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Application of ISO 9001 Industrial Standard to Herbal Drug Regulation

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1. Introduction

We noted earlier [1] that 1978 was the turning point in current public perception of traditional medicine (TM) following the famous WHO declaration at Alma-Ata. That declaration ushered in a positive attitude that paved the way for the present global popularity of TM, especially herbal medicine. We noted earlier also [2,3] that whereas herbal remedies are called dietary supplements in the US, thereby shifting emphasis away from their medicinal attributes, the Dietary Supplement Health Education Act of 1994 [4], which occasioned the shift, actually helped to promote herbal medicine in the US, albeit indirectly, through the innovative provision it made for user information [5,6]. A similar situation obtained in Europe, where the net effect of the laws and rules passed in 2004 on herbal remedies had been to promote their production and use [7, 8]. In terms of trade and economics of herbal drugs, the following fact is notable: Although, Asia contributed only US$ 7.3 billion to herbal world trade in 1999 [9], by 2005, a mere 6 years, China’s contribution alone rose to US$ 14 billion [10]. This stupendous growth was due to policies and programmes that favoured herbal medicine – the cornerstone of Traditional Chinese Medicine (TCM). Similar situations as in China held sway in Japan, South Korea and the Indian sub-continent, where government policies also favoured herbal medicine. However, in many developing countries like Nigeria, a totally different picture obtained, not because policies were expressly against herbal medicine, but in these countries there had been a lingering absence of proper policies and laws supportive of traditional remedies. Another key fact on the political economy of herbal drugs is that: Although, about 80% of people in developing countries depended on herbs, these countries contributed only 7.2% to herbal drug trade in 1999. By contrast, the developed nations, where people relied less on herbs, contributed 55.2%. Asia, less Japan and...
South Korea, contributed 37.6%. Equally interesting is the comparison of Brazil with Nigeria. Both are rich in medicinal plants and have high populations that depend substantially on herbs. But, while herbs contributed an unknown amount to the Nigerian economy in 2007, in Brazil it contributed US$ 160 million. By contrast, Nigeria’s entire federal budget for health in 2007 was a mere US$ 800 million [2]. These findings earlier led us [11,12] to conclude that developing countries need strategies that will enhance the regulation of herbal drugs and promote their trade. The present article is an attempt to enunciate one of such strategies. It is particularly of note that the superior performance of Brazil in comparison with Nigeria indicates that with proper policies and strategies, herbs can indeed contribute substantially to any economy.


2.1. ISO 9001:2008 industrial standard – A synopsis

ISO 9001:2008 industrial standard or quality management system (QMS) is a document of about 30 pages with 8 clauses, published by and obtainable from the International Organization for Standardization (ISO), Basle, Switzerland, or from any of its national affiliates. The standard is designed to be met by any organization that i) needs to demonstrate its ability to consistently provide product or service that meets both customer and applicable statutory and regulatory requirements (collectively legal requirements); ii) aims to enhance customer satisfaction by effectively and continually improving its QMS; and iii) plans to provide continual assurance of conformity to customer and applicable legal requirements. These aims/approaches (often called “QMS requirements” or “quality procedures”) are generic and intended to be applicable to all organizations regardless of type, size and product provided. Wherever any requirement cannot be applied due to the nature of an organization and its product, such can be considered for exclusion. But wherever exclusions are made, claims of conformity to the standard are not acceptable unless such exclusions are limited to requirements within clause 7 of the standard, and such exclusions do not affect the organization’s ability, or responsibility, to provide product that meets customer and applicable legal requirements. ISO 9001:2008 defines the minimum requirements for a well managed organization. In other words, noncompliance to an ISO 9001:2008 requirement puts at risk an organization’s ability to consistently and efficiently satisfy the expectations of its customers/stakeholders.

2.2. The six QMS requirements or “The Six Quality Procedures”

These procedures or requirements, as one may choose to call them, actually refer to sub-clause 4.1 (General requirements) under clause 4 (Quality Management System) of ISO 9001:2008. The sub-clause prescribes that organizations shall establish, document, implement, and maintain a QMS, and continually improve its effectiveness. To do so means that the organization shall operate its QMS with a view to carrying out (or meeting) the following six procedures (or requirements): determine the processes needed for the QMS, and their
application throughout the organization; determine the sequence of the processes and their interactions; determine the criteria and methods for operating and controlling the processes; determine and ensure the availability needed resources and supporting information; check, measure and analyze the processes, where applicable; and implement actions to achieve planned results and continual improvement of the processes.

