# Pharma Forum

July 2015 | Volume 20 | Number 2

An Independent review of
*Pharmaceutical News and Issues*

Published biannually by the
Ethiopian Pharmaceutical Association (EPA)

## In this Issue

## Message from Editors

Pharma Forum is one of the media through which the association communicates with its members. The Editorial committee is dedicated to give current information related to our profession through its two types of publications: the Pharma News Newsletter and the Pharma Forum Bulletin.

The committee plans to publish Pharma News quarterly and Pharma Forum bi annually. But active participation by EPA members is critical as the editorial committee members come from certain specializations and pharmacy practice fields in Ethiopia thus by no means they cannot able to cover the whole range of pharmacy news nor the recent updates in knowledge in the sector. The editors also want to emphasize that the Pharmaforum is not a scientific journal thus you should not have to been an "inventor" of the idea or the subject you submit to the publication. Just subjects/publications you feel relevant can be submitted to us by adopting them with our context. That is why the name "Compiled by" appears below the issues that appear in this bulletin.

Regarding the distribution of the publications, EPA office undertakes the responsibility of distributing the hard copies to members while the editorial committee forwards the soft copies to each member through E-mails.

The editorial committee would like to use this opportunity to thank those members who have made contribution to this and previous publications, as well.

We invite and encourage all members to contribute whatever they believe is appropriate for our publications be it articles, comments & suggestions, new experiences, educational issues, humor, etc., all are welcome.

We hope to hear from you.

Pharma Forum Editorial Committee

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# 1. News

## 1.1. Pharmacy Day Celebration

The Ethiopian Pharmaceutical Association (EPA) in collaboration with the Ethiopian Pharmaceutical Manufacturing Factory (EPHARM) and Medteck Ethiopia organized a national pharmacy day on December 04, 2014 at Ambassador Hotel to commemorate the 40$^{th}$ year founding anniversary of the association. The event was attended by more than 120 participants representing all the pharmacy practice sectors in the country. The topics that were subjected to presentations and discussions during the event include:

- Accessibility and the role of pharmacists: Global, Regional and National Perspectives
- Pharmaceutical manufacturing in Ethiopia: success and challenges
- Pharmaceutical import and distribution in Ethiopia: achievements and challenges
- Pharmaceutical retail services in Ethiopia: success and challenges
- Pharmaceutical Regulation in Ethiopia: Achievements and challenges

The event went on from 8:30AM to 1:00 PM. The participants of the event forwarded various recommendations to the association regarding the colorful celebration of the event in the coming years and how the challenges in the pharmaceutical sector could possibly be solved in collaboration with all relevant stakeholders and partners.

**A** **B**

**Photos A and B show the event activity i.e. discussions and deliberations on the thematic issues inside ambassador hotel**

## 1.2 Good Manufacturing Practice (GMP) Conference

The Ethiopian Pharmaceutical Association and Julphar Ethiopia jointly organized a two days GMP conference on January 14 and 15, 2015 at Elily International Hotel.


***Picture of the Poster for the event***

The conference was attended by participants from different governmental and non-governmental organizations. In this conference, the following topics were touched for the sessions in the presentations and discussion.

- Briefing about Ethiopian Pharmaceutical Association
- Overview of the Pharmaceutical Supply Chain Management in Ethiopia
- Assessment of local pharmaceutical industries with respect to validation and documentation
- Pharmaceutical facilities from design to realization
- Equipments for granulation process and tablet coating
- Qualification of medicine production rooms
- GMP approach to design for pharmaceuticals equipment
- USP/PQM Efforts to ensure GMP in Ethiopia

- Preparedness of the pharmaceutical quality Food, Beverage and Pharmaceutical Industry Development Institute; its Mandate and efforts made so far to capacitate the pharmaceutical industry in Ethiopia
- Opportunities and challenges to domestic pharmaceutical manufacturers in order to be GMP compliant and certified.

**Photo showing Key note Address by H.E. Mebrahtu Meles and Certificate handing over at the end of the conference**

### 1.3 Workshop on Quality of Pharmacy Education in Ethiopia

The Ethiopian Pharmaceutical Association in Collaboration with Higher Education Relevance and Quality Agency (HERQA) and Jhpiego Ethiopia organized a one day workshop on March 27, 2015 at Ambassador Hotel about pharmacy education quality. The following major topics were addressed during the workshop which went on from 8:30AM in the morning to 6:30 PM in the afternoon.

