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Directive on Administrative Measure Taking and Complaint Handling

This directive is issued by the Ethiopian Food, Medicine and Healthcare Administration and Control Authority pursuant to Article 55 (3) of the Food, Medicine and Healthcare Administration and Control Proclamation No. 661/2009.

Part One
General

1. Short title

This directive may be cited as “Administrative Measure Taking and Complaint Handling Directive No 8/2012.”

2. Definitions

Notwithstanding to the definition provided under Proclamation No. 661/2009 and unless the context require otherwise in this directive

1) “food” means, without prejudice to the definition provided under sub-article (1) of Article 2 of the Proclamation, a product that is produced by food manufacturer for more than one regional state or foreign markets;

2) “medicine” means any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in human and includes narcotic drugs, psychotropic substances and precursor chemicals,
3) “certificate of competence” means a work license issued for a person to carry out food, medicine, health or health related services or trade in accordance with the regulatory standards set;

4) “license” means a certificate issued for a health professional to provide medical or other health related services;

5) “health professional” means a professional who is registered as such by the appropriate organ to protect human health or deliver health service;

6) “administrative measure” means the range of actions taken against regulated persons or products by the Authority including denial, corrective notification, warning letter, suspension, revocation, detention, seizure and disposal of products; recall, and recommendation for prosecution;

7) “proclamation” means the Food, Medicine and Healthcare Administration and Control Proclamation No. 661/2009;

8) “authority” means the Ethiopian Food, Medicine and Healthcare Administration and Control Authority;

9) “regulation” mean the Ethiopian Food, Medicine and Healthcare Administration and Control Authority Establishment Regulation No.
10) “warning letter” is a written correspondence that notifies regulated person about violations that the Authority has found during its inspections and the corrective measure required to be in compliance with regulatory requirement;

11) "revocation" is the cancellation of a license or certificate of competence and the withdrawal of the authorization to perform regulated activities under the proclamation;

12) “suspension” means an administrative measure taken against regulated person or product when the Authority has a reason to believe that any of the grounds for suspension exist;

13) “serious violation” means a violation that entails threat of serious adverse health consequences or death to humans and/or that may lead to prosecution;

14) “minor violation” means a violation that presents little or no risk of injury or danger to health or life;

15) “denial” means refusal of license, certificate of competence or registration of products when defined regulatory requirements are not fulfilled;

16) “person” means any physical or judicial person
3. **Scope**

This directive shall be applicable with regard to administrative measures to be taken against regulated person or product under the proclamation and complaints made in connection with those administrative measures.

4. **Objective**

The objective of this directive shall be to:-

1. set up detailed legal framework on administrative measure taking procedure;
2. set up legislative checks whereby the appropriateness of administrative decision made against regulated person or product is in accordance with applicable laws;
3. set up procedure where regulated person have opportunity to complain and get redress against inappropriate administrative decision; and
4. promote transparency and accountability of the Authority while taking administrative measure;

5. **Principle**

1. Whenever there is non-compliance with the law the Authority shall take all appropriate administrative measure against the violating regulated person or product.
2. Depending on the nature and severity of non-compliance, the Authority shall take in to consideration all applicable laws when taking administrative measure.
3. The Authority shall give written
4. When violations are serious that may be subject to the criminal justice system, the Authority shall act promptly with a view to organizing evidences and preparing recommendation for prosecution.

5. Regulated person who feel that the administrative measure taken is inappropriate, not proportional, or illegal may present the case to be reviewed by the Panel established in accordance with this directive.

6. The Panel established in accordance with this directive shall balance the interest of the Authority with regulated person.

**Part Two**

**Administrative Measures**

6. General provision

1. Where regulated person or product is found in deviation from regulatory laws or standards, the Authority shall take the appropriate administrative measure in accordance with this directive.

2. Notwithstanding sub-article (1) of this Article, the Authority may take combination of administrative measures when it is appropriate to protect the public health.

