DOI Link: https://doi.org/10.61586/8AnIv
Vol.33, Issue.10, Part.1, Oct 2025, PP.2-9

Analysis of current trends in cattle immunoprophylaxis in Poland: national data, European context

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Received Feb 2025 Accepted Sep 2025 Published Oct 2025

Abstract

The aim of this work was to monitor the number of cattle vaccine doses released to the European market by the Polish Official Medicines Control Laboratory (OMCL) between 2022 and 2024, based on data from the batch control database of immunological veterinary medicinal products (IVMPs), including EU certificates issued. The results showed that among the 46 IVMPs in Poland under batch control, inactivated vaccines were the most numerous, representing 50% of the total. Over 282.5 million doses of IVMPs for cattle were released in Poland during this period. Vaccines against infectious bovine rhinotracheitis (IBR) were predominant (>18%), reflecting mandatory control programs in many herds. Products against bovine respiratory syncytial virus (BRSV), bovine viral diarrhea (BVD), *Staphylococcus* spp. and coliform infections were also common. Although tuberculosis (TB) ranked second, no vaccines against bovine tuberculosis exist - only tuberculin diagnostics are available. Immunopreparations against colibacteriosis were the least frequent (0.04%). These findings illustrate current trends in cattle immunoprophylaxis in Poland and confirm the utility of batch release data for monitoring vaccination practices.

Keywords: cattle, EDQM, IVMPs, vaccines, immunoprophylaxis, NVRI, OMCL

Introduction

IVMPs for cattle are rigorous controlled in Poland before and after placing them on the market by an OMCL located in the National Veterinary Research Institute (NVRI). NVRI is a member of the General OMCL Network (GEON) community, coordinated by the European Directorate for the Quality of Medicines and HealthCare (EDQM) in Strasbourg, France (1). EDQM has introduced the system of European quality control certificates of IVMPs, based on mutual recognition of these documents by all Member States of European Union. There are two types of European batch release certificates, OCABR (Official Control Authority Batch Release) and OBPR (Official Batch Protocol Review). The OBPR certificates are issued on the basis of documentation review in accordance with Article 128 of Regulation 2019/6 of the European Parliament and of the Council (EU), paragraph 1 (2). While the OCABR certificates are issued on the basis of both sample testing and documentation review in accordance with Article 128 of Regulation 2019/6 of the European Parliament and of the Council (EU), paragraph 3 (2). Once issued certificate must be recognized by OMCLs in another Member State. After the marketing authorization has been granted, the batch of IVMP may be placed on the European market only if OMCL performed its control and issued the certificate or it obtained the quality control certificate for this batch from another OMCL.

The concerned European Union Member States have agreed upon a Short List of IVMPs for which Article 128 will be applied using a reduced test scheme for OMCLs. Annex I to the EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6, consist of a Short List of IVMPs which require OCABR certificates with specific guidelines outlining the reduced test scheme for OMCLs for these IVMPs. The guidelines are widely available on the EDQM website (www.edqm.eu) (3). The list is updated depending on risk assessment. The abovementioned Short List contains six types of IVMPs intended for cattle (Table 1). Control tests performed by OMCLs on these IVMPs included assessment of appearance, potency, identity, solubility, virus titre, extraneous microorganisms, and sensitizing effects, depending on the type of IVMP (Table 1).

Table 1 List of cattle vaccines on the Short List in accordance with for which Article 128 will be applied using a reduced test scheme for OMCLs, with parameters tested for the purpose of issuing the EU OCABR certificate.

