

MEDICINES HARMONIZATION IN WEST AFRICAN ECONOMIC AND MONETARY UNION (WAEMU) COUNTRIES

Available online at www.ijdra.com

REVIEW ARTICLE

¹⁻³Amari A.S.G*, ¹N'Guessan A, ²Sackou J.G, ³Amonkou A.C, ³Alloukou P.M, ³Duncan R.

¹Department of Pharmaceutical regulation in the faculty of Pharmacy at Félix Houphouët Boigny University in Abidjan.

²Department of Health in the faculty of Pharmacy at Félix Houphouët Boigny University in Abidjan.

³Office for Drug and Pharmacy (ODP) of the Department of health of Côte d'Ivoire.

*Corresponding Author's E-mail: amarias_03@yahoo.fr

Abstract:

With the blessing of WHO, the different regions of West Africa engaged in Pharmaceutical regulation harmonization processes on the continent.

Indeed, In west Africa, WAEMU actions on the matter ended in the production of juridical rules opposable to member states who rationalize watching/control procedures and medicine marketing for both human medicine and veterinary products.

What remains then to member states is to appropriate community regulation hoping that Pharmaceutical cooperation reinforcement with ECOWAS, that other sub regional economical organization, grows stronger in order to improve drug use and manufacturing in West African area.

Keywords: WHO, WAEMU, ECOWAS, NMRA, ANRP.

Introduction:

Quality requirements related to manufacturing , placing on the market and the rational use of drugs have led through the world , developing mechanism for communication and collaboration , leading to similar approaches by countries or groups of countries for Pharmaceutical regulations duty performance necessary for the protection of consumers. Since several decades, there has been a harmonization movement for Pharmaceutical regulations worldwide: European Union Countries, ICH zone including entire regions (U.S., EU and Japan), Asian countries

In Africa, cross-border health problems have finally promoted governments' awareness of the need to combine their efforts to face with public health problems. More, following the example of other areas of the world, regional and sub-regional health policies harmonization processes have been initiated. Examples of the Pan African Health Organization (PAHO), the East African Health Community , the West African Health Organization (WAHO) , and

some actions in the field of health by the West African Economic and Monetary Union (WAEMU) are illustrative of this communautarisation phenomenon of overall health protection.

More specifically, concerning drug regulation, on World Health Organization (WHO) impulse, harmonization processes of Pharmaceutical regulations in Africa have emerged and continue to be built. The approach that seems to have been preferred is sub-regional blocs grouping. Thus, the CEMAC in Central Africa, SADEC in Southern Africa, the SEAC in Eastern Africa, the Maghreb in Northern Africa, ECOWAS and WAEMU in West Africa, are the bases of Pharmaceutical regulations harmonization in the different sub regions of WHO African area.

Indeed, in West Africa, as far as Pharmaceutical field is concerned , WAEMU member states being aware of the need for technical cooperation between them to better

appraisal of production and rational use of medicines and the performance of the Pharmaceutical profession contours in accordance with accepted standards, adopted Regulation No. 02/2005/CM/ WAEMU on the harmonization of drug regulation in the Member States of the WAEMU.

Under globalization and international requirements for medicines quality and Pharmaceutical market monitoring, resources pooling for better management of people is a necessity. West Africa must take its place in the international construction of legal bases of medicine quality particularly by assessing the level of integration of state policies of drug regulation. This paper intends to shed some light on this issue.

Drug Regulation Harmonization

Definition

Drug regulation harmonization means the measures taken to have consensual Community procedures in Pharmaceutical industry in general and medicine in particular. Harmonization should not be understood as a not uniform; what is sought, is not so much the similarity between countries national legal bases ranging harmonization; instead, it is the consistency of these textual provisions to achieve common objectives. Indeed, though some community legal standards such as regulations (1) are directly applicable in all aspects of Member States, others such as guidelines (2), decisions (3) and others, just set Community objectives, and leave countries adapt their own legislations to community requirements they adhere to.