7. Denying or delaying regulatory services

1. For the purpose of this directive, unduly delaying issuance of certificate of evidence regarding measures taken to the violating person.
1. Issuance of certificate of competence, license, product registration, import permit, laboratory result and other requested regulatory services shall be accomplished in accordance with applicable directives and guidelines once all required documentations and formalities are met.

2. When an application is delayed for unusually longer period of time because of reasons beyond the control of the Authority, the responsible unit shall inform the applicant, when requested, of the reasons why the respective regulatory service is unduly delayed.

3. Where it is appropriate to deny regulatory service, the measure taking unit of the Authority shall notify the applicant in writing and thereby include:

a. the reason and legal ground why an applicant should not be granted regulatory service,

b. how the application can get the service if certain requirements are fulfilled, if any, and

c. the opportunity to appeal to the Health Regulation Panel of the Authority for the case to be reviewed.

8. Corrective Notification

1. Corrective notification shall be given at the discretion of responsible inspector of
1. When minor violations occurred the responsible unit of the Authority shall issue

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<th>2.</th>
<th>Corrective notification shall be given in a written form to be signed by responsible person of the regulated person and the inspector right after completion of inspection. When appropriate, face-to-face discussion, phone calls, or electronic communications might accompany the written notice.</th>
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<td>If the responsible person of the regulated person is not available or otherwise unwilling to sign the document, the inspector may deliver the document by any means including posting at its door.</td>
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<td>It shall be the responsibility of the regulated person to take the necessary corrections within the time frame required and report to the Authority.</td>
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<td>5.</td>
<td>The inspectors shall take appropriate follow up measures with a view to check if necessary corrective actions are taken.</td>
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<td>If corrective measures are not partly or fully taken within the time frame required, it shall constitute a material ground to issue a warning letter in accordance with this directive.</td>
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<td>Issuance of warning letter</td>
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written warning letter to the responsible person with a view to correct the violations.

2. In determining where warning letter is an appropriate means, the unit issuing the warning letter should consider whether the evaluation or inspection report shows that a regulated person is in violation of the law and failure to achieve adequate and prompt correction may result in the authority’s consideration of suspension, revocation or other severe administrative measures; and there is a reasonable expectation that the responsible person will take prompt corrective action.

3. Warning letter shall be issued within a reasonable period of time not exceeding ten working days of the knowledge of non-compliance or knowledge of violation by the respective unit of the authority.

10. Content of warning letter and follow-up

1. The warning letter shall at least include the reason why and the legal ground why the measure in taken, the time frame within which the violation shall be corrected and the opportunity to appeal to the Health Regulation Panel of the Authority for the case to be reviewed.

2. While issuing letter the responsible unit of Authority shall have due regard to the circumstance of regulated person and the public health in determining the time frame within which violation shall be corrected.

3. The responsible inspector shall take the necessary follow up measures with a view to check if corrective actions are taken in accordance with the warning letter.
11. Instances where warning letter may not be issued

1. Warning letter may not be issued for one or more of the following reasons

a. the violation reflects a history of repeated or continual conduct of a similar or substantially similar nature during which time the regulated person has been notified of a similar or substantially similar violation;

b. the violation is intentional or flagrant that once having occurred cannot be retracted;

c. the violation presents a reasonable possibility of injury or death and

d. when notice has been given by other means and the violations have not been corrected, or are continuing.

2. Issuance of a warning letter in the past may not preclude issuance of an additional warning letter when the nature and cause of the violation have changed. However, such warning letter shall not be issued more than two times within three consecutive years.

12. Suspension

1. The responsible unit of the Authority shall suspend a license, certificate of competence or registration of product, import permit or market authorization if corrective measures are not partly or fully taken within the time frame required, it shall constitute a material ground to issue suspension in accordance with this directive.
permit if it has reasonable ground to believe that any of the ground for suspension defined under appropriate law exists.

