



Pharmacovigilance and Aquaculture

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Background

Atlantic salmon. Rainbow trout. Halibut. Turbot. Tilapia. Brown trout. Carp.
Sea bass and bream. Arctic charr.

All with their own diseases and pharmacokinetic profiles.

One fish is not the same as the next fish.

Seawater (cages and pump ashore), Fresh water in rivers, lakes,
recirculation, borehole....



Fish numbers

500,000 per cage

Up to 10m on one site

Always some background mortality

Always some lack of efficacy/tolerance to the medicine



Treatments

Treatments have the potential to be damaging to the fish, especially bath treatments that are NOT related to the medicine

Fish are enclosed and pumped/handled

Respiration can be compromised if concurrent gill disease

Skin and corneal abrasions are common

Equipment failure.

Environmental conditions (temperature/O₂)



Medicine availability

Very few licensed medicines available. Repeated use selects for resistance

Environmental agencies control the amount of medicine that can be used at any one time. Not possible to treat a whole site at the same time

E. A.s also are involved in the assessment of the dossier for new medicines

(These medicines are released into the environment so this scrutiny is quite justified)



Oral medication

Only the healthy fish are feeding

Sick fish receive a suboptimal amount of medicine selecting for resistance

Dominant behaviour and territorial aggression lead to underfeeding and therefore underdosing



What is reportable?

Mortality Physical damage Lack of efficacy

In the context of.....

Trapped in net.

Gill disease

Anorexic fish

Overuse of medicine

Oxygen failure

Weather conditions



Why report?

- Collection of the data too onerous.
- No feedback from the VMD.
- No information on outcomes and actions
- Is this a one off or part of a wider concern?
- Is this data confidential.? FOI considerations
- Anonymising the reports
- Concern that the medicine will be withdrawn



Why report?

“We know what’s going on and the reasons for the problem.”

Education. For vets, vet students, farmers.

Understanding the system

Understanding the importance



M A Holders/Fish farms have conflicting views with Vets/PVQPs

Fish kills and SLEEs : Production sensitivity

Pressure on vets/QPs not to report.

Confusion over what to report



Consider these points

Mandatory CPD for company vets and PVQPs

PV included in the vet curriculum

Submit data to MA holder and VMD *at the same time*

(Have submissions decreased since they are now sent to the MAH rather than the VMD?)

Legal requirement for vets/QPs to submit might give them some protection from company pressures

Vet to assist in the collection of the data

Feedback from regulatory authorities: actions and outcomes



Thank you