Background and Rationale

At the level of the African continent

From a general point of view (across Africa), this is the first National Conference of Drug Regulatory Authorities (NMRA) which was held from October 31 to November 3, 2005 in Ethiopia under auspices of WHO that unflattering diagnostic capacity ANRP to implement the functions of Pharmaceutical regulation (regulatory approvals exercises trades pharmacy, drug quality control,

inspection, information and advertising medication, clinical trials) has been prepared. It was then estimated that about 30 % of the 46 sub-Saharan countries have no national drug regulatory authority (NMRA), about 7 % of the remaining countries have ANRP whose capacity is moderately developed and that an overwhelming majority of 63% of countries have limited capacity ANRP or barely functioning. This diagnosis should then be the starting point of a comprehensive strategy across the African continent for a capacity of ANRP so as to make them better able to fulfill their regulatory function for the rational use of the drug. This commitment is reinforced in the second conference of the NMRA from 24 to 29 November 2009 in Maputo, Mozambique and several similar meetings. As part of capacity reinforcement program on Pharmaceutical regulation of countries in the African region, the Regional Office of World Health Organization (WHO) began in 2010 to conduct evaluations of drug control system. The last great sitting on the need to develop drug regulation in Africa was held from 2 to 3 December 2014 in Johannesburg, South Africa, the first scientific conference on drug regulation in Africa. (1)

On the scale of West Africa

West Africa is the western region of Africa. It includes 16 countries and covers an area of 6,000,000 km². The population of this region is estimated at 320 million people. This area of the world is characterized by increased poverty and a low level of living as well as the endemic presence of tropical infectious diseases. West Africa is full 75% HIV cases and 95 % cases of malaria mortality. The difference between drug needs and available resources is very large, leaving a significant portion of the population without care and without any social assistance. Mortality and morbidity are high. It is about a part of the world that pays a heavy price to malaria, HIV and tuberculosis. To those limits, are added problems in connection with medicines counterfeit phenomenon, that knows a prodigious development in the area, and which is next to illegal drugs sale (at street market) and in a more general way, the problem of lower quality drug. This issue of

populations accessibility to drugs worsen, for countries using the CFA franc, by the devaluation of that currency in 1993, has prompted governments to identify on one hand, local medicines production and; on the other, generic medicines promotion (multi- source) as solid alternatives to explore. Now, Pharmaceutical production of West African region is very low, barely covering 10% drug needs of peoples who live there, and fulfilling conditions of a high dependence vis-à-vis the outside for drug supply and a great fragility of health systems . In addition, despite stated intentions , we observe a lack of political will to promote a strong Pharmaceutical industry in the region. This will to solve the shortcomings of Pharmaceutical industry in West Africa unfortunately collides with an inadequate legislative and institutional framework and with constant derogatory and violations of drug regulation where it is possible to distinguish in the States a corpus of pharmacy and medicine regulation.

Devoid of implementation of Drug regulatory functions:

According to assessments conducted sometimes by WHO (2006, 2007 and 2009) , another time by sub- regional organizations (WAEMU , 2011) and information from the WHO country profile in 2011, it appears that NMRA , in charge implementing drug regulatory functions shows shortcomings that do not allow the execution of drug regulatory functions (official authorizations for pharmacy trades practicing, drug quality controlling , inspection, information and advertising on drug , clinical trials). These shortcomings are of several kinds. At the institutional framework, though most English speaking countries of the region have ANRP organized into autonomous agencies , francophone countries have ANRP which are essentially central offices at the Department of health. This central management organization does not give sufficient autonomy to the regulatory office, making it difficult to perform the function of drug regulation. Moreover, the height of this, WAEMU is preparing a directive to turn Central Offices for Drug and Pharmacy (CODP) into autonomous Agencies. It is the ANRP status itself that

hampers drug regulation development in those countries. At legislative and regulatory level, it should be noted the inadequacy of provisions in relation to the current realities of pharmacy and medicine. Medicines regulatory systems and legislation for most countries are made up of texts inherited from colonization.