2. The responsible unit of the Authority shall suspend a license, certificate of competence or market authorization certificate if the regulated person failed to correct violation following issuance of warning letter or happen to get more than two warning letters within three consecutive years or found to violate the same regulatory requirement within three consecutive years for which it has been previously served with a warning letter.

3. Regardless of the fact that a particular violation may be subject to a warning letter, regulated person shall be subjected to suspension where the said violation is intentional and the responsible inspector has evidence to that effect.

4. The responsible unit of the Authority shall immediately suspend a license, certificate of competence or market authorization certificate when the violation suspected is likely to cause serious danger or threat to the public health or life.

13. Review by legal service

1. Where the responsible unit of the Authority is considering suspension as an appropriate measure it shall seek review of its opinion by the legal service unit of the authority.

2. Where the legal service unit concurs with the opinion, the responsible unit of
the Authority shall decide accordingly and communicate its decision to the non-complying person about the suspension of the license.

3. Where the legal service unit partly or wholly deviates with the recommendation, parties shall forward the case to the appropriate Deputy Director General of the Authority with regard to issues under difference. The legal service unit shall list the reasons for the disapproval and provides other enforcement options, if appropriate, to the recommending unit. The Deputy Director General shall decide accordingly.

14. Suspension procedures

1. When suspension is the appropriate administrative measure, the responsible unit of the Authority shall suspend a license, certificate of competence or market authorization certificate after receiving the inspection or evaluation report.

2. Where the responsible unit of the Authority finally decides to suspend license, certificate of competence or market authorization certificate, it shall deliver an official letter of its decision to the regulated person. Such letter shall at least contain the reason why this measure is taken, its legal basis, length of suspension, the time frame within which the regulated person shall return the same to the issuing unit of the Authority and the possibility of appealing the decision to the Health Regulation Panel of the Authority.
3. While considering suspension measure the responsible unit of the Authority shall have due regard to the circumstance of the case and the interest of the public in determining the length of suspension required to discipline regulated person.

4. The person shall have the obligation to return license, competence certificate, product registration, market authorization or import permit within 3 working days to be under the custody of the issuing unit of the Authority during the suspension term.

5. After having the suspension period has elapsed, the responsible unit of the Authority shall return the license, certificate of competence or market authorization certificate to the regulated person.

6. The responsible unit of the Authority shall take the necessary follow up measures with a view to check if conditions of suspension measure are taken in accordance with the measure.

7. If conditions are not partly or fully met in accordance with the suspension, the responsible unit of the Authority shall consider other administrative measure suitable to achieve its regulatory purpose.

15. Revocation

1. The responsible unit of the Authority shall revoke a license, certificate of competence or market authorization certificate if it has reasonable ground to believe that any of the ground for revocation defined under applicable law exists. It will also be cancelled up on the request of the holder of a license.
2. Demonstrated not to be willful, the Authority, when appropriate, may provide a notice of intent to revoke the certificate of competence or license with a view to demonstrate or achieve compliance. In order to give notice of intent to revoke the responsible unit shall consult with and reach in agreement with the legal service unit of the Authority.

3. When notice of intent to revoke in accordance with sub-article (2) of this article is found to be an appropriate measure, the responsible unit of the Authority shall take the necessary follow up measures with a view to check if corrective measure is instituted.

4. If corrective actions are not taken within the time frame required or partially completed in accordance with sub-article (2) of this article, the responsible unit of the Authority shall issue revocation in accordance with this directive.

5. When violation is found to be willful, the Authority shall move directly to revocation without providing an opportunity to demonstrate or achieve compliance.

6. The responsible unit shall revoke a license, certificate of competence or market authorization if the regulated person happens to involve in regulated activities while in suspension, or subjected to suspension more than two times in three consecutive years; or found to violate same regulatory requirement within three consecutive years for which it has been previously served with suspension order.
16. Review by legal service

1. Where the responsible unit of the Authority is considering recommendation for revocation as an appropriate measure it shall seek review of its opinion by the legal service unit of the authority.

