AN INSIGHT ON INTERNATIONAL CONFERENCE OF HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE (ICH) .

BY

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Declaration

This Research Project is my own original work and has not been submitted for a degree at the University of Nairobi or any other university.

Singed_____ Date 05/10/2009

Kiprotich .S.L

This Research Project has been submitted for examination with my approval as a University of Nairobi Supervisor.

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Dedication

All my Friends and Family

ACKNOWLEDGEMENT

I would like to thank my family and friends for all the unconditional support they have given me.

I acknowledge of my supervisor Prof. C.K. Maitai.

I thank the Almighty God for the chance, ability and strength.

ACRONYMS

ICH - International Conference on Harmonisation

EU - European Union

EPHIA - European Federation of Pharmaceutical Industries and Association

MHLW - Ministry of Health Labour and Welfare (Japan)

JPMA - Japan Pharmaceutical Research and Manufacturers of America

FDA - US Food and Drug Administration

PHRMA - Pharmaceutical Research and Manufacturer of America

WHO - World Health Organization

EFTA - Europe Free Trade Association

IFPMA - International Federation of Pharmaceutical Manufacturers and Association

APEC -Asia-Pacific Economic Cooperation.

ASEAN -Association of Southeast Asian Nations

GCC -Gulf Cooperation Countries

PANDRH -Pan American Network on Drug Regulatory Harmonization

SADC -South African Development Community

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ABSTRACT

This study entails first the introduction of ICH, its initiation and history.

Secondly, it shows factors that led to initiation of ICH and gives a brief history of this organization.

It then moves to highlight the organisation's particulars, processes and activities.

Fourthly, it lists the products of the ICH which are basically the harmonized guidelines.

The fifth area highlighted are the regions covered by ICH.

Finally a conclusion is given and a reference.

CHAPTER I

1.0 INTRODUCTION

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a unique project that brings together the regulatory authorities of Europe Japan and the United States and experts on the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of the technical requirements for product registration in order to reduce or eliminate the need to duplicate the testing carried out during research and development of new medicines.

The objective of such harmonization is a more economical use of human animal and material resources and to eliminate the delay in the global development and availability of new medicines whilst maintaining safeguards on the quality safety and efficacy
regulatory obligations to protect public health.

ICH has therefore sought to accomplish the above objective by playing a universal unifying role that seeks to address all challenges faced by the global pharmaceutical market in terms of the requirements that have to be met before a product is approved.

The organization collects information on the above challenges and goes ahead to produce guidelines that iron out the disharmony in the global pharmaceutical market

CHAPTER II

A brief History of ICH

2.1 THE NEED TO HARMONISE.

The history of medicinal product registration, in much of the industrialized world, has followed a similar pattern which could be described as: *Initiation, Acceleration, Rationalisation and Harmonisation.*

The realisation that it was important to have an independent evaluation of medicinal products before they are allowed on the market was reached at different times in different regions. In the United States a tragic mistake in the formulation of a children's syrup in the 1930s was the trigger for setting up the product authorisation system under the Food and Drug Administration. In Japan, government regulations requiring all medicinal products to be registered for sale started in the 1950s. In many countries in Europe the trigger was the thalidomide tragedy of the 1960s, which revealed that the new generation of synthetic drugs, which were revolutionising medicine at the time, had the potential to harm as well as heal.

For most countries, whether or not they had initiated product registration controls earlier, the 1960s and 1970s saw a rapid increase in laws, regulations and guidelines for reporting and evaluating the data on safety, quality and efficacy of new medicinal products. The industry, at the time, was becoming more international and seeking new global markets, but the registration of medicines remained a national responsibility. Although different regulatory systems were based on the same fundamental obligations to evaluate the quality, safety and efficacy, the detailed technical requirements had diverged over time to such an extent that industry found it necessary to duplicate many time-consuming and expensive test procedures, in order to market new products, internationally.

The urgent need to rationalise and harmonise regulation was impelled by concerns over rising costs of health care, escalation of the cost of R&D and the need to meet the public expectation that there should be a minimum of delay in making safe and efficacious new treatments available to patients in need.