- Revitalization of the quality assurance system for health profession education in Ethiopia
- Quality of Pre-service Education in Private Medical Colleges in Ethiopia

- Quality of Pharmacy Education in Public Pharmacy Schools in Ethiopia
- Pharmacy Curriculum Harmonization and graduates diversification in line with the country's growth trajectory
- Employers' perception on the competency of pharmacy graduates
- National Accreditation and Quality Improvement standards for Pharmacy Education in the B. Pharm. Degree Program

***A photo depicting one of the sessions in the workshop***

At the conclusion of the workshop, the following action points were noted by the organizers to be the priority areas of action to improve pharmacy education quality.

- EPA to coordinate series of workshops on quality of pharmacy training and curriculum improvement in Ethiopia
- With EPA leadership, all schools of pharmacy to implement standards for quality improvement which is prepared by HERQA and their respective university initiatives for education quality improvements.
- EPA to coordinate the establishment of the consortium of the schools of pharmacy
- Schools of Pharmacy's in the country to document perception of employers towards the competency of pharmacy graduates using comprehensive study
- EPA to organize need based training in its continuous professional development Programme (CPD) to capacitate the competency of pharmacy professionals who are already at work
- EPA, schools of Pharmacy and concerned stakeholders to conduct inventory of pharmacy practice sites for graduating students and develop memorandum of understanding to smooth run the apprenticeship
- Schools of pharmacy should give serious attention while assigning students for practicum and to follow their progression too.

### 1.4 Antimicrobial Resistance Day

The Ethiopian Pharmaceutical Association (EPA) and Ethiopian Pharmaceutical Students Association *in Collaboration With* Federal Ministry of Health, Food Medicine and Health Care Administration and Control Authority of Ethiopia, Pharmaceutical Fund and Supply Agency, USAID/SIAPS and WHO organized a half day Antimicrobial Resistance day on June 16, 2015 at Ethiopia Hotel. The workshop was opened by H.E. Dr. Addis Tamre. The following topics were the subjects of presentations and discussions during the event.

- Current Status of Microbial Resistance in Ethiopia
- Updates on National AMR Containment strategy: Implementation and Challenges
- Global Strategy on AMR Prevention and Control

## 2. Current Issues

### Application of CPD and its Implication for Pharmacy Profession

**By: Mammo Engedayehu:**

Continuous Professional Development (CPD) is defined as a range of learning activities through which health professionals maintain and develop throughout their career to ensure that they retain their capacity to practice safely, effectively and legally within their evolving scope of practice.

No person shall practice as a health professional without having obtained a professional practice license issued by the appropriate organ and in Ethiopia Professional practice license given to any health professional in this regard shall be renewed every **five years** upon **ethical and competence evaluation** (Food, Medicine and Healthcare Proclamation No. 661/2009 Article 33/2). To get or renew professional practice license it is mandatory to have certificate of completion of the required CPD in his/her profession (Regulation No. 299/2013 Article 66/1.)

To implement the above legal frameworks and with the ultimate aim of improving the health status of Ethiopians through the delivery of quality health services by competent health professionals, Ethiopia is to implement this CPD system in the country through the process of accreditation of CPD courses and CPD providers and linking CPD with re-licensure.

### The Approaches to CPD Need Assessment

Two approaches of CPD need assessment will be implemented to assess course needs:

- ✓ Top down approach

- ✓ Bottom up approach

In top down approach, FMOH, FMHACA and Professional Associations will recommend relevant CPD activities for health professionals based on new scientific development, revised national guidelines and changes in health service delivery.

In bottom up approach, health professionals will identify their own individual learning needs based on their performance appraisal and ability to accomplish annual plans.

**The role of EPA in CPD**

According to the FMHACA's directive on the implantation of CPD for health professionals, issues on March 2013, the health professional associations got major opportunities to strengthen their professional associations and their members through CPD. Thus EPA is taking this golden opportunity and will actively engage on the following tasks:

- Will Serve as a course accreditor and/or a provider;
- Is serving as major initiators and promoter of CPD
- Propose CPD activities and recommend credit point requirements for pharmacy profession
- Actively participating in CPD activities need assessments

CPD Accreditors are institutions including professional associations to pre-accredit CPD providers and courses that need later approval by FMHACA that they meet the criteria set out. The role of Accreditors is to review and pre-accredit applications for the provision of CPD activities and send the pre-accredited documents to FMHACA for approval.