2. Where the legal service unit concurs with the opinion, the responsible unit of the Authority shall take the appropriate measure accordingly.

3. Where the legal service unit partly or wholly deviates with the recommendation, the responsible unit of the Authority shall forward the case to the appropriate Deputy Director General of the Authority. The legal service unit shall list the reasons for the disapproval and provides other enforcement options, if appropriate, to the recommending unit. The Deputy Director General shall decide accordingly.

17. Revocation procedures

1. When revocation is appropriate having due regards to the circumstance of the case and the interest of the public and the the Authority recommends revocation of a license, certificate of competence or market authorization certificate and the legal service supports, it shall be decided accordingly.

2. Where a license, certificate of competence or market authorization certificate is revoked, official letter of decision shall be delivered to the regulated person. Such letter shall at least contain the reason why this measure is taken, its legal basis, the time frame within which the regulated
person shall return the same to the issuing unit of the Authority and the possibility of appealing the decision to the grievance handling organ of the authority.

3. Regulated person shall have the obligation to return the license, certificate of competence or market authorization certificate within 3 working days after receiving the revocation letter to the authority.

4. The responsible unit of the Authority may suspend a license, certificate of competence or market authorization certificate when the regulatory law violation suspected is likely to result in revocation.

18. Detention, seizure and disposal

1. Whenever regulated products are found to be in violation of regulatory laws, the responsible unit of Authority in accordance with Article 48 (2) of the proclamation shall have the power and responsibility to take every essential measure in the public interest including detention, seizing and disposing products.

2. Inspector of the Authority shall be in compliance with this directive and other applicable laws when detaining, seizing and disposing illegitimate products.

3. Responsible officers of the authority, when necessary, shall work together with other public and private institutions.

4. Inspector of the Authority shall order the detention of any article of food or medicine that is found during an inspection, examination or investigation if the inspector has credible evidence or information indicating that the article of food or medicine presents a threat of serious adverse health consequences or
5. The inspector of the Authority shall be responsible to make sure all necessary precautions not to hamper normal business operations of the regulated person.

6. Inspector of the Authority shall be deemed to have sufficient reasons to order administrative detention when the quality, safety or efficacy of any products is suspicious including through organoleptical test, adverse Drug Reaction reports, and information from food poison outbreak; if the product can be identified as illegal without further laboratory test.

7. Without prejudice to sub-article 6 of this Article, when inspector is encountered with suspicious products whose quality, safety or efficacy cannot be readily determined without laboratory test, inspectors shall detain such products and sent sample to laboratory. However, the laboratory result for the continuity of this administrative measure shall be available within a reasonable period of time not exceeding twenty days. Detained products shall be given priority for laboratory test.

8. After the laboratory result is known or final inspection report is made, the concerned unit of the Authority shall notify the regulated person whose product is detained regarding the final decision within a reasonable period of time not exceeding one working day.

9. The responsible unit Authority shall issue the detention order to the owner or agent in charge of the place where the article of food or medicine is located. The detention order shall contain a brief, general statement of the reasons for the detention and state for how long the product is going to be under detention.
10. The notice prepared in accordance with sub-article (9) of this article shall be in writing and state whether the product under detention is seized or if the product is free to make its way back to the market. In respect of seized products, the product shall be disposed or send it back to its origin at the expense of its owner.

11. If the article of food or medicine is detained in a vehicle or other carrier used to transport the product, the responsible unit of Authority shall provide a copy of the detention order to the operator of the article or the owner of the food or medicine, if their identities can be readily determined.

12. The period of the detention must be for a reasonable period, not to exceed 20 days. However, the period of detention may be extended up to a total of 30 days, if necessary to provide sufficient time to institute a seizure or disposal of the product.