No.	IVMPs	Required control tests performed by OMCLs
1	Infectious Bovine Rhinotracheitis Vaccine (live and inactivated)	Inactivated IVMPs: ▪ Appearance ▪ Potency
		Live IVMPs: ▪ Appearance ▪ Solubility ▪ Virus titre ▪ Test for extraneous pestivirus
2	Tuberculin Purified Protein Derivative (PPD), Bovine	▪ Appearance ▪ Sensitising effect ▪ Potency
3	Tuberculin Purified Protein Derivative (PPD), Avian	▪ Appearance ▪ Sensitising effect ▪ Potency
4	Brucellosis Vaccine (brucella melitensis rev.1 strain and brucella abortus S19 strain) (live)	▪ Appearance ▪ Identity ▪ Extraneous microorganisms ▪ Determination of dissociation phase ▪ Live bacteria count ▪ Solubility
5	Brucellin Preparations	▪ Appearance ▪ Sensitising effect ▪ Potency
6	Rabies Vaccines (live and inactivated)	Inactivated IVMPs: ▪ Appearance ▪ Batch potency test
		Live IVMPs: ▪ Appearance ▪ Virus titre

Despite the established regulatory framework, there is limited information on the actual number of cattle vaccine doses released to the European market from Poland, the distribution of vaccine types, and the alignment of these data with EU trends. Therefore, the main research problem addressed in this study is to quantify and analyze current trends in cattle immunoprophylaxis in Poland, including the types and numbers of vaccines released, with the aim of providing a comprehensive overview that can support evidence-based decision-making in national and European cattle health programs.

Material and methods

Data from the IVMPs batch control database (2022–2024) were analyzed, including issued EU OBPR certificates. The electronic batch control database project was awarded in 2018 with the Polish Minister of Agriculture and Rural Development award. A total of 934 batches of cattle biopreparations were examined. Information was collected on the number of doses released to the EU market by the Polish OMCL, as well as on the type of vaccines authorized for marketing in Poland, their pharmaceutical forms, and target diseases. Vaccines were categorized as inactivated, live, immunomodulators, or tuberculins, and doses were quantified by disease entity. The research results were compared with data from the EDQM Short List document.

Results and discussion

The results showed that currently there are 62 IVMPs for cattle, authorized for marketing in Poland of which 46 were subject to batch control. The largest number of registered IVMPs for cattle consists of inactivated vaccines – 50%. Live vaccines represent only 27 % of the total bovine IVMPs, and the rest are immunomodulators (7%) and tuberculins (6%) (Fig. 1). Vaccines for cattle are distributed in a variety of pharmaceutical forms, i.e. suspension for injection, lyophilisate and solvent for suspension for nasal administration, emulsion for injection and also solution for injection.

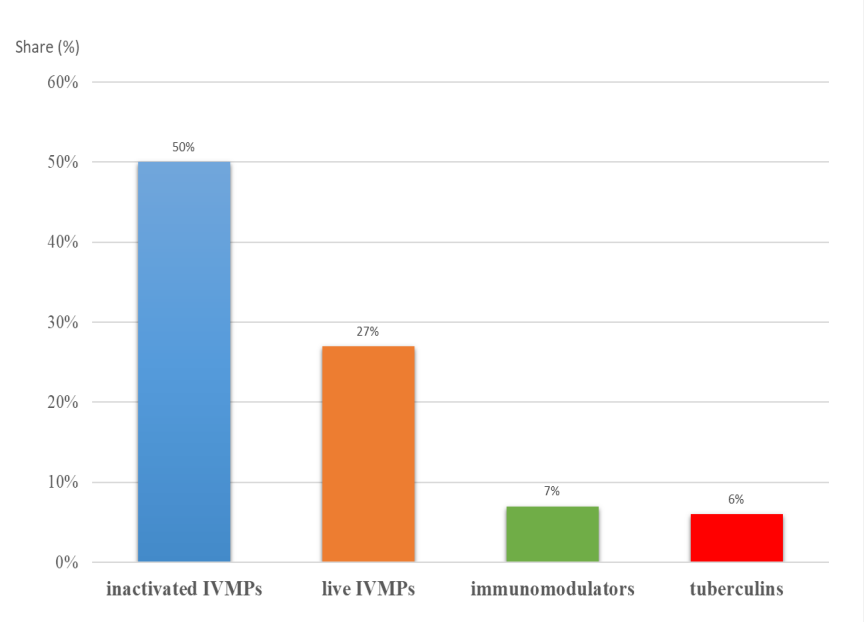

Fig. 1 Comparison of cattle IVMP categories released to the EU market.