2.2 INITIATION OF ICH

Harmonisation of regulatory requirements was pioneered by the European Community, in the 1980s, as the EC (now the European Union) moved towards the development of a single market for pharmaceuticals. The success achieved in Europe demonstrated that harmonisation was feasible. At the same time there were bilateral discussions between Europe, Japan and the US on possibilities for harmonisation. It was, however, at the WHO Conference of Drug Regulatory Authorities (ICDRA), in Paris, in 1989, that specific plans for action began to materialise. Soon afterwards, the authorities approached IFPMA to discuss a joint regulatory-industry initiative on international harmonisation, and ICH was conceived.

The birth of ICH took place at a meeting in April 1990, hosted by the EFPIA in Brussels. Representatives of the regulatory agencies and industry associations of Europe, Japan and the USA met, primarily, to plan an International Conference but the meeting also discussed the wider implications and terms of reference of ICH.The ICH Steering Committee which was established at that meeting has since met at least twice a year, with the location rotating between the three regions.

At the first SC meeting of ICH the *Terms of Reference* were agreed and it was decided that the Topics selected for harmonisation would be divided into *Safety*, *Quality* and *Efficacy* to reflect the three criteria which are the basis for approving and authorising new medicinal products. It was also agreed that six-party Expert Working Groups (EWGs) should be set up to discuss scientific and technical aspects of each harmonisation topic. Eleven such Topics were selected for discussion at the First International Conference on Harmonisation.

The "pattern" of ICH work was also established in those early Steering Committee meetings, that is, that the EWGs meet in the same week as the Steering Committee and report on their progress to the Committee.

CHAPTER III

ICH PARTICULARS

ICH is a joint initiative involving both regulators and research-based industry representatives of the European Union, Japan and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines.

The complete name of ICH is the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use".

3.1 PURPOSE OF ICH

The objective of ICH is to increase international harmonisation of technical requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most efficient and cost-effective manner. These activities have been undertaken to promote public health, prevent unnecessary duplication of clinical trials in humans, and minimize the use of animal testing without compromising safety and effectiveness.

3.2 GOAL OF ICH

The goal of ICH is to promote international harmonisation by bringing together representatives from the three ICH regions (EU, Japan and USA) to discuss and establish common guidelines.
Another goal of ICH is to make information available on ICH, ICH activities and ICH guidelines to any country or company that requests the information, and to promote a mutual understanding of regional initiatives in order to facilitate harmonisation processes related to ICH guidelines regionally and globally, and to strengthen the capacity of drug regulatory authorities and industry to utilise them. The ICH Global Cooperation Group (GCG) was formed in 1999 and is charged with this task.

3.3 THE ICH GLOBAL COOPERATION GROUP

The ICH Global Cooperation Group (GCG) was formed on March 11, 1999, as a subcommittee of the ICH Steering Committee. It is made up of one representative from each of the six parties on the ICH Steering Committee, plus the ICH Secretariat at IFPMA. Three Observers (WHO, Canada and EFTA) are also part of the GCG. Other regional harmonisation initiatives (RHIs), namely Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Gulf Cooperation Countries (GCC), Pan American Network on Drug Regulatory Harmonization (PANDRH) and South African Development Community (SADC), have been invited to designate permanent representatives to the GCG.

3.4 LOCATION OF ICH

ICH does not have "offices" as such because it is a voluntary cooperative effort of cosponsors from the three regions. The ICH Secretariat is based in Geneva. The biennial meetings and conferences of the ICH Steering Committee rotate between the EU, Japan, and the USA.

3.5 MEMBERS OF ICH

ICH is comprised of representatives from six parties that represent the regulatory bodies and research-based industry in the European Union, Japan and the USA.

In Japan, the members are the Ministry of Health, Labour and Welfare (MHLW), and the Japan Pharmaceutical Manufacturers Association (JPMA).

In Europe, the members are the European Union (EU), and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

In the USA, the members are the Food and Drug Administration (FDA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Additional members include Observers from the World Health Organization (WHO), European Free Trade Association (EFTA), and Canada. The Observers represent non-ICH countries and regions.

3.6 STRUCTURE OF ICH

ICH is a joint initiative involving both regulators and industry as equal partners in the scientific and technical discussions of the testing procedures which are required to ensure and assess the safety, quality and efficacy of medicines.

The focus of ICH has been on the technical requirements for medicinal products containing partners in the scientific and technical discussions of the testing procedures which are required to ensure and assess the safety, quality and efficacy of new drugs.

The vast majority of those new drugs and medicines are developed in Western Europe, Japan and the United States of America and therefore, when ICH was established, it was agreed that its scope would be confined to registration in those three regions.