CPD Providers are public or private institutions including, Professional Associations, Universities, Health science colleges, and other training institutions which meet the criteria and have been accredited by FMHACA or its designated accreditor to present learning activities for CPD. CPD providers and courses have to be accredited by FMHACA or its delegate accreditors. Generally the implementations on the CPD apply the following:

- Professionals in all health science fields are required to earn at least 30 continuing educational unit (CEU) per year and 150 CEU per five years to get a re-licensure,
- Credit points for a CPD course shall be obtained only if the course received is accredited by a Course Accreditor and approved by FMHACA,
- Credit points should only be claimed if the activity or the course is relevant to the applicants practice,

| S.No | Activity | Credit (CEU) |
|---|---|---|
| | In-service training (group based) | 1 CEU per 1 contact hour |
| | Workshop | 0.5 CEU per 1 hour of attendance |
| | e-learning (enduring materials, on-line etc) | 1 CEU per 1 hour of engagement |
| 1. | Scientific Conference | 0.25 CEU per 1 hour of attendance |
| 2. | Review a research article for journal | 3 CEU per article reviewed |
| | Publish a research article in a peer reviewed journal: | |
| | Principal author | 20 CEU per article |
| | Co-author | 10 CEU per article |
| | Chapters in a book/training module in area of specialization: | |
| | 1st (or single) author | 10 CEU per chapter or module |
| | 2nd author (and beyond) | 5 CEU per chapter or module |
| | Writing a book in area of specialization | All the required CEUs per annum |
| | Presentations in conference: | |
| | Oral presentation | 10 CEU per presentation |
| | Poster presentation | 5 CEU per presentation |
| | Delivering training/workshop | 2 CEU per 1 hour session |
| | Guest lecture (non-routine tasks) | 2 CEU per 1 hour session |
| | Panelist | 1 CEU per 1hr of engagement |
| | Assessing masters or doctoral thesis | 5 CEU Per Thesis |

- The maximum credit point that can be earned from a single CPD course shall not exceed 15 CEUs,
- Credit points should be earned from a particular course only once within a licensure period,
- CPD credit points collected during one budget year cannot be transferred to another year,
- Professionals attending courses leading to a degree may not be obliged to fulfill the credit points requirement for that year. The crediting system and allocated CEU for sleeted activities is narrated on the following table:

The Ethiopian Pharmaceutical association (EPA) is taking this opportunity to be course provider/accreditor to pharmacists/other professions. Since we are one of the oldest professional associations, we can receive the service provision responsibility to other professions too. Currently all applicants who showed their interest to be course accreditors/ providers have submitted their applications to FMHACA and it is under evaluation.

Our association can take advantage from this move in two ways. Primarily and above all others, it can maintain its professionals' competency and increase public trust through provision of CPD. Secondly; it can generate income through course accreditation/ provision service.

**Roles and obligations of** Pharmacists **in CPD**

All pharmacists are expected to participate, as mandatory requirements, in CPD activities in order to acquire re-licensure (to renew professional license).

- Are required to complete the specified CEUs of accredited continuing education activities each year.

- Pharmacists who are registered in more than one profession are required to obtain CEUs for each profession.
- Each pharmacist shall avail certificate of attendance during re-licensing.

**Advantage of CPD for pharmacists:**

- Can maintain their competency with other professions
- Increase knowledge
- Stay up to date with scientific dynamics
- Improve the image of profession and work situation
- Increase job satisfaction
- Increase income as there will be more demand of competent and accredited pharmacists

**EPA has now its own compound!**

Ownership of its own office and having what the profession calls "Home" for the Association is one of the milestone achievements in its history. For this critical asset all members had played a great role.

But during different executive committee times, many bricks had been laid that result for the achievement of this. The final goal of owning its own property as office compound was realized in the present location near Sanford School. A villa was purchased by the association with adequate rooms for the current office operation of the association. This is a good celebration in which the association is proud to be. However, building its own "purpose suited stories" remains at large. Based on the current needs a building that caters in service training and other needs of the association is a critical task that does not require any delay. The generous hands of the members and the organizations that support the profession of Pharmacy should be extended to achieve this tremendous goal.

## 3. Continuing Education

**Pharmaceutical regulatory Affairs**:

Compiled by: Ayenew Ashenef

## INTRODUCTION

Regulatory Affairs (RA), also called Government Affairs, is a profession with in regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods) (1). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals (2). The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents(3).