Where post-independence legislation has been developed, it is sometimes insufficient or ignored without health authorities having means to enforce it. To these in adapted texts must be added the absence of drug policy in many countries; even though it exists, its faces with deficit implementation; ANRP Deficit in sufficient qualified human resources ; especially for the development of specific work tasks to Pharmaceutical regulation are screaming and varies from one country to another; some countries of the region had dozens of pharmacists as others counted less than five . Staff training is not provided in that field in which technological innovations are progressing at a frantic speed. To all these deficits must be added the lack of equipment, logistics and means of suitable equipment (hardware, vehicles, office equipment etc ...), lack of circulation of objective and independent information, giving to ANRP ,ultimately, a state of living in autarky.

In total , due to lack of human resources , material, financial and technical means, NMRAs are unable to ensure their optimal drug regulatory functions . For some of them, their status make them dependent on funds allocated to their activities by the Ministry for the implementation of national action plans. The equipment available to them are not suitable for decentralized procedure for authorizations granting on the market, insofar as it would have a software management system. The bodies responsible for the evaluation of dossiers are not always set up in the way that the mechanism for file validation conforms to public health requirements. This results in an inability to curb illicit drug market, markets flooding (official and illegal) by counterfeit medicines (lack of monitoring and control on imported medicines). All these factors, combined with poverty and lack of drugs resources helps to make difficult access

to quality medicines and exposes the people of West Africa in consecutive certain dangers resulting from the use of poor-quality medicines.

Purpose of Harmonization

The ultimate objective of the process of Pharmaceutical regulations harmonization is none other than to ensure consistency of public health interventions particularly in the Pharmaceutical sector, in concerns to provide population with quality medicines at lower cost. This objective is well summarized by Article 2 of Regulation No. 02/2005/CM/WAEMU on drug regulation harmonization in the Member States of the WAEMU drug regulation harmonization is a dynamic process that EU Member States intend to use to improve the accessibility, availability and the free movement of quality medicines within the Community . While this regulation concerns WAEMU member states but in fact, any harmonization of drug regulation is the ultimate goal of providing the population with quality medicines. It is therefore primarily a process; that is to say, an action not included in the finite but rather intended to continue, always aiming at the same objective. The dynamic nature of such a process arises from the need to continuously enrich innovations and technological innovations, regulatory, institutional necessitated by social change and health needs. Drug Regulatory Harmonization is expected to be leveling out differences between States Parties in order to introduce among themselves cooperation mechanisms likely to induce a certain similarity of procedures to ensure quality, efficiency and availability of drugs. Under these conditions, mutual recognition is often seen as a result of harmonization, at least as far as drugs approval is concerned. Without necessarily aiming standardization, harmonization intends to introduce to practices and method of drugs assessing, a shared consistency such that can reassure state authorities and populations on a rational use of drug .

West African Economic and Monetary Union (WAEMU)

Presentation

West African Economic and Monetary Union (UEMOA) is a sub -regional organization working to achieve economic integration of the Member States, through the strengthening of economic competitiveness in an open and competitive market and in a legal streamlined and harmonized environment. (2)

West African Economic and Monetary Union (WAEMU) was established by the Treaty signed at Dakar on 10 January, 1994 by Heads of State and Government from seven countries of West Africa having in common the use a common currency, the CFA .They are: Benin, Burkina Faso , Côte d'Ivoire, Mali, Niger , Senegal and Togo. The Treaty entered into force on 1 August 1994, after ratification by the Member States. On May 02, 1997, Guinea - Bissau became the eighth member of the Union. 30% of the population of West Africa live in member countries. WAEMU covers an area of 3.5 million square kilometers and a population estimated at 804 million. WAEMU aims at creating between Member States a common market based on the free movement of persons, goods, services, capital and the right of establishment of self-employed persons and employed , as well as a common external tariff and trade policy by including a harmonization of legislation of Member States, namely the regime of taxation. The union establishes a coordination of national sectoral policies through the implementation of joint actions, and possibly common policies, particularly in the areas of human resources, land use, agriculture, energy, industry, mining, transport, infrastructure and tele-communications.