13. The Detention Termination Notice shall be delivered to the person(s) who received the detention notice, or his agent or representative.

14. Any regulated product unfit for use shall be disposed off in accordance with the applicable laws or be sent to back to its origin at the expense of its owner.

19. Movement and transfer of detained or seized products

1. It shall be a prohibited act to move detained product in violation of a detention order or to remove or alter any mark or label required by a detention order that identifies the product as detained.

2. Notwithstanding to sub-article (1) of this
3. Where the Authority approves a request based on good causes for modification of a detention order to allow the product to be moved, the product may be transferred but remains under detention before, during, and after the transfer.

4. No person may transfer a detained product within or from the place where it has been ordered to be detained, or from the place to which it was removed, until the detention order is legally terminated.

20. Recall

1. The Authority may order medicine or food institutions to recollect their distributed products and to immediately cease distribution of the product when it has a reason to believe that the use or exposure to the product will have adverse health consequences or would result in death.

2. Recall order by the Authority shall be supported by evidences to the satisfaction of the measure taking unit that the marketed product is a threat to public health and life and final order shall be approved by the Director General of the Authority.

3. When medicine or food trade institutions have the information that use or exposure to a particular batch of product is likely to have adverse health consequences or
would result in death, they shall recollect their marketed products in their own and immediately notify the Authority of the self-initiated actions and the Authority should follow the recall procedure and take appropriate action.

4. When an institution refuses to recall after being requested to do so by the Authority or the institution fails to complete a recall in a timely fashion or the Authority has reason to believe that a recall strategy is not effective; the Authority shall take such other regulatory actions against the institution.

5. The recalling institution shall halt distribution, start collecting immediately and collect the entire recalled product within 20 days from the date of notification and report action taken to the Authority within five working days after recollection is completed. However, it shall make sure to immediately notify to halt distribution of the product from being marketed through telephone and other means of communication.

6. Recalled products in accordance with this directive shall be disposed of or sent back to the manufacturer or supplier at the expense of the institution and the Authority shall follow up all necessary measures are taken.

7. The Authority, up on request by the manufacturer or importer, shall give the reason why recall measure has been taken.

8. The Authority shall make sure all concerned stakeholders are informed regarding the recall.

21. Recommendation for prosecution

1. Unless violations are minor as defined
under this directive, the relevant unit of the Authority shall report violating cases to the legal service unit for an appropriate consideration of the case and its implication with the criminal justice system.

2. If the legal service unit has a reason to believe that the case forwarded to it in accordance with the sub-article (1) of this article may violate criminal provisions, it shall work with relevant units of the Authority in organizing evidences and eventually to institute recommendation for prosecution.

3. The legal service unit of the Authority after having duly considered cases forwarded to it shall recommend prosecution on any person to the concerned regional or federal prosecutors when a violation of criminal law has been established and it has evidence in support of the case in court.

4. The legal service unit shall closely follow all cases and work closely with police and prosecutor.

5. The legal service unit shall notify final decision of court to relevant units of the Authority.

6. Record of final decision of the court shall be kept on file for regulatory purposes.

Part three
Complaint Handling

22. Establishment of grievance hearing body
1. In accordance with the power bestowed by Article 49 (1) of the proclamation the Authority hereby established the Health and Health Related Regulation Grievance Hearing Panel (hereinafter referred to as "the panel").

2. The Panel shall be accountable to the Director General of the Authority.

3. The Authority may establish such organ at Branch Office level as it deems necessary.

23. Objective

The objective of the panel shall be to review complaints lodged against administrative measures taken by various responsible units of the Authority, review its legality and fairness and take the appropriate decision.

