue vaccines [1] [2]. Once the blue tongue vaccination cases excluded, Anses-ANMV recorded about 1300 serious adverse effects cases with a large disparity depending on the class of drugs used. In 2012, there were 435 cases of adverse events in humans caused by veterinary drugs, involving 228 drugs, mainly anti-parasiticide products (44%) and vaccines (23%). Adverse events caused by euthanasia drugs represent 4% of notifications, but stand out as suicide attempts.

A trend has been materializing since a couple of years: adverse events mainly concern pets (blue tongue vaccination campaign excluded). Dogs and cats account for 82% of notifications. Rural activity represents about 10% of notifications, while the remainder is distributed between equines and exotic pets. In 2009, at the time of the blue tongue vaccination campaign, the difference was not so large. Eight hundred serious cases pertained to the blue tongue vaccination. Yet, notifications concerning pets have always been more frequent.

In total, 3764 drugs were mentioned in the notifications of the year 2012 (some products being mentioned many times). Most of them were anti-parasiticide products, both external and internal, representing 50% of notifications. Seventy-four percent of them were not serious. Vaccines accounted for 19% of notifications, but as opposed to antiparasitics, 74% were cases of serious adverse effects. Anti-microbials, anti-inflammatory drugs and anaesthetics follow.

As the main contributors to the system, veterinarians naturally report most of the adverse events transmitted to institutional actors in France (Veterinary Pharmacovigilance Centre of Lyon [CPVL] and Anses-ANMV). Owners and breeders account for 8% of notifications, followed by veterinary schools and pharmacists, accounting for less than 1% each.