Figure 1. NIPRD’s core business in the context of Plan-Do-Check-Act process-based QMS.¹

The organization shall manage the processes above in accordance with ISO 9001:2008 requirements. It shall also define the type and extent of control to be applied to any outsourced process that can affect product conformity to requirements. ISO 9001:2008 specifically notes as follows:

¹ Management responsibility corresponds to clause 5 of ISO 9001; while Resource management, Product realization and Measurement/ analysis/ improvement correspond to clauses 6, 7 and 8 respectively.
1. Processes needed for the QMS include the processes for management activities (clause 5), provision of resources (clause 6), product realization (clause 7), and measurement, analysis, and improvement (clause 8).

2. An outsourced process is a process the organization needs for its QMS, and which the organization chooses to have performed by an external party.

3. Ensuring control over outsourced processes does not absolve the organization of the responsibility to conform to customer and legal requirements.

The type and extent of control applied to an outsourced process can be influenced by factors such as: the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements; the degree to which the control over the process is shared; and the capability of the organization in achieving the necessary control via the application of sub-clause 7.4 (Purchasing). Philosophically, ISO 9001:2008 is formulated on the basis of management by objectives (MBO) and draws upon eight quality management principles. Ideally therefore, quality assurance covers activities in research, development, production and documentation. It embraces the rule: "do it right the first time". It involves regulating the quality of raw materials, the state of production line and works-in-progress, the product and related management processes. One of the most widely used paradigms for quality assurance management (QAM) is the “Shewhart cycle”, also called “PDCA approach”, meaning, “Plan-Do-Check-Act” [13,14]. The foregoing is illustrated in Figure 1 using NIPRD QMS processes as an example.

2.3. The eight quality management principles that underlie ISO 9001:2008

Like other ISO standards (Example: ISO 9004 - Managing for Sustained Success), ISO 9001:2008 is based on 8 quality management principles that are aligned with the philosophy and objectives of most quality award programmes in the world’s most industrialized nations. The 8 principles are associated with the following themes:

1. Customer focus.
2. Leadership.
3. Involvement of people.
5. System approach to management.
6. Continual improvement.
7. Factual approach to decision making.
8. Mutually beneficial supplier relationships.
2.4. Key terminologies of ISO 9001:2008

2.4.1. Process approach to management

A process is an activity or operation that receives inputs and converts them to outputs. Practically all activities or operations involved in generating a product or providing a service are processes. For an organization to function, it must define and manage several inter-linked processes. Most often, the output of one process becomes the input into the next process. The systematic identification and control of the various processes employed within an organization, and the interactions between such processes, is termed “process approach” to management. Thus process approach to management is a way of obtaining a desired result, by controlling activities and related resources as a process. Process approach is a key element of all ISO 9000 standards, including ISO 9001:2008.

2.4.2. System approach to management

System approach to management is based on the premise that the efficiency and effectiveness with which an organization achieves its quality objectives are contributed and enhanced by identifying, understanding and managing all the interrelated processes within the organization as a system.

2.4.3. Quality policy

Quality policy is a formal statement from the management of an organization that is linked to the nature of its business and its plans to meet the needs of its customers/ stakeholders. The policy is designed to be understood and followed at all levels and by all staff.

2.4.4. Quality objective

Quality objective is the factual or tangible basis upon which quality policy and plans for implementing the quality programmes of an organization are built. Quality objective should be SMART (ie: specific, measurable, achievable, realistic and time-bound). Each staff of the organization is expected to work towards measurable objectives.

2.4.5. Decision

Decision simply means the selection of one or more options from a multitude of options in tackling a given organizational task. As far as the QMS is concerned, an organization should make SMART decisions based on recorded data. An example of a SMART decision is: The QMS must be audited and evaluated regularly for conformance and effectiveness, so as to assure quality and continual improvement.
2.4.6. Traceability

Traceability is concerned with and refers to the fact that typically, recorded data are meant to show how and where raw materials and products were processed, in order to allow products and problems to be traced to their sources.

2.4.7. Product realization

Product realization refers to the scenario in which, when developing a new product, an organization plans the stages of development, with appropriate testing at each stage. The organization tests and documents whether the product meets design requirements, legal requirements, and user or customer needs.

2.4.8. Quality plan

Quality plan refers to a document specifying the QMS processes (including the product realization processes), and the resources to be applied to a specific product or project.