## PHARMACEUTICAL DRUG REGULATORY AFFAIRS

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified4)

Regulatory Affairs is a comparatively new profession which has developed from

the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.

The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals – and those who don't, rely on the expert advice of independent regulatory consultants to meet their obligations.

The Regulatory Affairs department will take part in the development of the product marketing Concepts and is usually required to approve packaging and advertising before it is used commercially. Many companies operating in the high-technology health-care and related industries operate on a multinational basis and are very significant exporters. Their Regulatory Affairs departments must be aware of the regulatory requirements in all the company's export markets.

As an added complication, despite recent international efforts towards harmonization of requirements, the regulations laid down by different governments and their interpretation by the regulatory agencies, rarely match. Consequently, the registration data prepared for one country frequently fail to meet the requirements for another. Therefore great care has to be taken in drawing up efficient and economical research and development programs whose results may be used as widely as possible. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

## IMPORTANCE OF REGULATORY AFFAIR

In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

Inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug may have cost many millions of pounds, Euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse, failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall. Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific Endeavour with regulatory demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources.

The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs professionals will condition the perceptions of the government officials to the company –for better, or for worse! Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent. The importance of the Regulatory Affairs function is such that senior Regulatory Affairs professionals are

increasingly being appointed to boardroom positions, where they can advise up on and further influence the strategic decisions of their companies(5).

## REGULATORY BODIES

Regulatory bodies such as the Food and Drugs Administration (FDA) in the USA are responsible for approving whether a drug can proceed to clinical trials and whether it should be allowed on the market. The regulatory body has to evaluate the scientific and clinical data to ensure that the drug can be produced with consistently high purity, that it has the clinical effect claimed, and that it does not have unaccepted side effects. It must also approve the labeling of the drug and the directions for its use. In general, the regulatory body is interested in all aspects of a drug once it has been identified as a potential useful medicine.

Different Countries in the world have their own regulatory departments in their Ministry of Health dealing with these issues while a separate authority also exists for such purpose independent of the Ministry of Health. UN organizations like the WHO also play great role in regulatory aspects. Similarly some unions like the EU have specific organizations that deal with regulatory affairs and have a harmonized regulatory system.

## PRACTICE OF REGULATORY AFFAIRS Information

Information is often described as the currency of the 21st century, and for RA this has been the case since the earliest days of the profession.

Regulatory is the interface between the company/sponsor and the outside world (in terms of regulators/regulatory authorities). As a conduit or a funnel, the regulatory department is a focal point of information, both incoming and outgoing. In order to practice regulatory and succeed, both in objective public measures (e.g., approvals) and internal ones (e.g., recognition and reward), recognizing the power of

information and learning to manage it is critical process.