In total, over 282,5 million doses of IVMPs for cattle were released into the market between 2022 and 2024. Most of these were IVMPs against IBR (over 18%) (Fig. 2). The next cattle diseases against which vaccines were introduced into the market were: BRSV infections**,** BVD, *Staphylococcus* and coliform infections. Although TB ranked second, it should be emphasized that there are no vaccinations against bovine tuberculosis, there is only tuberculin diagnostics. More than 97% were bovine tuberculins, while the remainder consisted of avian tuberculins. Immunopreparations against colibacteriosis were introduced least frequently (0.04%) (Fig. 2).

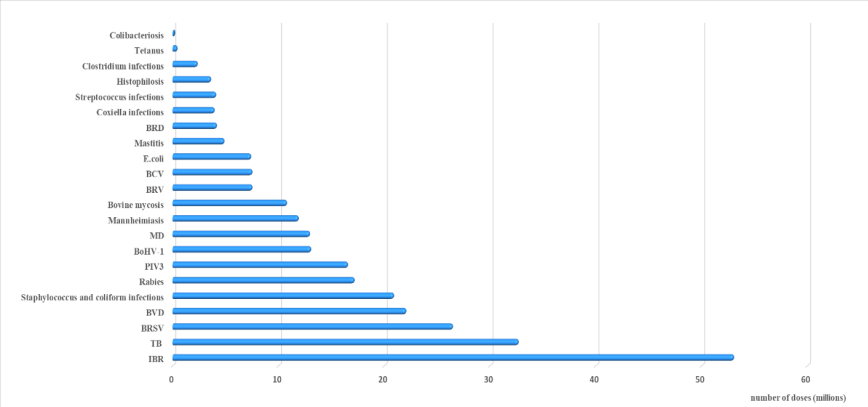

Fig. 2 Doses of IVMPs for cattle released to the EU market (2022–2024) by disease entity. List of abbreviations: IBR (Infectious Bovine Rhinotracheitis), TB (Tuberculosis), BRSV (Bovine respiratory syncytial virus infections), BVD (Bovine viral diarrhea), PIV3 (Parainfluenza virus type 3 infections), BoHV-1 (Bovine herpesvirus type 1 infections), MD (Mucosal disease), BRV (Bovine rotavirus infections), BCV (Bovine coronavirus infections), BRD (Bovine Respiratory Disease).

Why is IBR the disease for which the highest number of vaccine doses has been released on the EU market? This is most likely due to the fact that control programs are mandatory in many herds. Infectious bovine rhinotracheitis, caused by bovine herpesvirus type 1 (BoHV-1), represents a major infectious disease of cattle worldwide, contributing substantially to morbidity, mortality, and economic losses in the dairy industry (4,5,6). Vaccination remains the most direct and effective strategy to enhance immunity and prevent the spread of IBR, making it an essential measure for safeguarding herd health (5,6). IBR virus is a major pathogen in cattle, which causes infectious bovine rhinotracheitis, and gives a range of clinical signs, such as respiratory disease, vulvovaginitis, rhinitis, traeheitis, conjunctivitis, enteritis, encephalitis, abortion and fatal systemic infection in

neonatal calves (7,8). Morover, vaccines against IBR constitute the first IVMP group for cattle to be included on the Short List (4).

The second type of IVMPs for cattle at Short List is bovine Tuberculin also called PPD (purified protein derivative). The Tuberculin preparation are applied to diagnose bovine tuberculosis in cattle by causing a late-type allergic reaction in animals infected with *Mycobacterium bovis* (9). Bovine tuberculosis is a form of lung tuberculosis. Cattle suspected to have tuberculosis are tested using the skin test with Tuberculin.