In terms of health it should be noted the adoption of a Community Action Plan on promoting essential generic drugs and improved traditional medicines , the local manufacture of essential medicines and quality control , to improve accessibility to populations of the Union to care quality. Actions taken by the WAEMU under Pharmaceutical regulations are part of the logic of that Community Action Plan..



Figure 1: West African Economic and monetary Union member states.

Role of West African Economic and Monetary Union (WAEMU) in drug regulatory harmonization in west Africa

The process of drug regulatory harmonization in Africa has been based on sub-regional economic organizations. Western Africa is no exception to this rule.

The involvement of this economic union in the drug regulatory harmonization process is limited to eight member States of the union. Involvement of WAEMU is characterized by the definition (creation) of precise legal standards enforceable to member States which produces different effects according to their legal strength. Thus, WAEMU is involved in making regulations, directives, decisions, opinions and recommendations. Regulation is a legal standard of general scope and shall be binding in its entirety and directly applicable to Member States. In regards to the directive, it binds the Member States as to the result to be achieved, whilst leaving national authorities the choice of form and methods within a previously fixed period, in order to achieve the indicated community goals. A decision shall be binding in its entirety on all those to whom it is addressed.

Historic dates

While considering, at the African continent level, Addis Abba's meeting in 2005 as the starting point of drug regulatory harmonization

process in the continent, it is necessary to underline that the process had originated earlier in WAEMU area. Already in 2000, a framework agreement of cooperation was concluded with World Health Organization and on July 29th, 2000, WAEMU Health ministers have recommended the implementation of joint actions in the health area.

In 2003, The WHO-led WAEMU launched a reflection on drug regulatory harmonization process within Member States of the union. This precocity is accounted for by multiple factors including the devaluation of the CFA franc (African Financial Community). Indeed, in 1994, there was a devaluation of the common currency of WAEMU member states by 50 % which caused a reduction by half of purchasing power of populations already weakened by poverty.

The governments of these countries were, as a result, faced with the need to examine several alternative solutions to the problem of population affordability to medicines. The development of local drug production and promotion of generic drugs (because they are less expensive) have been retained as solutions. These approaches were also based on the decision taken at the summit of Heads of States in Libreville, Gabon to promote generic drugs and also the adoption in 1999 of guidelines for the essential generic drug registration in Ouagadougou. But, whether it be one or other

of both solutions, reinforcement of national drug regulatory authorities and a strong and harmonized drug regulation were identified as intervention strategic areas.

Reflections started in 2003 should lead to the development of a strategy that ensures coherence of actions as regards drug regulation within the WAEMU

In March 2004, during a meeting which brought drug regulation authorities together, the proposal of the creation of a committee for Harmonization and Pharmaceutical cooperation within the UEMOA, was examined and adopted.

Drug regulation authorities meeting on March 2004 examined and endorsed the committee of harmonization and Pharmaceutical cooperation project within WAEMU.

In July 2005, the first guidelines on drug regulatory harmonization within WAEMU member States identifying harmonization priority areas was adopted. Subsequently, a harmonization program by performing actions of harmonization and Pharmaceutical cooperation committee was formed in 2008

Regulation No. 02/2005/CM/WAEMU on drug regulatory harmonization in Member States of the WAEMU (3)

This regulation demonstrate member States awareness of pooling (sharing) their limited human, technical and financial resources, in order to ensure drug quality and accessibility to populations with limited access to drugs. It is also a way, through which greater Pharmaceutical cooperation between member states can combat counterfeiting and the illegal marketing of drugs. According to article 2 of the regulation n°02/2005/CM/ WAEMU, “drug regulatory harmonization as referred to in this Regulation, means adopting measures in order to provide Community Pharmaceutical procedures in general and drugs specifically. The drug regulatory harmonization is a dynamic process in which union member States reach agreement to improve accessibility, availability and free circulation of quality drugs in Community space”.