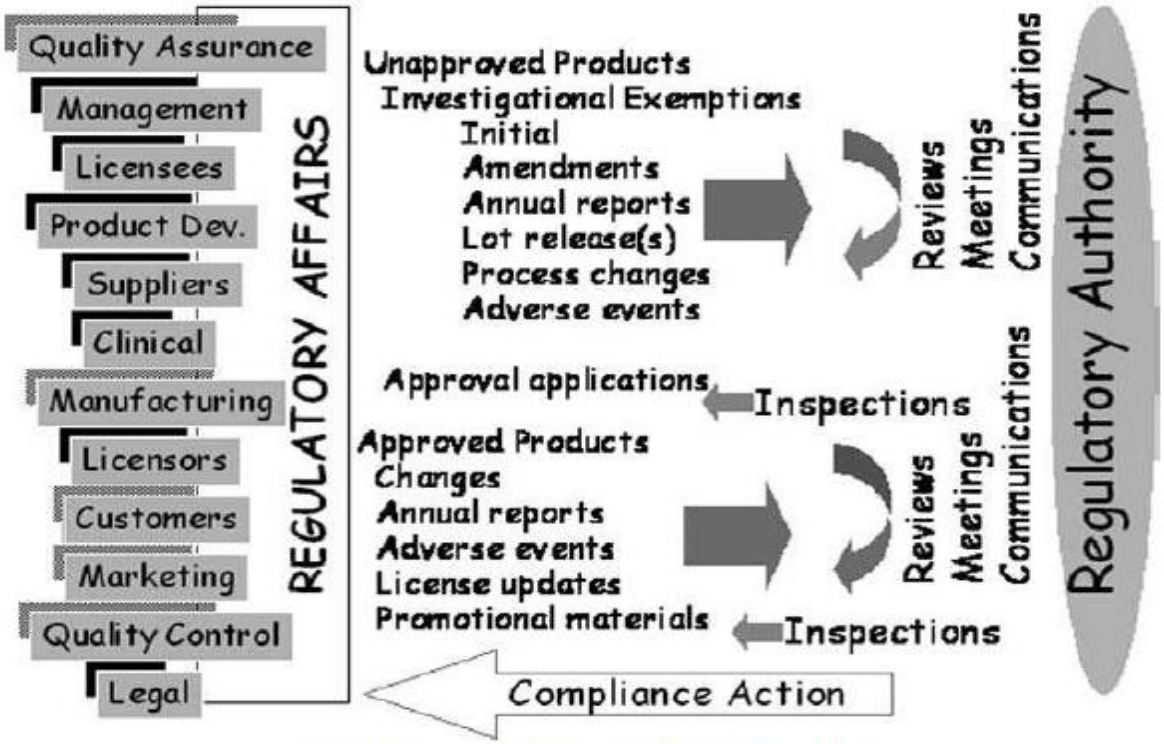


***Fig 1:*** *The spectrum of regulatory affairs*

**Gathering Information**

There should be no need to go over published sources of information, both commercial and governmental. The sources of gathering information are, any opportunity to see, hears, or talks with a regulator, a more experienced drug development expert, a colleague, or a sworn enemy is an opportunity to gather information.

Never be afraid to ask a question, never be afraid to approach a new person who might have information need, and always be willing to listen.

**Communicating Information**

The easiest information to share and communicate is non critical information. These are findings and data from public presentations and widely available sources that simply need to be put into a logical and relevant form and shared within the organization. The main issue with such information is getting to the right audience without boring them into forgetting that they're getting useful data.

Most companies subscribe to news updates or have internal regulatory information updates via e-mail. However, these updates often have a hard time grabbing attention and actually being used as a resource. One suggestion is to make them playful and user-friendly, using popular Web pages as guides.

The difficult information to communicate is critical information. This could mean anything vital to the success or failure of a project, specific and important feedback from the FDA, subtle insight that weighs heavily on the future of the company, etc. While it would be simple to just shoot an e-mail off to the entire company, it
Is neither in the company's interest nor your interest to take that approach. The first thing to do is document the information carefully, so that we can fully understand it and its implications. Then think of those individuals who are that combination of "need to know" and "know who else needs to know." At small start-ups this might be the CEO or the president. At larger companies, the head of clinical, a project manager, or a similar middle- to senior level manager fits the bill. Using these first points of contacts allows the information to pass through appropriate channels. It also allows for the dissemination of the information in the proper context.

## Documentation

One of the first things one learns in regulatory and compliance is “if it isn’t documented, it wasn’t done.” Not following this basic principle leads to a large number of compliance failures and can also lead to the downfall of critical development projects. Projects in drug, device, and biologics development can take upward of years to complete and cost tremendous amounts of money. The time involved can be upward of five times longer than the average stay in a regulatory job, depending on location and industry. This means projects need to outlast the people who work on them, and the only way they can do this is to have solid documentation to support them. Document progress, document decisions,
Document information, document failures, and document successes. This need to document is important at large companies, where complex dynamics may move a project through the hands of multiple teams, and at small companies, where key decisions may be questioned by advisory boards, investors, potential investors, and potential partners.

## Submissions

Submissions to regulatory authorities are the ultimate “product” created by a regulatory department, and they also, in terms of content, format, and quality, represent the company and product. Often voluminous and spanning multiple technical areas, regulatory submissions are complex documents in every sense—from an editorial, scientific, and paper-management perspective. At the same time, these documents represent the ideal opportunity for a regulatory professional to shine—not just in the quality of the final product but in the way the document is brought together.