The third type of IVMPs for cattle at Short List is Tuberculin PPD, Avian. Although the name suggests use in birds, this tuberculin is used in cattle for comparative tuberculin testing to differentiate reactions to *Mycobacterium bovis* from infections with *M. avium* (environmental acid-fast bacteria commonly found in cattle). In practice, the test involves administering both tuberculins and comparing the skin reactions after 72 hours – which is why both tuberculins are used in cattle (10).

As our research has shown, tuberculins rank second in terms of the number of immunopreparations marketed for cattle (Fig. 2), accounting for 32,6 mln of doses. They constitute one of the four categories of immunoprotection types for cattle.

The inclusion of IBR and TB on the Short List is therefore fully justified and demonstrates the appropriate selection of control tools by the EDQM.

The next types of IVMPs are Brucellin Preparations and also IVMPs against brucellosis. The principal source of this zoonosis in cattle is *Brucella abortus* (11). The Gram-negative bacteria cause such clinical signs in cattle as arthritic joints, high incidences of abortions and retained placenta. The likelihood of brucellosis infection depends, among others, on the number of bacteria to which the animal was exposed, but also such parameters as age of animals and pregnancy status (12). New sources indicate that *Brucella abortus* causes disease mainly in cattle, and the principal symptoms include abortion in the last stage of pregnancy in female cattle, retention of the placenta, stillbirths, and birth of weak calves (13). Our analysis confirmed that there are no registered vaccines for cattle against brucellin (Brucellin) or against brucellosis (e.g. *Brucella abortus/melitensis*) in Poland, as the country has a "bovine brucellosis-free" status.

The last type of cattle IVMPs on Short List are against Rabies which is a major zoonotic disease affecting domestic, wildlife mammals and also humans. This dangerous virus causes large economic losses (14). Rabies vaccines for cattle were ranked 6th in terms of the number of doses introduced to the market (approximately 17 million doses).

Due to the recent situation of foot-and-mouth disease (FMD) in Europe, the batch release register was also analyzed for FMD vaccines. Although one FMD vaccine is registered in Poland, it has never passed batch control and therefore no doses have been introduced to the market, likely reflecting the absence of FMD cases in the country. However, FMD is as an endemic challenge worldwide and cause large economic losses (15). The situation in Europe is under continuous monitoring, as outbreaks of this disease have been lately reported in few EU countries with emergency vaccination implemented in Hungary and Slovakia (15).

In conclusion, the batch release database is an effective tool that enables the analysis of cattle immunoprophylaxis trends and can be valuable for evaluating and developing vaccination programs. The results of our analysis highlight several important aspects of cattle immunoprophylaxis in Poland. First, the predominance of inactivated vaccines and high distribution of IBR vaccines reflect both mandatory herd health programs and targeted disease control strategies. The substantial number of tuberculin doses indicates ongoing surveillance for bovine tuberculosis, even in the absence of active vaccination. In contrast, the very low frequency of immunopreparations against colibacteriosis and the lack of registered vaccines against brucellosis emphasize gaps in available prophylactic measures, underlining the reliance on disease-free status and monitoring rather than active immunization. Comparisons with the European context show that Poland's vaccine distribution largely mirrors EU trends for major cattle pathogens, although some diseases, such as FMD and rabies, remain controlled primarily through emergency preparedness and targeted vaccination rather than routine immunization. Overall, the data suggest that while the current immunoprophylaxis program effectively addresses priority diseases, there remains room for expansion and adaptation to emerging risks, highlighting the value of batch release data for strategic planning in both national and European cattle health programs.

Acknowledgements

This study was supported by the multiannual program *"Protection of Animal Health and Public Health"*, funded by the Polish Ministry of Agriculture and Rural Development, task no. 58: *"Analysis of sales data and qualitative studies of selected immunological veterinary medicinal products in Poland."*

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