Evaluation of the Regulatory Review Process of the FDA Ghana: Challenges and Opportunities for Improvement

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The African Medicines Agency:

Towards a unified continental regulatory framework

Background

The current dynamic regulatory environment in Africa in particular with the establishment of the African Medicines Agency (AMA), highlights the importance of evaluating the effectiveness and efficiency of the national regulatory authorities as well as that of the regional initiatives to ascertain their readiness for their new role in the operationalisation of the AMA.

Aims

1. To assess the regulatory review process of the FDA Ghana from 2019-2021.
2. Identifying key milestones, target timelines, good review practices, quality decision making practices as well as the challenges and opportunities for improvement.

Methods

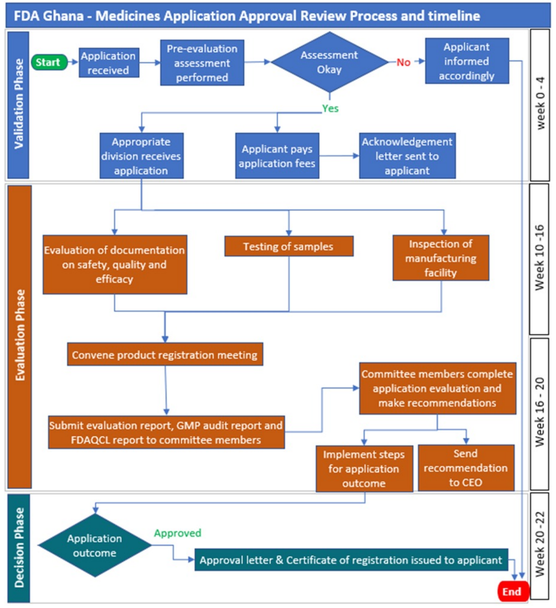
The Optimising Efficiencies in Regulatory Agencies (OpERA) questionnaire was completed by FDA Ghana including:

1. Organisation of the agency
2. Types of review models
3. Key milestones in the review process
4. Good review practices
5. Quality decision-making processes

Results

- The FDA Ghana carries out three types of established regulatory processes namely verification, abridged, full and a priority fast track review (Figure 1)
- There was a successive annual increase in the number of products registered over the period, which was largely due to the 80% reduction of application fees for marketing authorization.
- 91% NAS's were processed by full or abridged review pathways (Figure 2 & 3)
- 97% of generics were processed by verification or full review pathways (Figure 2 & 4).

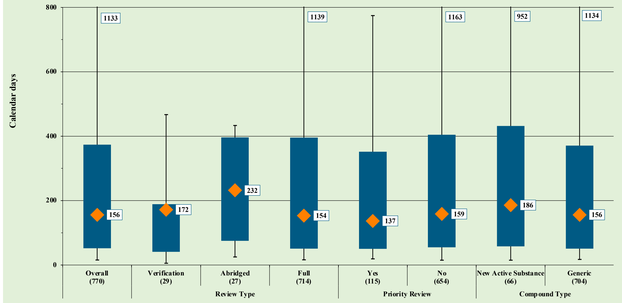
Figure 1: Regulatory review process map for Ghana showing target times in calendar days; represents the review and authorization of a product that goes to approval after one review cycle.



Results

- The FDA Ghana conducts a full review of quality, safety and efficacy data for new active substances (NASs) and generics which have not been reviewed by the World Health Organization (WHO) or a reference agency,
- Conducts an abridged review for products previously approved by a stringent regulatory authority,
- And a verification review for WHO prequalified products under the collaborative registration procedure.
- Guidelines, standard operating procedures and review templates were in place and the majority of indicators for good review practices were implemented as well as quality decision-making practices (Table 1).

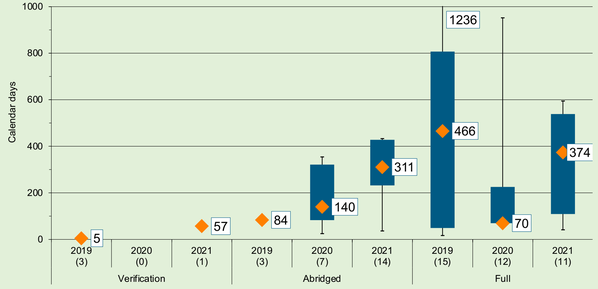
Figure 2: Overall approval times for all products between 2019 – 2021



Data are shown for applications that were approved ("Date of Final Recommendation/Registration") between 01/01/2019 and 31/12/2021.

(n) = number of drug applications. ◆ Median

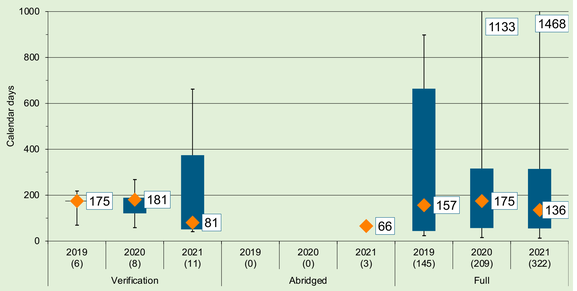
Figure 3 New Active Substances Overall Approval Times. (Date of Dossier Receipt to Date of Final Recommendation/Registration)



Data are shown for applications that were approved ("Date of Final Recommendation/Registration") between 01/01/2019 and 31/12/2021. (n) = number of drug applications.

◆ = Median. Where (n) is less than 5, only the median is displayed.

Figure 4 Generics Overall Approval Times (Date of Dossier Receipt to Date of Final Recommendation /Registration)



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◆ = Median. Where (n) is less than 5, only the median is displayed.

Table 1 The FDA Ghana implements certain aspects of the quality-decision making practice framework as the basis to approve or reject a marketing authorisation application

Practice	Implemented into framework		Adhered to in practice	
	Fully	In progress	Fully	In progress
1. Have a systematic, structured approach		✓		✓
2. Assign clear roles and responsibilities (decision makers, advisors, information providers)	✓		✓	
3. Assign values and relative importance to decision criteria	✓		✓	
4. Evaluate both internal and external influences/biases	✓		✓	
5. Examine alternative solutions	✓		✓	
6. Consider uncertainty	✓		✓	
7. Re-evaluate as new information becomes available	✓		✓	
8. Perform impact analysis of the decision		✓		✓
9. Ensure transparency and provide a record trail	✓		✓	
10. Effectively communicate the basis of the decision	✓		✓	

Recommendations

1. Product specific guidelines should be produced to help applicants comply with the registration requirements and obtain approval after one review cycle.
2. An electronic tracking system should be implemented to enable the FDA Ghana and applicants to track applications for marketing authorisation.
3. Annual training workshops should be arranged for applicants to help them to improve the quality of the dossiers
4. Efficient ways should be explored to review marketing authorisation applications for NAS's that are assessed by the full review pathway.
5. A comparison of other stringent regulatory authorities should be carried out to identify best practices.
6. Public assessment reports for all marketing authorisation applications should be made available.
7. A systematic and well-structured quality decision-making practice framework should be implemented.
8. The timelines for review decision of a product should be established in terms of both agency and industry time.

Conclusions

The FDA Ghana monitors its regulatory performance and currently meets its target timelines. The extent to which quality, safety and efficacy data are assessed depends on the review model.

However, to achieve World Health Organization's maturity level 4 an electronic tracking system, a benefit risk assessment framework and template and the publication of assessment reports are recommended

It is hoped that the implementation of the recommendations would prepare the FDA Ghana to effectively contribute to the work of the newly established African Medicines Agency.