## Regulatory Review: Continuity and Connection

Most large regulatory submissions involve multiple technical sections that are written by separate technical groups. As the overall "owner" of the submission, regulatory is responsible to assure the overall quality. This can usually be broken down into the concepts of continuity and connectivity. Earlier it was implied that regulatory should avoid writing a submission— when it comes to continuity, regulatory must take the lead in writing. Sections of the document need to flow
In to each other, so the document appears at some level to have one voice. This is particularly important when concepts and data from multiple sections are brought together, as in introductory sections, synopses, and summary conclusions— cut and paste doesn't cut it. The language needs to be fluid, and the order of data logical. Connectivity is a concept that is seldom recognized overtly by the regulatory community, but is in fact one of our most important responsibilities when it comes to submissions. As the owner of a submission, regulatory is really the only "person" who sees the entire document, and the document is not a linearly attached series of sections it has multiple internal cross-references and connections.

## Presenting Data in Submissions

With the advent of electronic submission production (e.g., Word, Excel, multiple graphics packages), we far too often resort to a quick "cut and paste job" when it comes to presenting data. It is benefit that rather than blindly including graphs and tables of data, it is regulator's job to look at these data presentations and make sure that the message behind them is clear and that the presentation is suited to the message. If an upward trend in the data is what you want a reviewer to see, a graph is better than a table, for example. Having a y-axis that has a maximum value of 100 when all data skirt between 0 and 10 may not make sense (of course, if message is that the data are all well below some threshold, let's say 30, it might

make sense!). One of the most important concepts is to make sure the data speaks as loudly as possible, and that it speaks the right message without being lost in the noise of the presentation. Bold colors and three- or four-dimensional artwork mean little if a reader cannot grasp the data or the experiments behind the data. A classic example is when multiple experimental points (e.g., subjects in a clinical trial) are compressed into a small number of data points. The goal was clarity, but power is lost—a reader may assume only a few experiments (or a small number of subjects) produced the data. The power of the data is thus diminished (6).

## THE DRUG REGULATORY AFFAIRS PROFESSIONAL

The pharmaceutical research and development process of bringing a new drug to the market takes many years; it is therefore essential that the process be managed effectively from beginning to end in order to meet the regulatory requirements and permit a favorable evaluation of efficacy and safety in the shortest possible time. The drug regulatory affairs (DRA) professional plays an important role in every phase of this process, from developing regulatory strategies following the discovery of a new chemical entity to planning post-marketing activities.

The main responsibility of the DRA professional within a pharmaceutical company is to secure approval of drug submissions from Health Therapeutic Products Program (TPP) and to ensure regulatory compliance of marketed and investigational drugs with the Food and Drug Act and Regulations and TPP Guidelines/Policies. In this position, the DRA professional must possess a proficient scientific background (B.Sc, M.Sc., Ph.D., M.D. B. Pharm, M.Pharm or Pharm.D.) and have acquired a thorough knowledge of Country regulations as well as international regulations. Because the regulatory environment is evolving rapidly toward global harmonization (several ICH guidelines have now been adopted by TPP) and mutual recognition between different health authorities

across the world, it is a major challenge for the DRA professional to keep abreast of policy changes and determine how these changes affect the approval process. Consequently, the importance of DRA in the development and approval of new drugs have increased significantly over the last decade. Whether a submission is filed to the TPP for the conduct of a clinical trial (Investigational New Drug Submission, or IND), for the approval to market a new drug (New Drug Submission, or NDS), for a new indication or dosage form for a marketed drug (Supplemental NDS, or S/NDS), or for the maintenance of a marketed drug's regulatory status, the submission's preparation entails the close collaboration of multidisciplinary team. The DRA professional must actively participate in discussions and coordinate team activities to obtain all the necessary documentation as per the current TPP policies and then assess it for completeness and accuracy. Therefore, the effective DRA professional must exhibit the organizational and interpersonal skills of a "team player" and also be thorough and detail-oriented.

The scope of responsibilities is wide and may vary significantly according to the organizational structure of the pharmaceutical company. The responsibilities of some DRA professionals may focus exclusively on pharmacovigilance activities or on the electronic representation of information (electronic submissions).Other responsibilities may include provincial formulary submissions, review of advertising materials, product launch activities, and quality assurance, to name a few. The common point, however, is that the DRA professional is the primary liaison between the sponsor and the TPP. In this capacity, the individual must possess excellent writing and communication skills and be an effective negotiator. This is to ensure that the requests or comments generated during the submissions review process are promptly and satisfactorily answered and to negotiate the

most favorable labeling (Product Monograph) consistent with the sponsor's business objectives.