2.4.9. Monitoring and measurement

Monitoring and measurement refer to the scenario in which an organization must regularly review its performance through meetings and internal audits, and determine whether the QMS is working and what improvements can be made. The organization must have a documented procedure for internal audits and a procedure for dealing with past problems and potential problems. It must keep records of these activities and the resulting decisions, and monitor their effectiveness. It must have documented procedures for dealing with actual and potential non-conformances (problems involving suppliers, customers, or internal problems).

2.4.10. Continual improvement

Continual Improvement refers to the scenario in which an organization 1) makes sure no customer uses a bad product, 2) determines what to do with a bad product, 3) deals with the root cause of problems, and 4) keeps records to use as a tool to improve the QMS.

2.4.11. Customer requirements

Customer requirements refer to the attributes that the buyer of a product (or user of a service) wants. The core business of an organization is to determine customer requirements and to meet them, in accordance with sub-clause 5.2 (Customer focus).

2.4.12. Drug Regulatory Agencies (DRAs)

Drug regulatory agencies (DRAs) are organizations set up by the State on behalf of the general public with a Mandate to regulate drugs and related products and services. The Mandate of some DRAs may include production and distribution of certain goods like vaccines and orphan drugs. Either the State or the general public can be regarded as customer, stakeholder or shareholder. DRAs like all other organizations must have a system for communi-
cating with customers or stakeholders about product information, inquiries, contracts, orders, feedback, and complaints. All DRAs are “service providers” but some produce and even distribute certain specific items, as mentioned above. Nigeria’s National Agency for Food and Drug Administration and Control (NAFDAC) is a national DRA, while the European Medicines Evaluation Agency is a regional DRA.

2.4.13. Mandate

Mandate is a piece of legislation or instruction from a constituted authority to another constituted authority or body to carry out a named task. DRAs are mandated by the State to regulate drugs and health related products.

2.5. The new industrial revolution and the aim of this chapter

It is well established that the high state of development in the chemical/pharmaceutical industrial sector in the US, Japan, South Korea, Britain, Germany and other European countries owes much to the powerful synergy between regulatory legislations, industrial standards and a focused political will. It is also manifest that the rapid, all-round industrial revolution in China in the past decade or so owes much to China’s embrace of ISO standards, especially ISO 9001, as shown in Table 1 after a recent [15].

<table>
<thead>
<tr>
<th>Country</th>
<th>Ranking</th>
<th>No. certificates</th>
<th>Pertinent remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>1</td>
<td>257,076</td>
<td>Relies mostly on ISO standard.</td>
</tr>
<tr>
<td>Italy</td>
<td>2</td>
<td>130,066</td>
<td>Relies mostly on ISO standard</td>
</tr>
<tr>
<td>Japan</td>
<td>3</td>
<td>68,484</td>
<td>Relies only partly on ISO standard</td>
</tr>
<tr>
<td>Spain</td>
<td>4</td>
<td>59,576</td>
<td>Relies substantially on ISO standard</td>
</tr>
<tr>
<td>Russia</td>
<td>5</td>
<td>53,152</td>
<td>Relies substantially on ISO standard</td>
</tr>
<tr>
<td>Germany</td>
<td>6</td>
<td>47,156</td>
<td>Relies only partly on ISO standard</td>
</tr>
<tr>
<td>UK</td>
<td>7</td>
<td>41,193</td>
<td>Relies only partly on ISO standard</td>
</tr>
<tr>
<td>India</td>
<td>8</td>
<td>37,493</td>
<td>Relies substantially on ISO standard</td>
</tr>
<tr>
<td>South Korea</td>
<td>9</td>
<td>28,935</td>
<td>Relies substantially on ISO standard</td>
</tr>
<tr>
<td>US</td>
<td>10</td>
<td>23,400</td>
<td>Relies only partly on ISO standard</td>
</tr>
</tbody>
</table>

*Source ISO Survey 2009 [15]. Most countries have their own national standards in addition to ISO standards. For example the UK is well known for its industrial standards pre-sufixed by BSI (British Standards Institution).

Table 1. The top 10 countries in ISO certification in 2009.

It must be stated that countries like Japan, Germany, Britain and US use their own national standards in addition to those of ISO. Based on the foregoing, we state that the specific aim of this article is: To examine the QMS requirements of ISO 9001:2008 and the requirements
for regulating herbal drugs in Nigeria (a developing economy) and Europe (a developed economy), with a view to devising a framework that will better regulate herbal drugs and facilitate their trade worldwide. Such a framework will greatly benefit developing countries like Nigeria that are yet to benefit optimally from their comparative advantage in the abundance of spices, herbs and medicinal plants. In addition, marketers and users of herbs in consumer nations like the US, Canada, Germany, UK and France, where consumption now runs in to billions of US dollars, will also profit greatly from an improved and regularized world trade in herbs.

