

# WHAT AN OUTREACH FORUM MEMBER SEE AS THE BENEFIT OF VICH

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# 1. DEFINITIONS

(a) VICH: International Cooperation on harmonization of technical requirement for the registration of Veterinary Medicinal Products (VICH) is an international tripartite Cooperation (EU, Japan and USA) Programme which brings together Regulatory Authorities and Industry in constructive, Science-based dialogue for the purpose of implementing a single standard of practice in the registration of Veterinary medicinal Products in line with Global International best practices.

# 1(b)VOF – VICH Outreach Forum (VOF)

- Is a VICH initiative with the main objective of providing a basis for wider international harmonization of technical registration requirements required for the marketing of Veterinary medicinal products. It improve information exchange and raise awareness of VICH and VICH guidelines with non VICH countries/regions.
- The outreach forum is composed of countries and regional organization that have expressed interest in the work of VICH and are motivated to participate in the activities of VICH outreach forum.
- The key issue of interest to the non- VICH countries coming together in the forum are to better understand and actively contribute to the VICH guideline development process, to suggest topic for practical issues related to VICH guidelines, to receive training on the guidelines and collaborate and share translation of guidelines into their language.

## 2. WHAT IS REGULATORY AFFAIRS?

a). Regulatory Affairs is a comparatively new profession which has developed from the desire of National government to protect public health, by controlling the safety, quality and efficacy of a wide range of products including: Pharmaceuticals, Food, Cosmetics, Medical Devices, Complementary medicines, Veterinary medicines and Agrochemicals.

(b) Why are there regulations?

- Regulation exists because of the following reasons:
- Patients and Prescribers must have access to safe, quality and effective regulated products
- Industry and academia must have a clear understanding of what is required.
- Government must decide whether the benefit to the population is commensurate with the potential risk.
- An extensive legal framework exists to help all three make the right decisions.

c). What is regulated?

- Regulation of clinical research (e.g. clinical trials application – CTAs)
- Review of risk: benefit for marketing authorization applications
- Compliance with standards (GMP, GLP, GCP, GHP, GAP and others)
- Compliance with registered information in advertising and promotion
- Pharmacovigilance

## 2d). What do regulatory authorities do?

- Regulatory authorities aim to: assess the safety, quality and efficacy of regulated products and authorized their sale, supply and use in clinical trials
- Safeguard the health of the citizens by operating post marketing surveillance and other system for reporting, investigating and monitoring adverse reactions to medicines and taking any necessary follow up actions
- Operate a quality surveillance system to sample and test medicines and to address quality defects (e.g defective medicines and counterfeiting)
- Offer scientific, technical and regulatory advice on medicines and other regulated products

### 3. How Do New Regulations Arise?

Historically, regulations were introduced as a reactions to events such as, the thalidomide tragedy, the elixir sulfanilamide disaster and the melamine disaster.

(i)

The thalidomide tragedy (Thalidomide was the tragedy preventable). In the late 1950s and early 1960s, the thalidomide causes an estimated 10,000 birth defects and thousands of fetal death worldwide. Thalidomide was manufactured and indicated for among other conditions, the treatment of morning sickness in pregnancy. From 1958 the drug has been widely praised, advertised and prescribed just on the ground that it was unusually safe, largely because it was impossible to commit suicide with it.

Then in 1961-1962, it was found to cause terrible malformations in unborn children (Amelia, Polymelia) in addition to the tragedy of the late 1950s and early 1960s.

Due to thalidomide's effect on fetuses both nationally and abroad, the US congress passed the 1962 Kefauver – Harris amendments to the 1938 Food, Drug and Cosmetics act. These amendments imposed guidelines for the processing of drug approval in the US and required that a drug be safe as well as effective before it could be approved and marketed.

Thalidomide also influenced the FDA's creation of pregnancy category a ranking of drugs based on their effect in reproduction and pregnancy.



(ii)

The Elixir Sulfanilamide Disaster (Elixir Tragedy 1937)

In the fall of 1937, more than 100 (109) citizens, many of whom were children, died after consuming Elixir Sulfanilamide mixed with di-ethylene glycol. The manufacturer, Massengil Company of Bristol, Tennessee, only tested the Elixir for its appearance and palatability before its nationwide distribution. The catastrophic event prompted the passage of the 1938 Food, Drug, and Cosmetics Act.