ICH is comprised of Six Parties that are directly involved, as well as three Observers and IFPMA. The Six Parties are the founder members of ICH which represent the regulatory bodies and the research-based industry in the European Union, Japan and the USA. These parties include the EU, EFPIA, MHLW, JPMA, FDA and PhRMA.

The Observers are WHO, EFTA, and Canada (represented by Health Canada). This important group of non-voting members acts as a link between the ICH and non-ICH countries and regions.

ICH is operated via the ICH Steering Committee, which is supported by ICH Coordinators and the ICH Secretariat

3.7 ICH INTERESTED PARTIES

Interested Parties are those organisations that are expected to implement or to be regulated by the outcome of ICH efforts. These parties include the World Self-Medication Industry (WSMI) and the International Generic Pharmaceutical Alliance (IGPA), and other parties as determined by the Steering Committee. Where deemed appropriate, the Steering Committee may invite nominations from Interested Parties to Working Groups (EWG, IWG, Informal Working Group) or Discussion/Brainstorming Groups.

3.8 RHIs

Regional Harmonisation Initiatives (RHIs) namely Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Gulf Cooperation Countries (GCC), Pan American Network on Drug Regulatory Harmonization (PANDRH) and South African Development Community (SADC), have been invited to designate permanent representatives to the GCG. RHIs are founded on the principle of harmonising drug regulation across a defined group of non-ICH countries.

CHAPTER IV

4.1HOW ICH WORKS

ICH operates through the ICH Steering Committee with administrative support from the ICH Secretariat and ICH Coordinators. The Steering Committee meets at least twice a year, rotating meeting sites among the three regions. During these meetings, new topics will be considered for adoption, reports are received on the progress of existing topics, and maintenance and implementation of the guidelines are discussed. The topics identified for harmonisation by the Steering Committee are selected from Safety, Quality, Efficacy, and Multidisciplinary matters. Other issues, including preparations for major ICH conferences, are also addressed as they arise.

Working Groups also meet during the same week as the Steering Committee meetings and report on their progress to the Committee. Considerable work also occurs between meetings.

How a new topic is proposed

When one of the six parties feels that it has a suitable topic for harmonisation, the party prepares a proposal (or concept paper) that outlines the subject, the need for harmonisation, the anticipated effort and timetable for completion, and a recommendation on the type of working group required. The Steering Committee discusses intensively before deciding whether or not a topic requires harmonisation.

4.1 The steps in the ICH process

Step 1The Formal ICH procedure is a stepwise process. Preliminary discussions of which, consider existing guidelines in the region and elsewhere, known areas of similarity and differences, and scientific advances in the subject area. Under the leadership of the Rapporteur, drafts are prepared and circulated through many revisions until a "final harmonised draft" is completed.

Step 2This draft is signed by the EWG as the agreed-upon draft and forwarded to the Steering Committee for signing which signifies acceptance for consultation by each of the six co-sponsors

Step 3The three regulatory sponsors initiate their normal consultation process to receive comments. This comment period normally takes six months.

Step 4 After obtaining all regulatory consultation results, the EWG who organised the discussion for consensus building will be resumed. This EWG consists of regulatory and industry parties, and Observers. If the Rapporteur was designated from an industry party until *Step 2*, then a new Rapporteur will be appointed from the regulatory party, preferably from the same region as the previous Rapporteur. The same procedure described in *Step 1* is used to address the consultation results into the *Step 2* Final Document. The draft document to be generated as a result of the *Step 3* phase is called *Step 4* Experts Document.

If both regulatory and industry parties of the EWG are satisfied that the consensus achieved at *Step 2* is not substantially altered as a result of the consultation, or consensus is reached on any alterations, the *Step 4* Experts Document is signed by the EWG regulatory experts. The *Step 4* document with regulatory EWG signatures is submitted to the Steering Committee to request adoption as *Step 4* of the ICH process.

(*Step 4*) is complete when the Steering Committee agrees that there is sufficient scientific consensus on the technical issues. This endorsement is based on the signatures from the three regulatory parties to ICH affirming that the Guideline is recommended for adoption by the regulatory bodies of the three regions.

Step 5The process is complete and the guidelines are incorporated into national or regional internal procedures.