This declaration shows that the ultimate purpose of harmonization process is to provide quality drugs to populations through consensual community procedures.

It represents a commitment on the part of Member States to confront their points of view and agree on drug regulation issues of common interest in order to maintain an acceptable level of public health protection to Union nationals.

Committee of Regulation Harmonization and Pharmaceutical Cooperation (CRHPC)

To implement the drug regulatory harmonization within WAEMU member States, the committee of the union set up the CHRCP. As per the article 7 of the Regulation, The committee is responsible for encouraging and gradually monitoring the drug regulatory harmonization in member states with the aim of improving quality of life of populations by providing quality and safety drugs". The committee is, thus, the key component (player) in the harmonization process.

The committee is composed of a steering committee, a group of experts and a secretariat. The steering committee is the principal policymaking organ on matters of drug regulations. It is made up of (i) directors of pharmacy and medicinal products directorate member States, (ii) members of WAEMU commission, (iii) representatives of WHO and OOAS. The group of experts is constituted of national, regional and international experts selected on the basis of their competence. The secretariat is provided by the WAEMU commission.

Article 8 of the Regulation on drug regulatory harmonization within WAEMU member States assigns (trustee) CHRCP missions. This includes:

- Harmonizing standards, guidelines and procedures on drug regulations within the union member states.
- Strengthening drug regulation capacity within union countries through staff training in the regulation, drug registration, inspection and quality assurance.

- Strengthening the capacities of national drug regulatory authorities.
- Promoting and arranging the implementation of harmonization projects of the regulation and Pharmaceutical cooperation.
- Strengthening management systems and information sharing between national of drug regulation authorities.
- Encouraging network and technical cooperation.

Achievement of Drug regulatory harmonization in WAEMU

The process of drug regulatory harmonization conducted by WAEMU has led to a number of legal norms. These achievements cover both drugs and other health products such as cosmetics and food supplements. Drugs are distinguished between human drugs and veterinary ones.

Health Products intended for human medical use

Main achievements of harmonization process related to health products are summarized in table 1.

Table 1: Harmonized act for human health in WAEMU

Harmonized matters	Nature of Act	Exact act Title
Approval of medicinal products for Human use	Regulation	Regulation no 06/2010/CM/UEMOA on approval procedures of medicinal products for human use in WAEMU member States /annex 3 for regulation no 06/2010 /CM/UEMOA (4)
Approval of Cosmetic products and food supplements	Decision	Decision n°06/2010/CM/UEMOA for food supplements approval Guidelines adoption in WAEMU /annex 3 for regulation no 07/2010 / CM/UEMOA/WAEMU (5)
	Decision	Decision no 07/2010/CM/UEMOA for cosmetic product guidelines adoption in WAEMU member states /Annex of decision no 08/2010/CM/UEMOA (6)
Monitoring	Decision	Decision no 08/2010/CM/UEMOA for the adoption of good manufacturing practice guidelines on medicinal products. For human use in WAEMU member states /Annex of decision no 09/2010/CM/WAEMU (7)
	Decision	Decision no 09/2010/CM/ WAEMU for adoption of good Distribution Practice. And importation of medicinal products for human use in WAEMU member states/Annex of decision no 10/2010/CM/WAEMU. (8)
Advertising and information	Decision	Decision n°10/2010/CM/UEMOA for adoption of guidelines on medicinal products information and advertising control with health professionals a in WAEMU member states/Annex of decision no 10/2010 /CM/WAEMU. (9)

Veterinary Products

Component of Harmonization are summarized in table 2.

