THE NEW REGULATIONS FOR THE APPROVAL OF MEDICINAL PRODUCTS IN IVORY COAST: APPLICATION OF REGULATION N ° 06/2010 / CM / WAEMU RELATING TO PROCEDURES FOR THE APPROVAL OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE IN WAEMU MEMBER STATES.

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REVIEW ARTICLE

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ABSTRACT

Harmonization of procedures for the approval of medicines in the WAEMU area allows Member States to have a standard tool for the examination of applications for marketing authorization for medicinal products for human use. The objective of this study was to highlight the textual provisions adopted by a member state, Côte d'Ivoire for optimal application of the Community norm. The methodology used consisted, on the basis of a reminder of the main points of Regulation No. 06 / CM / UEMOA concerning the approval of medicinal products for human use, to show how the national implementing decrees taken in Côte d'Ivoire the Regulation. However, the need for Member States to act more expeditiously with regard to the application of Community standards is clear.

Keywords: Harmonization, Homologation, UEMOA, Ivory Coast.

INTRODUCTION

The registration of medicines in Côte d'Ivoire has always been strictly regulated. Already in 1954, the Public Health Code stated in Article L601: "A visa is granted to the proprietary medicinal product (...) when the technical committee finds that it is novel and therapeutic in nature, it does not present a danger to the moral and physical health of the population ". These criteria for the registration of medicines (safety, therapeutic interest, novelty) have been constantly reaffirmed by successive legal provisions, namely Act No. 65-250 of 4 August 1965 amending articles of the Health Code and especially Decree No. 94 - 669 of 21 December 1994 on the registration and dispensing of medicines in Côte d'Ivoire. (1) Since 2010 the approval of medicines is governed by a Community standard, Regulation No. 06/2010 / CM / UEMOA on the procedures for the approval of pharmaceutical products for human use in the WAEMU member states (2), whose principles and provisions have recently been made effective in Côte d'Ivoire by three decrees relating to the establishment of a committee of experts for the technical analysis of marketing authorization dossiers (AMM), a national commission and licensing fees. The objective of this work is to describe these innovations and to highlight their anchoring with the Community norm.

I ECONOMY OF REGULATION N°06/ 2010/CM/UEMOA ON THE PROCEDURES FOR THE APPROVAL OF PHARMA-CEUTICAL PRODUCTS FOR HUMAN USE IN THE WAEMU MEMBER STATES.

I.1. Organization of Approval

1. The bodies responsible for approval

In addition to the National Pharmaceutical Regulation Authority responsible for the administrative examination of the application for authorization (module 1), the Regulation establishes two bodies responsible for examining applications for the approval of medicinal products: on the one hand, a committee of experts responsible for the preliminary technical evaluation and on the other hand the National Medicines Committee responsible for validating the work of the technical committee and giving a final opinion to the Minister of Health on the application for approval. By introducing a mandatory committee of experts for the technical evaluation of applications for marketing authorization, the WAEMU Regulation is an innovative work, since in most national regulations the use of experts was only a possibility in the process of reviewing the application files. In addition, under the second paragraph of Article 9 of the Regulation "the Committee of Experts shall be composed of persons of sufficient quality outside the pharmaceutical regulatory authority from universities, research institutes, hospitals and peripheral health centers ". This independence and technicality of the committee of experts is a guarantee of the quality of the analysis of the files.

2. The common format of the application for approval

The Regulations require a standard format for the application for registration, consisting of five modules 1, 2, 3, 4 and 5 relating respectively to the administrative file, the product characteristics summary, the safety dossier, the clinical file and the clinical record. In fact, this format is inspired by the format applicable in the countries of ICH * as adopted by the European Community code on medicinal products. This format therefore presents a real advantage from the point of view of harmonization, uniformity with a large number of countries subject to the ICH area approval procedures. The legibility of the files from one State to the other is thus ensured facilitating the exchanges and the successive registrations in the Member States of WAEMU by the applicants pending the effectiveness of the procedures of mutual recognition.

3. Charges for type-approval

Recognizing the inadequate resources of the National Pharmaceutical Regulatory Authorities, notably in terms of financial resources, the Community Regulation provides for the Member States to introduce approval fees to cover the expenses inherent in the analysis of application dossiers, AMM. If in many countries the fees paid in connection with approval were paid for several countries in the public treasury, the fees imposed by the Community regulation, the amount of which must be fixed by each Member State, should increase the financial power of the National Pharmaceutical Regulatory Authorities and thus have a positive influence on the quality of the expertise and therefore of medicines intended for the market.