CHAPTER V

THE PRODUCTS OF ICH

ICH has developed over 50 harmonised guidelines aimed at eliminating duplication in the development and registration process, so that a single set of studies can be generated to demonstrate the quality, safety and efficacy of a new medicinal product. These guidelines also include the Common Technical Document (CTD), which describes the common format for the preparation of a well-structured CTD for applications that will be submitted to regulatory authorities.

5.1How are the ICH guidelines used

Industry and governments in ICH and non-ICH countries can use the ICH guidelines to address technical issues during the product development process. In addition to providing state-of-the-art guidance, the guidelines may well also serve as teaching tools. Harmonised ICH guidelines can reduce duplication in meeting technical requirements, thereby saving financial and material resources.

5.2 THE ICH Guidelines

The ICH Topics are divided into four major categories and ICH Topic Codes are assigned according to these categories.

Q	S	E	M
"Quality" Topics, i.e., those relating to chemical and pharmaceutical Quality Assurance (Stability Testing, Impurity Testing, etc.)	*"Safety" Topics*, i.e., those relating to in vitro and in vivo pre-clinical studies (Carcinogenicity Testing, Genotoxicity Testing, etc.)	*"Efficacy" Topics*, i.e., those relating to clinical studies in human subject (Dose Response Studies, Good Clinical Practices, etc.)	"Multidisciplinary" Topics, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories.

5.3 LIST OF GUIDELINES

REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE ***GUIDELINES INDEX***

BATCH Q: Quality		
	Finalised Guidelines *(Step 4)*	
Q1A(R2)	Stability Testing of New Drug Substances and Products (Second Revision)	Feb. 2003
Q1B	Stability Testing: Photostability Testing of New Drug Substances and Products	Nov. 1996
Q1C	Stability Testing for New Dosage Forms	Nov. 1996
Q1D	Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	Feb. 2002
Q1E	Evaluation for Stability Data	Feb. 2003
~~Q1F*~~	~~Stability Data Package for Registration Applications in Climatic Zones III and IV~~ *(Guideline withdrawn in June 2006).*	~~Feb. 2003~~
Q2(R1)	Validation of Analytical Procedures: Text and Methodology *(The Addendum dated November 1996 has been incorporated into the core guideline in November 2005).*	Oct. 1994
Q3A(R2)	Impurities in New Drug Substances	Oct. 2006
Q3B(R2)	Impurities in New Drug Products	Jun. 2006
Q3C(R4)	Impurities: Guideline for Residual Solvents	Feb. 2009
Q4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions	Nov. 2007

Q4B Annex 1	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Residue on Ignition/Sulphated Ash General Chapter	Nov. 2007
Q4B Annex 2	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Extractable Volume of Parenteral Preparations General Chapter	Jun. 2008
Q4B Annex 3	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Particulate Contamination: Sub-Visible Particles General Chapter	Jun. 2008
Q4B Annex 4A	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	Nov. 2008
Q4B Annex 4B	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-Organisms General Chapter	Nov. 2008
Q4B Annex 4C	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	Nov. 2008
Q4B Annex 5	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Disintegration Test General Chapter	Jun. 2009
Q4B Annex 8	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Sterility Chapter General Chapter	Jun. 2009
Q5A(R1)	Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or	Sep. 1999

	Animal Origin	
Q5B	Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	Nov. 1995
Q5C	Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products	Nov. 1995
Q5D	Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/	Jul. 1997

ICH Guidelines Index BATCH Q: Quality

Biological Products

Q5E	Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process	Nov. 2004
Q6A	Specifications : Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products : Chemical Substances	Oct. 1999
Q6B	Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	Mar. 1999
Q7	Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients	Nov. 2000
Q8(R1)	Pharmaceutical Development	Nov. 2008
Q9	Quality Risk Management	Nov. 2005
Q10	Pharmaceutical Quality System	June 2008

Guidelines released for consultation (Step 2)

Q4B Annex 6	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on University of Dosage Units General Chapter	Nov 2008
Q4B Annex 7	Evaluation and Recommendation of	Nov

	Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter	2008
Q4B Annex 9	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Tablet Friability General Chapter	June 2009
Q4B Annex 10	Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Polyacrylamide Gel Electrophoresis General Chapter	June 2009