Table 2: Legal standards for veterinary drug regulatory harmonization in WAEMU

Harmonized matters	Nature of act	Act Title
Creation of a veterinary committee within WAEMU	Regulation	Regulation no 01/2006/CM/UEMOA on the creation and operational procedures of veterinary committee in WAEMU (10)
Veterinary Drug quality control	Regulation	Regulation no 04/2006/CM/WAEU for quality control management laboratory network establishment in WAEMU (11)
Marketing authorization of Veterinary drug	Regulation	Regulation n°02/2006/CM/UEMOA on -the establishment of community procedures for marketing authorization and veterinary drug monitoring. The establishment of a regional committee of veterinary drug. (12)
		Regulation n°3/2006/CM/UEMOA for establishment of royalties in veterinary drug within WAEMU. (13)
		Regulation no 08/2010/CM/ WAEMU on the modification of regulation no 02/2006/CM/ WAEMU on communitary procedures for veterinary drug marketing authorization. Monitoring. The establishment of a regional committee of veterinary drug. (14)

Looking to the Future

Harmonizing Pharmaceutical regulation in West Africa can be reality if some steps are brightly/cleverly gone through. Actions to be undertaken are various and require method, implication of member states as well as participants involvement.

At sub region level/scale, cooperation between OOAS and WAEMU for common and coordinated actions is a requirement for success in Pharmaceutical regulation harmonization.

Schematically, strategies to use can be put into four major ways:

- Institutional capacities development and human resources optimization.
- Development of common technical documents/brochures available to member states.

- Communication improvement and cooperation between member states.
- Mutual recognition/acknowledgement of Pharmaceutical regulation.

Institutional capacities development and human resources optimization

A strong regulation system rests on autonomous and fitted/qualified ANRP to implement Pharmaceutical regulation functions.

While English speaking countries ANRP are organized into autonomous Agencies, those in French speaking countries are still central offices at the Department of health; whose status does not enable them efficiently display their regulative actions.

Taking into account that observation, WAEMU undertook a feasibility study during year 2011 to turn some Central Offices for Drug and

Pharmacy (CODP) into autonomous Agency. That state of fact confirms ANRP incapacity to implement Pharmaceutical regulation functions if they keep their status of central offices. A statement is being written at WAEMU Commission to compel member states to commit to turn Central Offices for Drug and Pharmacy into autonomous Agencies to increase their capacity to implement Pharmaceutical regulation functions.

Human resources optimization

To build regional and national capacity to implement medicines registration harmonization in ECOWAS region is a key objective which will ensure effective utilization of available experts in the Region thereby addressing the skills shortage. This will have the impact of reducing timelines for registration, improving the efficiency and effectiveness of the registration process nationally and regionally and building capacity for joint activities.

Region Human resources potentiating implies the training of an experts pool at each member State level, some focuses to give life and to coordinate experts pool activities.

In particular, a database of good practices standards from evaluators and inspectors, should be gathered.

Some regional centers of first rating in Pharmaceutical regulation must be set up as well as some training programmes on good practices of drugs manufacturing must be developed.

Development of common technical documents/brochures as well as the adoption of work procedures reached by consensus available to member states.

Technical cooperation between sub region States is necessary in the process of Pharmaceutical regulations harmonization. That technical cooperation goes through the availability of technical documents of work reached by consensus.

It is also necessary to develop and implement a Quality Management System (QMS) for

medicines registration services. Quality management in medicine registration is vital to the provision of efficient and effective regulatory services to the Pharmaceutical industry and the public at large. In addition it will facilitate a common application format and guidelines for assessment of safety, efficacy and quality. A common approach to development of Standard Operating Process (SOP) must be established.

The establishment of a clearly defined and documented process and procedures of registering medicines in member states thus ensuring quality, consistency, traceability of regulatory decisions and transparency is a work the members states have to do.