24. Organization of the panel

1. The panel shall have:
   a. a chairperson and a deputy chairperson;
   b. members, and
   c. a secretariat.

2. The chairperson of the panel shall be appointed from members by the Director General of the Authority.

3. The Deputy Chairperson shall be elected with simple majority from members by the panel.

4. The legal unit of the Authority shall serve as the panel’s secretariat.

25. Members of the panel

1. Members of the panel shall be
composed from each technical units of the Authority.

2. Notwithstanding sub-article (1) of this article, the unit that took the administrative measure shall not be considered as a member of the panel during the review process of the particular complaint.

3. Each member of the panel shall be accountable to the panel.

4. The Ethics and Anti-corruption Reform unit of the Authority shall be a non-voting member of the panel.

5. The assigned individual from the legal unit in accordance with sub-article (4) of this article shall also serve as a permanent secretary of panel.

6. The legal unit of the Authority shall provide legal advice to the panel when necessary.

26. Power and duties of the panel

The panel shall have the power and responsibility to:

1. to notify and give copy of the complaint to the unit that approved the administrative measure and give order to the same unit to come up with response with supporting documentations;

2. hear, review and decide on complaints made against any administrative measure taken by unit of the authority;

3. give order for the presentation of documents, evidences or witness, including inspection report and inspector, necessary for the
determination of a case submitted to it;

4. in reaching final disposition on a particular case the Panel shall give due regard to applicable proclamation, regulations and directives;

5. uphold, modify or reverse any administrative measures as well as give further consequential order necessary for the final disposition of the case. In doing so the panel shall state in its decision, the legal basis upholding, modifying or reversing the earlier decision made by unit of the Authority;

6. serve parties to the dispute with a copy of its decision;

7. advise the Director General of the Authority on matters of repeated deviation from appropriate regulations and grave faults of units of the Authority while taking administrative measures;

8. adopt its own rules of procedures; and

9. exercise other incidental and necessary activities to achieve the abovementioned powers and responsibilities.

27. Powers and duties of the chairperson

The chairperson of the panel shall have the following powers and duties:

1. to preside over meetings of the panel;
2. to assign individual member of the panel to do the preliminary review of complaints and come up with concrete legal reasons for the panels consideration;

3. to delegate part of his powers and duties to the Deputy chairperson or other members of the panel;

4. to represent the panel and made communication, when necessary, with the Director General of the Authority;

5. to report final decisions of each cases up on determination to the Director General; and

6. to prepare bi-annual report to the Director General.

28. Power and duties of secretariat of the panel

The secretariat shall have the power and responsibility to:

1. coordinate regular and urgent meetings of the panel in consultation with the chairperson of the panel;

2. provide all administrative support necessary to the panel including keeping complaint records, minuets, panel’s decision and other documents on file;

3. receive complaints and make sure necessary compliant formalities are met before notifying the chairperson about the complainant and communicate amendment order to the complainant,
where necessary;

4. accept complaints where it satisfies the necessary requirement and notify the complaint to the chairperson of the panel; and

5. Perform such other duties as may be assigned by the panel.

### 29. Meetings of the panel

1. There shall be a quorum where simple majority of the members of the panel are present at its meeting.

2. The Panel shall decide on complaints by a majority vote; in case of a tie, the chairperson of the panel shall have a casting vote.

3. Dissenting opinion of any member shall be stated in the decision thereof. The secretariat shall be responsible to keeping dissenting opinions on file.

4. The panel shall meet periodically every one week to review complaints lodged in accordance with this directive.

5. Notwithstanding sub-article (4) of this article, where a particular administrative measure is likely to fully hamper the business, the chairperson may call an urgent meeting with a view to prioritize the case at hand and reach into final decision within reasonable time.
30. Complaint submission

1. Complaints may be submitted by the licensee, owner of the business or a duly authorized agent of the owner or licensee.

2. Complaints shall be made in writing and submitted to the secretariat of the panel. The complaint shall be submitted within 30 days from the time when decision is rendered.

3. The complaint prepared in accordance with sub-article (2) of this article shall, at least, state the authorities’ alleged reason to take the measure, decision of the authority, reasons of the complainant why he/she believes the measure is unjustifiable or inappropriate and shall be signed and dated by the complainant.