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BATCH S: Safety		
	Finalised Guidelines (Step 4)	
S1A	Guideline on the Need for Carcinogenicity Studies of Pharmaceuticals	Nov. 1995
S1B	Testing for Carcinogenicity of Pharmaceuticals	July 1997
S1C(R2)	Dose Selection for Carcinogenicity Studies of Pharmaceuticals	March 2008
S2A	Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals Currently being revised in S2(R1)	July 1995
S2B	Genotoxicity : A Standard Battery for Genotoxicity Testing of Pharmaceuticals Currently being revised in S2(R1)	July 1997
S3A	Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	Oct. 1994
S3B	Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	Oct. 1994
S4	Duration of Chronic Toxicity Testing in Animals (Rodent and Non Rodent Toxicity Testing)	Sept. 1998
S5(R2)	Detection of Toxicity to Reproduction for Medicinal Products and Toxicity to Male Fertility (the Addendum dated November 1995	June 1993

	has been incorporated into the core guideline in November 2005)	
S6	Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	July 1997
S7A	Safety Pharmacology Studies for Human Pharmaceuticals	Nov 2000
S7B	The Non-clinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals	May 2005
S8	Immunotoxicity Studies for Human Pharmaceuticals	Sept. 2005
	Guidelines released for consultation (Step 2)	
S9	Nonclinical Evaluation for Anticancer Pharmaceuticals	Nov 2008
S2(R1)	Guidance on Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use (this guideline replaces and combines S2A and S2B guidelines).	March 2008

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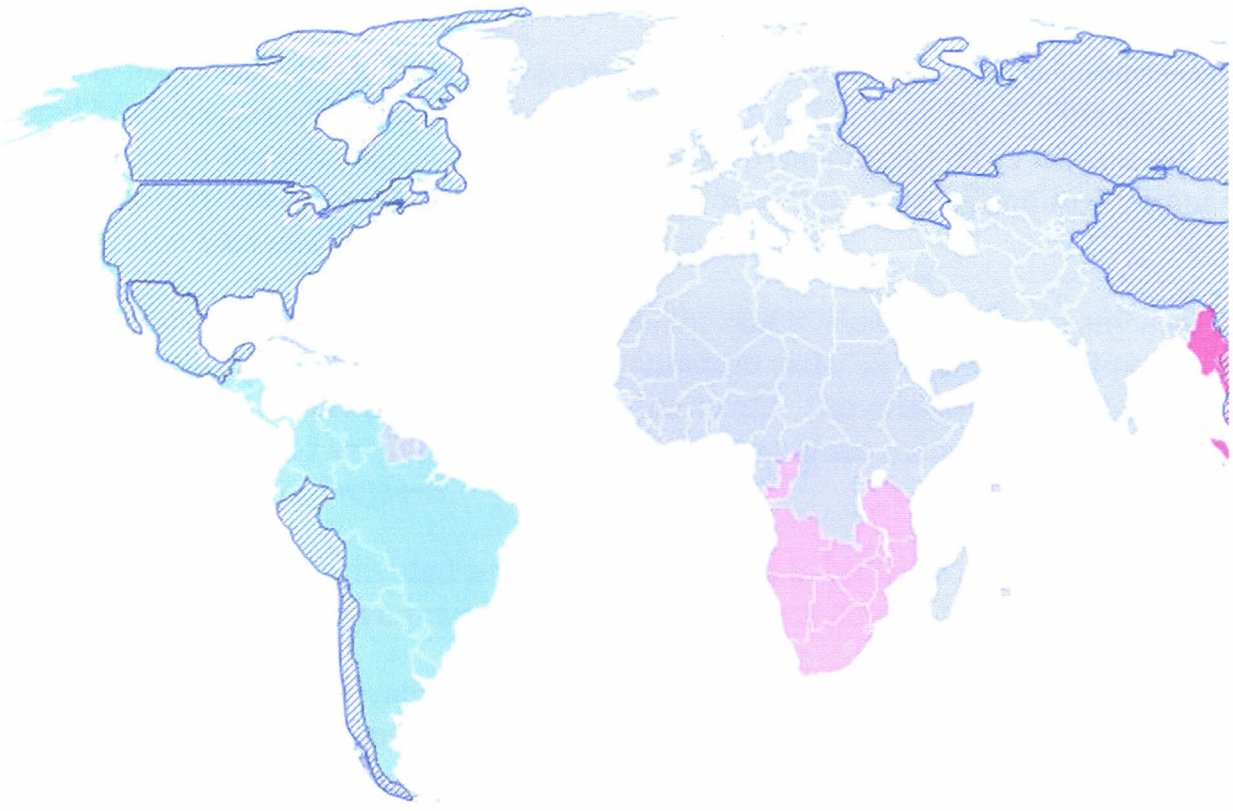
BATCH E: Efficacy		
	Finalised Guidelines (Step 4)	
E1	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions	Oct. 1994
E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	Oct. 1994
E2B(R2)	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (This guideline is re-opened for revision under Step 2. See E2B(R3)).	Feb. 2001