Improve cooperation, communication and information circulation between sub region National Pharmaceutical regulation Authorities

It will be necessary to implement a common information management system for medicines registration in every WAEMU Member States' NMRAs which are linked to each other and the WAHO Secretariat. The sharing of information is vital to a successfully harmonized medicines registration system.

By developing and implementing a MIS, this will ensure easier access, retrieval and rapid dissemination of information within the region. Through this, more effective utilization of available experts in WAEMU, quicker decision making, information sharing, use of a regulators shared network will be exploited.

Undertake an advocacy campaign to build stakeholder support and commitment for Medicine Registration Harmonisation and related activities.

Reaching Mutual recognition / Acknowledgement

Mutual recognition/acknowledgement of documents delivered by a National Pharmaceutical Regulation Authority (Permission for Put on Market and other licenses) by another one is rightly considered as the ultimate logical step to Pharmaceutical Regulations harmonization.

Indeed, if legislations are coherently put together and procedures are standardized, one can satisfactorily acknowledge other member States' evaluation who, because they have used the procedures and supports, should get the same evaluation results.

This outcome stands, nowadays, for pious hope there still are many challenges to take; those because all the country are not at the same level of technical development as far as drugs evaluation is concerned.

Some steps have been passed but other needed to be crossed. Hence, in WAEMU, drugs confirmation rule provides for each member state to send to Pharmaceutical Harmonization and cooperation secretary, expert report done on a medicine after a AMM request so that another member state, if called to give an opinion, could draw inspiration there from. That constitutes an embryo mutual recognition to be developed to get to a complete mutual acknowledgement.

At the region level, it is necessary to stress cooperation between ECOWAS and WAEMU on Pharmaceutical field in order to bring ANRP at level and reach mutual acknowledgement.

Capacities of the NMRAs need to be improved to enable them to fulfill their statutory legal and regulatory functions.

Conclusion

Although it is undisputed that the harmonization of Pharmaceutical regulations processes are built on the foundation formed by regional economic organizations, it is worth noting with regard to West Africa, the existence or the coexistence of two major economic institutions such as ECOWAS and WAEMU, as regards to the conduct of harmonization actions. Without being confined to any of these organizations, harmonization of drug regulation in the region results from the concerted action of these two entities. (15)

It is necessary to strengthen ECOWAS-WAEMU cooperation with a view to ensure mutual recognition of decisions taken by other NMRAs in the ECOWAS-WAEMU regions.

Existing disparity among health standards, expertise and policies in West Africa is a significant.

A platform for engaging key stakeholders on the harmonization of medicines registration system at national and regional level can also be created, for clearer and common understanding of the harmonization process by stakeholders; broader ownership of the outcome at both regional and national.

Results-based framework which will assist to monitor progress and measure performance; play a key role in ensuring that the project implementation is in line with the set project goal and objectives, this approach will focus on the results obtained rather than just the inputs used or the activities conducted.

The states of west Africa are optimistic that in the near future the medicines registration procedures in the whole WAEMU-ECOWAS region would be harmonized. Political will is absolutely necessary to reach this goal. (16)

References

1. NEPAD. First Biennial Scientific Conference on Medicines Regulation in Africa [Internet]. Johannesburg, South Africa: NEPAD; 2013 Dec [cited 2013 Dec 3]. Available from: <http://www.amrh.org/events/first-biennial-scientific-conference-medicines-regulation-africa-theme-building-partnerships>.
2. West African Economic and Monetary Union [Internet]. West Africa: UEMOA; 2013 [cited 2014 Jan 7]. Available from: Site de l'UEMOA : www.uemoa.int/
3. The Council of Ministers of Economic Union and West African monetary (UEMOA) [Internet]. Regulation No. 02/2005/CM/WAEMU; 2005 Jun 17 [cited 2014 Jan 30]. Available from: http://www.uemoa.int/Pages/Actes/NewPages/REGL_02_2005_CM.aspx
4. West African Economic and Monetary Union (WAEMU) [Internet]. Regulation no 06/2010/CM/UEMOA /annex 3 for regulation no 06/2010/CM/UEMOA; 2010 [cited 2014 Jan 15]. Available from: http://www.uemoa.int/Documents/Actes/Annexe_Reg_06_2010_CM_UEMOA.pdf
5. West African Economic and Monetary Union (WAEMU) [Internet]. Decision no 06/2010/CM/UEMOA /annex 3 for regulation no 07/2010/CM/UEMOA/WAEMU; 2010 [cited 2014 Jan 17]. Available from: http://www.uemoa.int/Documents/Actes/Dec_06_2010_CM_UEMOA.pdf