4. The granting of the marketing authorization

From now on, 120 days separate the application from the granting of the marketing authorization. The marketing authorization is issued by the Minister in charge of health on the proposal of the National Medicines Committee after satisfaction of all the conditions prescribed by the Regulation. Article 13 of the Regulation stipulates that the marketing authorization is granted to a legal person. The Regulation excludes natural persons from the scope of ownership of a marketing authorization under the Community Regulation.

Unlike the marketing authorization for veterinary medicines issued after analysis of the dossiers by a sub-regional committee of experts, the marketing authorization issued in the case of medicinal products for human use is a purely national marketing authorization which is not valid from the outset member. Mutual recognition is not a reality in the WAEMU zone; a secretariat exists, however, within the pharmaceutical cooperation and regulation unit where each Member State is required to submit the evaluation reports of applications for marketing authorization, which could be of interest to other Member States called upon to rule on the same records.

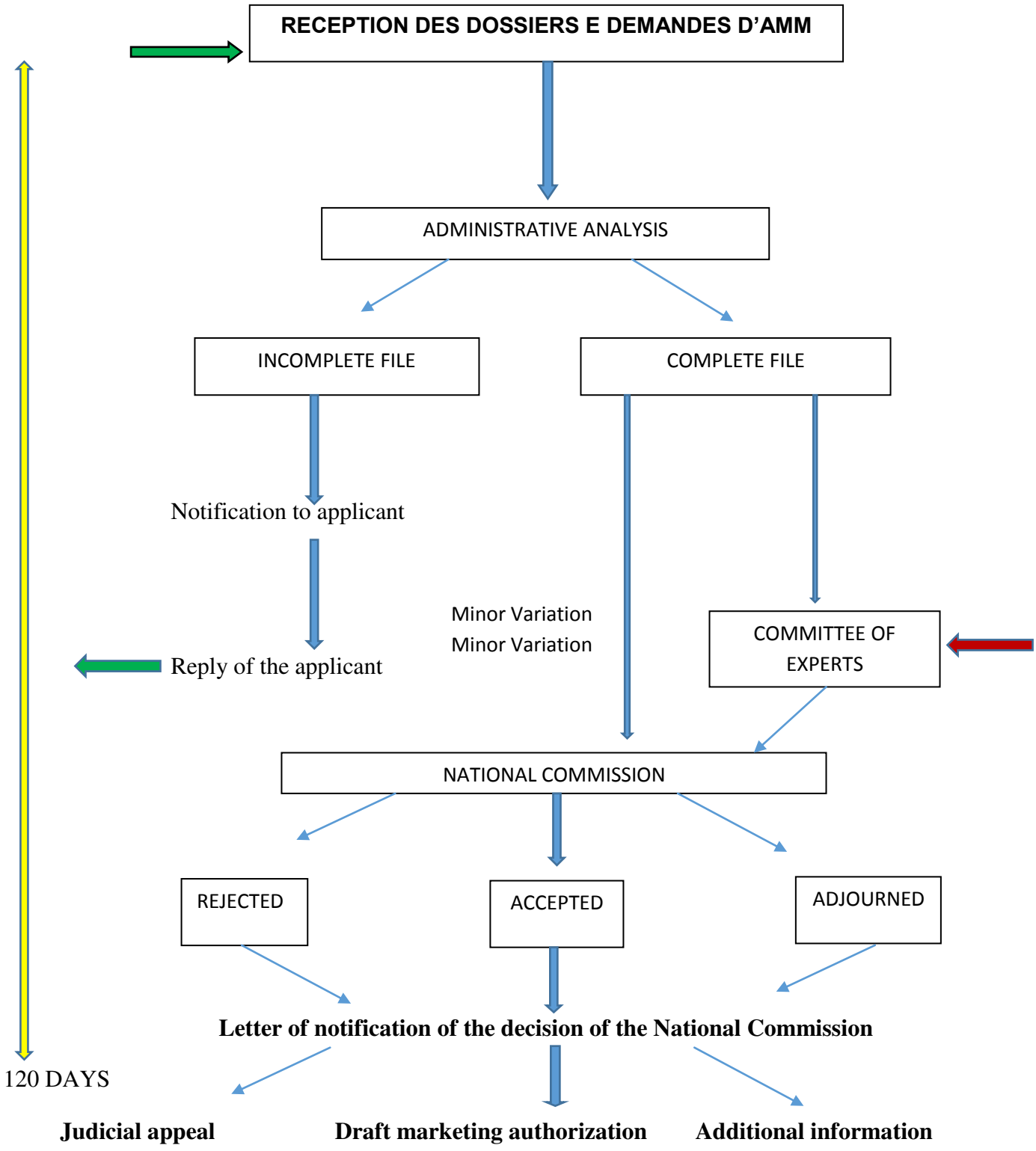

Figure 1: Procedure for the processing of an application for marketing authorization according to the WAEMU regulation for the approval of medicinal products for human use

*The International Conference on Harmonization of Criteria for Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 by the pharmaceutical regulatory authorities and pharmaceutical laboratories of the European Union, Japan and the United States to define standards for the development of new drugs.

II APPLICATION IN THE IVORY COAST OF THE COMMUNITY PROCEDURE

FOR THE APPROVAL OF MEDICINAL PRODUCTS FOR HUMAN USE

II.1. Decisions for the application of regulation no. 06/2010 / CM / UEMOA on the procedures for the approval of Pharmaceutical products for human use in WAEMU member states.

The need to take national texts for the application of the Community regulation on the approval of medicinal products for human use in the WAEMU member states is not a transposition in the legal sense of the term. As a regulation, the Community standard is directly applicable and enforceable against the Member States in all these respects. It should simply be noted that the Community "legislator" wishes to leave the discretion to the Member States to find the precise details necessary for the application of Regulation No 06 / CM / WAEMU.

1. The Decree establishing a committee of experts for the technical analysis of approval dossiers