E2C(R1)	Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (The Addendum dated February 2003 has been incorporated into the core guideline in November 2005).	Nov. 1996
E2D	Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting	Nov. 2003
E2E	Pharmacovigilance Planning	Nov. 2004
E3	Structure and Content of Clinical Study Reports	Nov. 1995
E4	Dose-Response Information to Support Drug Registration	March 1994
E5(R1)	Ethnic Factors in the Acceptability of Foreign Clinical Data	March 1998
E6(R1)	Good Clinical Practice: Consolidated Guideline	May 1996
E7	Studies in Support of Special Populations: Geriatrics	June 1993
E8	General Considerations for Clinical Trials	July 1997
E9	Statistical Principles for Clinical Trials	Feb. 1998
E10	Choice of Control Group and Related Issues in Clinical Trials	July 2000
E11	Clinical Investigation of Medicinal Products in the Pediatric Population	July 2000
E14	The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	May 2005
E15	Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories	Nov. 2007

	Guidelines released for consultation (Step 2)	
E2B(R3)	Second Revision of the Clinical Safety Data Management : Data Elements for Transmission of Individual Case Safety Reports To read together with M2 ICSR (R2) Message Specification (ICH ICSR DTD Version 2.1, February 2001).	May 2005
E2F	Development Safety Update Report	June 2008
	Consensus Draft Principle	
E12	Principles for Clinical Evaluation of New Antihypertensive Drugs	March 2000

BATCH M: Multidisciplinary		
	Finalised Guidelines (Step 4)	
M2 ICSR (R2)	Electronic Transmission of Individual Case Safety Reports Message Specification (ICH ICSR DTD Version 2.1) companion document to E2B(R3)	Feb. 2001
M3(R1)	Maintenance of the ICH Guideline on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals. (This Guideline is re-opended for revision under Step 2. See M3(R3)).	Nov. 2000
M4(R3)*	Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use (Edited with Numbering and Section Header Changes, September 2002) Including the Annex : the Granularity Document (Revised November 2003).	Nov 2000
M4Q(R1)*	The Common Technical Document for the Registration of Pharmaceuticals for Human Use : Quality (Edited with Numbering and Section Header Changes, September 2002)	Nov 2000
M4S(R2)*	The Common Technical Document for the Registration of Pharmaceuticals for Human Use : Safety (Edited with Numbering and Section Header Changes, September 2002)	Nov 2000
M4E(R1)*	The Common Technical Document for the Registration of Pharmaceuticals for Human Use : Efficacy (Edited with Numbering and Section Header Changes, September 2002)	Nov 2000
	Guidelines released for consultation (Step 2)	
M3(R2)	Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	July 2008
M5	Data Elements and Standards for Drug Dictionaries	May 2005

REGIONAL HARMONISATION INITIATIVE (RHI) PROFILES



APEC ASEAN GCC PANDRH SADC

CHAPTER VII

CONCLUSION

The objective of this study was to give an insight on the activities processes and guidelines of INTERNATIONAL CONFERENCE ON HARMONISATION OF THE TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE

It is important to first create awareness due to it being relatively a young body and has been growing feasibly since its initiation in the year 1990. This can be attributed to the relevance of this organization to the present day Pharmaceutical practice and Trade and seeks to synchronise the activities rules and regulations that govern the vast and dynamic world of pharmaceuticals.

The mandate of ICH is therefore to assess the challenges that arise in any aspect of pharmaceutical practice and the global market in order to device guidelines that can be adopted in any part or country in the world. The primary ICH Regions were the three founders Europe, USA and Japan but has since incorporated many other willing partners and regions.

In addition, ICH has divided its regions according to climatic regions so as to make guidelines that would be practical, suitable and implementable in those regions.

Thirdly, ICH Seeks to cater for the disharmony that results from the development of new drugs in different places and their subsequent registration by providing harmonized guidelines for this situations

ICH is therefore in the forefront in leading the harmonization of the worldwide market of pharmaceuticals in the spirit of globalization.

REFERENCES

The *official ICH website: www.ich.org*