6. West African Economic and Monetary Union (WAEMU) [Internet]. Decision no 07/2010/CM/UEMOA/Annex of decision no 08/2010/CM/UEMOA; 2010 [cited 2014 Jan 18]. Available from: http://www.uemoa.int/Documents/Actes/Dec_07_2010_CM_UEMOA.pdf
7. West African Economic and Monetary Union (WAEMU) [Internet]. Decision no 08/2010/CM/UEMOA/Annex of decision no 09/2010/CM/WAEMU; 2010 [cited 2014 Jan 19]. Available from: http://www.uemoa.int/Documents/Actes/Dec_08_2010_CM_UEMOA.pdf
8. West African Economic and Monetary Union (WAEMU) [Internet]. Decision no 09/2010/CM/WAEMU/Annex of decision no 10/2010/CM/WAEMU; 2010 [cited 2014 Jan 16]. Available from: http://www.uemoa.int/Documents/Actes/Dec_09_2010_CM_UEMOA.pdf
9. West African Economic and Monetary Union (WAEMU) [Internet]. Decision no 10/2010/CM/UEMOA/Annex of decision no 10/2010/CM/WAEMU; 2010 [cited 2014 Jan 26]. Available from: http://www.uemoa.int/Documents/Actes/Dec_10_2010_CM_UEMOA.pdf
10. West African Economic and Monetary Union (WAEMU) [Internet]. Regulation no 01/2006/CM/UEMOA; 2006 [cited 2014 Jan 25]. Available from: http://www.uemoa.int/Documents/Actes/reglement_01_2006_CM_UEMOA.pdf
11. West African Economic and Monetary Union (WAEMU) [Internet]. Regulation no 04/2006/CM/WAEMU; 2006 [cited 2014 Jan 25]. Available from: http://www.uemoa.int/Documents/Actes/reglement_04_2006_CM_UEMOA.pdf
12. West African Economic and Monetary Union (WAEMU) [Internet]. Regulation no 02/2006/CM/UEMOA; 2006 [cited 2014 Jan 25]. Available from: http://www.uemoa.int/Documents/Actes/reglement_02_2006_CM_UEMOA.pdf
13. West African Economic and Monetary Union (WAEMU) [Internet]. Regulation no 3/2006/CM/UEMOA; 2006 [cited 2014 Jan 25]. Available from: http://www.uemoa.int/Documents/Actes/reglement_03_2006_CM_UEMOA.pdf
14. West African Economic and Monetary Union (WAEMU) [Internet]. Regulation no 08/2010/CM/; 2006 [cited 2014 Jan 25]. Available from: http://www.uemoa.int/Documents/Actes/Reg_08_2010_CM_UEMOA.pdf
15. Emergence of a local pharmaceutical industry in West Africa: Constraints and Opportunities [Internet]. West Africa: Dakaractu; 2012 [cited 2014 Jan 9]. Available from: http://www.dakaractu.com/Emergence-d-une-industrie-pharmaceutique-locale-en-Afrique-de-l-Ouest-Contraintes-et-Perspectives_a29177.html
16. Pola EY. Harmonization initiatives [Internet]. Africa: Consultant OCEAC; 2010 sept [updated 2010; cited 2014 Jan 23]. Available from: <http://www.aedes.be/>.