By decree n ° 2015-569 of 29 July 2015 (3), Côte d'Ivoire creates a committee of experts responsible for the technical evaluation of applications for the approval of medicinal products in accordance with Regulation No. 06 / CM / UEMOA on the harmonization of procedures for the approval of medicinal products for human use, which stipulates that "Each Member State shall establish by an order of the Minister for Health a committee of experts responsible for:

- carry out a technical evaluation of applications for the approval of pharmaceutical products for human use;

- give its opinion on the quality, safety, safety and efficacy of pharmaceuticals for human use subject to approval (...) the Expert Committee shall be composed of ex-quality resource persons, outside the Authority of pharmaceutical regulation and coming from universities, research institutes, hospitals and peripheral health centers (...) ".

This decree (a legal standard superior to a decree) shows the importance accorded by Côte d'Ivoire to the provisions it contains and also embraces questions of ethics, professional conduct and conflict of interests as required by the Community norm ; it states to this effect that "the Committee of Experts shall be independent. Its members shall not have any conflict of interest with the applicants for Marketing Authorization ".

2. The decree establishing and organizing the National Drug Commission

With regard to the national drug commission, article 10 of Regulation No. 06 / CM / UEMOA stipulates in Article 10: "Each Member State shall establish a National Medicines Committee responsible for, on the one hand, to validate the work of the Committee of Experts and to give its final opinion on:

- Applications for marketing authorization;

- Temporary suspension of marketing authorization;

- The final withdrawal projects for marketing authorization;

- Variations in Marketing Authorization;

- Transfers of the Marketing Authorization;

Decree No. 2015-568 of 29 July 2015 on the establishment (4), organization and functioning of the National Medicines Committee has remained faithful to the powers of the National Commission created as set out in the Community text. Moreover, the legal form of the text chosen (decree) is in conformity with the legal principles in force; A national drug commission existed in Côte d'Ivoire under Decree No. 94-669 of 21 December 1994 establishing and operating the National Commission for Proprietary Medicinal Products. The principle of parallelism of forms therefore required the adoption of a text at a hierarchical level at least identical in order to establish the national drug commission as recommended in the Community text.