In line with today's growing technological developments, knowledge of several computer applications is essential to effectively fulfill the job requirements. DRA is a dynamic, rewarding field that embraces both scientific and legal aspects of drug development. DRA professionals are dedicated individuals who take pride in their contribution to improving the health and quality of life of peoples (7).

**Responsibility of Regulatory Affairs Professional's**

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to obtain and maintain marketing authorization for the products concerned. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole.

It may take anything up to 15 years to develop and launch a new pharmaceutical product and many problems may arise in the process of scientific development and because of a changing regulatory environment. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where

regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labeling or in advertising.

**What Makes a Good Regulatory Affairs Professional?**

Most regulatory professionals are graduates in a scientific discipline, commonly life sciences or pharmacy, although increasingly biotechnology based degrees are valuable. Some choose to have an additional legal qualification. The ability to tackle data in a wide range of scientific areas and to quickly grasp new concepts and complex technical information is vital. Communication skills are very important. Analyzing issues and presenting both written and oral evidence before a panel of experts such as scientists, pharmacists, doctors and lawyers who run the government agencies require considerable understanding of both legal and scientific matters. An attention to detail is a pre-requisite. An analytical frame of mind is important, too. An ability to evaluate the strengths and weaknesses of the technical and legal options open to a company and to the agency concerned is crucial.

A high degree of sensitivity is required when proposing and executing the strategy and tactics needed to obtain marketing approval in a way which will satisfy the authorities and serve the best needs of the company. Considerable care must be exercised if the best possible case is to be presented to the authorities for the company. It must be done without obscuring the facts, enabling the authorities to arrive at a proper and rightful conclusion regarding safety, efficacy and quality of the product under application. Regulatory professionals must always exercise considerable judgment in the practice of their role. Integrity and the ability to inspire trust and confidence are valuable attributes. Good regulatory people ‘make it happen’. Project management skills help to achieve the challenging goals they

are set. They can work as part of multi-disciplinary teams and lead them when necessary. They can work under pressure and inspire and motivate others to do the same (8).

## NEED OF REGULATORY AFFAIRS IN THE PHARMACY CURRICULUM

The pharmaceutical biotechnology and medical device research and development industries are among the most highly regulated industries in the country. As Ethiopia is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition.

Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries. The present article discusses the regulatory education and its need, learning resources, courses available, syllabus contents, and job opportunities in regulatory affairs As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

## REGULATORY AFFAIRS EDUCATION

The person indulging in the regulatory affairs must be familiar with all the guidelines, guidance's and regulatory documents. He should have a thorough understanding of a particular regulatory document which has been drafted. Such people are the primary communication link between the company and worldwide regulatory agencies such as USFDA (1) (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA). A number of organizations such as the Regulatory Affairs Professional Society (RAPS), the Drug Information Association (DIA), the Food and Drug Law Institute (FDLI) and international organizations such as the European Society of Regulatory Affairs play a vital role in providing relevant information. Commercial training companies such as Parexel-Barnett and the Pharmaceutical Education and Research Institute (PERI)conduct meetings on the regulatory affairs, which would be helpful to the professionals(9).

The curriculum deals with the USFDA and EUDRA guidelines concerning filing for New Drug Applications and Abbreviated New Drug Applications; FDA, International Conference on Harmonization (ICH), EUDRA and Pharmaceutical Inspection Convention (PIC) guidelines for various operational activities; Intellectual Property Rights such as Patents, Copy Rights, Trademarks; etc for patenting. In general, the curriculum comprises of introductory foundation that outlines the health care product research, development process and the regulatory oversight of the complex processes. There are both part-time and fulltime courses available for the subject. Part-time courses are suitable for the professional who will come across these terms occasionally where as full-time course is meant for the professional who intends to make his career in the regulatory affairs (10).