(iii)

Today, advancing scientific knowledge is the key driver for legislation changes. However, increasingly politics and cost also play a part in shaping regulation

I stand bold to declare at this juncture that, all the regulations required in the control of regulated products are derivative of the regulations used in granting marketing authorization, otherwise called licensing or registration regulations. This implies that licensing regulations are the building block of other regulations. It suffice also to state that the development of quality regulations and guidelines is a capital intensive venture.

## 4.0. BENEFIT OF VICH IN THE EYE OF VICH OUTREACH FORUM(VOF) MEMBER

The benefit of VICH in the eye of VOF member can never be over emphasized . These includes but are not limited to the following:

- First and foremost , in the eye of a VOF member, VICH is a charitably magnanimous organization for creating VOF (in November 2011) shortly after the creation of VICH (in April, 1996) with the enormous benefit it has in store especially for non-VICH countries/regions
- VICH is the chief facilitator of adherence to standards in line with global best practices in the registration of veterinary medical products (VMPs). The benefit of this is that countries round the world are made to have almost equal access to safe, efficacious and quality VMPs.
- VICH is considered to be an efficient manager of time and financial resources require in bringing essential VPMs to the markets. With VICH, there is reduced time and cost of bringing new VMPs to the markets
- VICH is a major investor in advancing the course of access to quality VMPs by building capacity in the personnel of National Regulatory Authorities ((NRAs) , those of industries and building/developing quality guidelines and guidance documents. During VOF meeting, experts from the tripartite owner of VICH train VOF members on the implementation of old guidelines and engage them on the guideline development process so that they can learn on the job

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- VICH is seen as an executor of the pivotal will of international community in adapting to best practices in the regulation of VMPs.
- COST SAVING – VICH removes from NRAs the financial burden of developing guidelines for the registration of VMPs. The money so saved by NRAs is invested in other appropriate project or facilities to move NRAs from a lower class of WHO classification to a more stringent regulating class.
- VICH is considered a big player in ensuring food safety and food security because it emphasises the specialities of VMPs in line with Codex Alimentarius Commission good practice of veterinary medicine (GPVM)
- VICH is seen as promoting trust and dignity of veterinary clinicians before their clients because it enables veterinary clinicians to have access to quality VMPs for effective management of animal diseases
- VICH helps in establishing and promoting friendly mutual relationship between NRAs which may in turn result in the facilitation of trade and other socio-cultural relationships .
- VICH organizes VOF meeting which helps in creating a conducive platform for NRAs, their governments, industries and donor organizations to interact freely leading to monumental regulatory upgradation on the part of NRAs on the lower WHO class (e.g the East Africa Mutual Respect process of licensing veterinary vaccines).

- VICH ensures information sharing among the participating NRAs in VOF meetings which could translate into transfer of technology and eventually into technological advancement on the part of the NRAs from developing countries.
- ViCH, through its meetings and conferences, is fast reeplicating the systems on edifices of International Council on Harmonization (ICH). The outcome of this will surely lead to attraction of huge investment in veterinary pharma industries.
- The strict collaboration between VICH and organization international epizootic (OIE) is a veritable tool in ensuring food safety and food security, as the agent of emerging and re-emerging food borne diseases are organisms of veterinary origin
- In collaboration with OIE, VICH does organize training for policy makers and NRAs globally thereby building capacity in such participants
- VICH's collaboration with OIE has helped in ensuring the availability of irreplaceable protein, vitamins and amino acids of animal origin required in body building. This is made possible because the collaboration helped in ensuing the availability of quality VMPs for safeguarding animal health
- VICH is seen as a bridge builder because VOF meeting is an avenue for interaction between poorly regulating NRAs and the stringent regulating NRAs thereby bridging the gap between the two.

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- VICH, through its guidelines and activities is seen as aiding the world against the global menace of anti-microbial resistance super bug.
- VICH Pharmacovigilance project is a tool that is considered helpful in the promotion of safety, quality and efficacy of VMPs globally. This is a replication of the project being carried out by USP in the pharmaceutical for human use, tagged “Promoting quality of drug”

## 5. CONCLUSION

With this short presentation, you will agree with me that in the eye of a VOF member, justice can hardly be done to the topic “What an Outreach Forum member (VOF Member) See as the benefit of VICH”



THANK YOU FOR YOUR TIME