3. The Decree establishing the approval fees

The Decree establishing the approval fees by proclaiming in Article 23 of Community Regulation No. 06 / CM / UEMOA on the approval of medicinal products for human use that "a fee paid to the regulatory authority for

any application for authorization on the market, the amount of which is fixed by ministerial decree ", the Community regulation intends to regulate the question of the financial means for an effective homologation, which is a major concern for most countries of the Union. By choosing the way of the ministerial decree, the Community regulation leaves it to the Member States to fix the amount of these royalties according to the realities of the country concerned. In Côte d'Ivoire, it was even by decree (decree n ° 2015-602 of 02 September 2015 establishing fees for the authorization for the placing on the market of medicines that the approval fees and their amounts were set. (5) The basic fee was thus set at five hundred thousand CFA francs (763 euro) per form and per dosage. The choice of the nature of the text is explained by the concern to respect the legal principle of the parallelism of forms since it is by decree (Decree No. 66-382 of 9 September 1966) (6) that the rate of the right of registration of medicines was fixed at ten thousand CFA francs (15 euros) before another decree (Decree No. 75-364 of September 22, 1975) (7) brings this rate to fifty thousand CFA francs (76 euros) rate in force until decree of 2 September 2015.

II.2. THE EFFECTIVE IMPLEMENTATION OF THE COMMUNITY REGULATION AND THE IMPLEMENTATION TEXTS

As soon as the three decrees issued for the application of Regulation No. 06 / CM / UEMOA on the approval of medicinal products for human use in the WAEMU area were abolished, the former regime for the approval of medicines was abolished. All applications for marketing authorization applications are filed and processed in accordance with the new provisions in force, and in particular the preparation of application files in the CTD format in five modules (Administrative file, technical dossier, pharmaceutical dossier, clinical and clinical record). Thus, for the first session of files studied under the new procedure on 500 files received only 187 files passed the administrative analysis and were eligible for technical evaluation by the committee of experts. This technical evaluation having been completed with the expert reports, these reports are awaiting validation by the National Commission which has not yet met. Administrative difficulties explain this delay, which was brought to the attention of the applicant in order to justify the extension of the period for applying for marketing authorization beyond the 120-day regulatory period.

Table I shows the changes in the regulation of the approval of medicinal products for human use in Côte d'Ivoire.

CONCLUSION

The application of Community provisions, in particular those relating to the harmonization of procedures for the approval of medicinal products for human use in WAEMU Member States, that were inspired by the European directives on the homologation of medicines of 2001 (8) and 2004 (9) should increase the level of expertise for the analysis of application dossiers, And give Member States the means to optimize this evaluation. It is at this price that medicines of quality and at lower cost can be made available to the populations. It remains for those Member States to fully play their part by taking national texts implementing the Community standard where necessary and ensuring that the relevant pharmaceutical regulations are effectively applied as well as covered by the regulation No. 02/2005 / CM / UEMOA on the harmonization of pharmaceutical regulations in WAEMU Member States. (10)

Table 1: Main developments due to the new regulations for the approval of medicinal products for human use in Côte d'Ivoire

CHARACTERISTICS	DECREE N ° 94-669 of 21 December 1994 (Côte d'Ivoire)	REGULATION N ° 06/2010 / CM / UEMOA	NEW REGULATIONS APPLICABLE
Application deadline	90 days	120 days	120 days

Technical bodies for the evaluation of marketing authorization applications	1. ANRP 2. National Commission for Proprietary Medicinal Products	1. ANRP 2. Committee of Experts 3. National Medicines Commission	1. ANRP 2. Committee of Experts 3. National Medicines Commission
Fees payable in respect of the application for marketing authorization	1. Registration fees fully remitted to the State Treasury (50,000 FCFA)	Approval fees paid back to the ANRP (500,000 FCFA)	500,000 FCFA per form and per presentation
Format of the application for a marketing authorization File containing	The applicant's letter, the applicant's summary, the technical file of the product and the administrative file.	CTD (Common Technical Document) format with 5 modules: Module1: Administrative file Module 2: Summary of Technical File Module 3: Quality file Module 4: Non-Clinical Folder Module 5: Clinical Record	Format CTD
Authority issuing marketing authorization	Ministers responsible for Health and Trade	The only Minister of Health	Minister of Health
Marketing Authorization Holder	No specific details	Only legal persons	Legal persons
Scope of regulation	National, applicable only in Côte d'Ivoire	National scope	National scope

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CONFILCTS OF INTEREST

The authors declare that there are no conflicts of interest.

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