**Ethiopian Regulatory Affairs System and training:**

Like any other country, in Ethiopia, the Pharmaceutical sector is highly regulated and thus organizations or institutes of the like the Ministry of Health, the Ethiopian Food Medicines and Health care administration and control Authority( EFMHACA), The Ministry of Agriculture, VDFHACA at the federal level and similar organizations at the regional level exist for such purpose. Pharmacists are the major Professionals involved in the practice of the Pharmacy regulation although some other professionals have supportive purposes. Hence the training of the Pharmacists includes issues related to Pharmaceutical regulation. Thus, the Pharmacy curriculum in the B.Pharm. programme has some topics/titles dealing with the regulatory affairs issues. Titles dealing with this subject were present in the courses like Professional pharmacy and ethics, Pharmaceutical analysis in the previous B. Pharm. Curriculum in which the majority of pharmacists in the country trained. In the new curriculum this topic is also addressed on the courses like Pharmaceutical analysis, an elective course on quality control and assurance as well as regulatory affairs attachment. Besides the MSc programme in Pharmaceutical analysis and quality assurance had modules incorporating topics directly related to regulatory affairs. Some topics are also dealt in the social Pharmacy and Pharmacoepidemilogy MSc curriculum and Programme too. But the depth of coverage in the previous and current pharmacy curriculums about regulatory affairs topic is minimal. However, there is a demand to address Pharmaceutical regulatory affairs training scientifically and deeply to cope with the advancements in the profession as well as in line with the rest of the world.

Hence the School of Pharmacy in collaboration with EFMHACA and other stake holders is planning to train regulatory professionals at higher levels like certificate, Post graduate diploma and MSc levels.

Carefull preparation and planning to inaugurate the programme including study of need assessments, identification of partner universities and organizations, resource mobilizations, consultative workshops and other necessary steps are going currently. Hopefully, the programme will be launched next September, 2008 E.C. This is to cope with the rest of the world where regulatory sciences/affairs is professionalized with the level of training at MSc and PhD levels. Moreover such training will help to fill some of the gaps in the Ethiopia Regulatory affairs practice that are manifested by the lack of such trained personnel working in organizations like EFMHACA, VDFHACA, Ministry of trade, Ministry of Health, Radiation Protection agencies, Pharmaceutical and food industries, Food, beverage and Pharmaceutical development institute. Such federal level and also similar organizations at the regional levels require high amount of workforce trained in this profession.

## CONCLUSION

Many in the Regulatory Affairs Profession believe the New Approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety. Regulatory Affairs department is constantly evolving and growing and is the one which is least impacted during the Acquisition and Merger, and also during recession. Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfill the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers. In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is

therefore of considerable economic importance for the company. Ethiopia as a dynamic developing country that aspires to accelerate growth in pharmaceutical sector and having a good regulatory authority should also work hard on the professionalization of the task force practicing in the sector. Hence training of pharmacists or other related health professionals in the sector will contribute in alleviating the trained human power needs and also to cope with the rest of the world in this profession. Therefore the strong support and desire showed in launching training programmes in Regulatory affairs should keep the momentum until programme launch and realization as well as successful production of graduates in the programme.

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Laugh Corner:

Jokes: From www.WorkJoke.com: Compiled by: Ayenew Ashenef

Lady says to pharmacist: "Why does my prescription medication have 40 side effects?"

Pharmacist replies: "Because that's all we've documented so far."

---

A woman and her husband approach their pharmacist and begin to ask questions like if the pharmacy checks for medications past their expiration date and the reliability of a certain company that makes birth control pills. Finally the pharmacist asks the couple what's the matter. The wife explains, "In spite of using birth control pills I continue to get pregnant."

The pharmacist is astounded and asks the woman if she takes them every day.

The woman replies, "My husband takes them every day."

"What?" the pharmacist croaks.

"Yep. After we read all those potential side-effects, my husband said ' Ah honey. I don't what you taking that stuff.. It's too dangerous,.....let ME take them.' "

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**How pharmacists do it...**

Pharmacists do it with drugs.
Pharmacists do it by prescription.
Pharmacists do it with side effects.
Pharmacists do it over the counter.
Pharmacists do it with scruples.
Pharmacists do it with a grinding motion.

---

How many pharmacists does it take to change a light bulb? Just one, but he has to do it ten days, three times a day.

---

Two young pharmacists are talking professionally at their office.

Boy Pharmacist. : What do you want this time, with coat or without coat ?
Gal Pharmacist: with coating, because I don't want to release granules earlier.
Boy Pharmacist: So, Shall I start molding?
Gal Pharmacist: No, No... First close the door and window and switch off, because this work is light sensitive.

---

What do you call a pharmacist working at a veterinary drug company... a FARM-ASSIST

pharmacist
Guy runs into a pharmacy. He dashes to the counter and exclaims, "Please, help! I've got a splinter in my finger and I don't know what to do!" The pharmacist grabs a bottle of Ichthammol Ointment and says to the man, "Here my good sir...Try this black salve." To which the man replies, "This is no time for heavy metal music!"

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