4. The complainant may also provide appropriate documentary evidences and attach list of witnesses relevant to the case when necessary.

5. Where the complaint fulfills the above mentioned requirements, the secretariat shall receive the complaint and notify the chair person within a reasonable time no later than three working days after receiving the complaint.

6. Where a complaint is rejected for reason of not fulfilling requirements in accordance with this directive, the secretariat shall inform in writing the complainant to correct the submission accordingly and re-submit the complaint.
7. Where the complainant believes its complaint fulfilled the requirements of the law and if the secretariat insists that the application is not fulfilled, the complainant may appeal the case to the Director General of the Authority.

8. The General Director of the Authority shall see in to the case and render the appropriate decision.

31. Complaint notice and response

1. The chair person shall notify and serve with copy of the complaint within a reasonable period not to exceed three working days to the measure taking unit and require the same to respond to the complaint in writing within reasonable period of time not to exceed three working days.

2. The response to be prepared in accordance with sub-article (1) of this article shall, at least, include the reasons why it is legal to take the challenged measure and why the complaint should not be acceptable for any reasonable ground.

3. The measure taking unit shall provide copies of relevant evidences supporting its decision and may list witnesses with the response.

4. Where the measure taking unit fails to respond in accordance with sub-article (1) of this article the chairperson may request in writing the measure taking unit again to respond in two working days. This letter shall state the case will be reviewed in the absence the measure taking unit if it fails for the second time.
5. Where the measure taking unit fails to respond for the second time the chair person shall present the case to full panel review.

32. Review procedure and decision

1. The panel has the Authority to deny review when the complaint raises no genuine and substantial issue of fact and application of regulatory requirements.

2. The decision not to review the complaint shall be made in accordance with Article 29 of this directive.

3. Where, the panel decides to review the complaint it shall review the complaint in accordance with the following procedures:

   a. When the panel believes that the complaint and response submitted in accordance with the previous articles are sufficient to conduct review of the compliant, it may undertake the same without granting hearing and decide the case accordingly.

   b. When additional documentation or evidences are necessary to decide on the case the panel may request the same from parties and decide the case without hearing the parties.

   c. When additional documentation or evidences are necessary to decide on the
Part four

Miscellaneous

33. Record keeping and notification

1. Every administrative measure taken in accordance with this directive shall be...
2. Every administrative measure, as much as possible, shall be kept together with primary dossier of regulated person or product available with the Authority. If such dossier is not available with the measure taking unit copy of this measure shall be delivered to the unit in charge of keeping the file and shall be kept together.

3. The measure taken in accordance with this directive shall be communicated to relevant units of the Authority.

34. Service fee

1. The complainant for his complaint to be reviewed shall pay service fee in accordance with the Authority’s directive.

2. The fee payable by a complainant who gives notice of a request for review will be payable at the time of filing the complaint.

3. The Authority will refund to the complainant 50% of that fee if the complainant withdraws the notice before review of the case.

4. Where the complainant’s request for a change of decision in the authority’s administrative measure is accepted the Authority shall fully refund the amount paid for service fee.

35. Public and media disclosure
1. Disclosure of administrative measure shall only be allowed after 30 days of the decision by the Authority or if the case is under complaint procedure after the final decision on the complaint by the panel.

2. Notwithstanding sub-article (1) of this article, the Authority may publicize administrative measures where failure to publicize would result public health risk.

3. Publication in accordance with sub-article (2) of this article shall be approved by the Director General of the Authority.

36. Inapplicable laws

Any directive which is inconsistent with this directive shall not be applicable with respect to those matters provided for in this directive.

37. Effective date

This directive shall enter into force as of Date 05 November, 2012.

Yehulu Denekew  
Director General  
Ethiopian Food, Medicine and  
Healthcare Control and Administration Authority