3. Results & discussion: A Framework for Efficient Herbal Drug Regulation (HDR)

3.1. Justification for establishing national or regional DRAs

Most or all countries have a national or regional agency that regulates the production, distribution and use of drug products. The process of regulation commences with the registration of the producer, the product, the distributor and in some cases the user. In some countries drugs, foods and dietary supplements are regulated by the same body (eg: Nigeria’s NAFDAC and US-FDA). The EU’s EMEA however regulates only drug products. States or regions need to have DRAs in order to ensure order in the production, distribution and use of drugs. Without DRAs utter chaos and pandemonium will result in production (eg: manufacturers will do as they please without a uniform control), distribution (distributors and suppliers will do as they choose without a uniform order) and use (prescribers and users will do as they think without a uniform regime), which would allow incidences of counterfeit and expired drugs in drug distribution chain, drug abuse and emergence of drug resistant disorders, especially infective conditions like malaria and TB.

3.2. Comparative analysis of Nigeria’s and EU’s requirements for herbal drug regulation

A careful scrutiny of the requirements for registering and regulating herbal drugs in Europe and in Nigeria reveals their basic similarity, as shown in Table 2.

<table>
<thead>
<tr>
<th>Type of data</th>
<th>Details of data required</th>
<th>Regulatory aspect</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>These include: name, strength, dosage</td>
<td>Legal status of applicant -</td>
<td>Applicant must be certified by the Corporate Affairs Commission as a business. A marketer must show evidence of Power of Attorney.</td>
</tr>
<tr>
<td>Summary of product characteristics</td>
<td>contraindications, and special precautions. These are used as basis for inserts or advertisement, which must undergo a process called “readability”.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of product information:</td>
<td>form, list of excipients, shelf life, posology, indications,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Characteristics</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Table 2. Requirements for herbal registration compared between EU and Nigeria.**

But, while the EMEA approach is technically more explicit, though not necessarily more exerting than NAFDAC’s, the latter is administratively much more cumbersome, and therefore more liable to inefficiency and abuse. Table 3 shows the extra bureaucratic demands of NAFDAC. We stated earlier that, although, 80% of people in developing countries like Nigeria depended on herbs, these countries contributed only 7.2% to herbal drug trade in 1999. By contrast, the developed nations, where people relied less on herbs, contributed 55.2%. This scenario is explained by the fact herbal drugs are better regulated in developed regions like the China, India, Japan and South East Asia, the EU and North America [2].
3.3. Justification for selecting ISO 9001:2008 for this study

Although most of the OECD countries and other highly industrialized economies, where herbal drugs are well regulated, have their own national standards, all do embrace ISO standards, especially ISO 9001:2008. For example, the British Standards Institution (BSI) is well known and widely adopted in many other countries worldwide, and although international in application, such national standards do not bear the tag “international”. By contrast, the ISO family of standards bear the tag “international”. ISO 9001:2008 is an international standard designed to address systemic change (i.e., a change that affects an organization as a whole). The global popularity of ISO 9001:2000 - the predecessor of ISO 9001:2008, is attributable to the following factors: a) major purchasers require their suppliers to hold ISO 9001 certification [15, 19]; b) studies indicate significant financial benefits for organizations certified to ISO 9001 [19,20]; and c) similar superior operational performance of ISO certified firms has been severally confirmed [21-24]. As just noted, ISO 9001:2008 is an update of ISO 9001:2000, and we have selected it for this study by reason of its popularity and versatility, and because it is a process-based QMS that addresses systemic change affecting whole organizations like a national or regional drug DRA, like Nigeria’s National Agency for Food and drug Administration and Control (NAFDAC), the US Food and Drug Administration (US-FDA) and the European Medicines Evaluation Agency (EMEA).

<table>
<thead>
<tr>
<th>S/No</th>
<th>Extra requirement</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Five (5) copies of the product dossier.</td>
<td>Probably unreasonable</td>
</tr>
<tr>
<td>2</td>
<td>Three (3) packs of the products samples.</td>
<td>Probably reasonable</td>
</tr>
<tr>
<td>3</td>
<td>Notarized original copy of the duly executed Power of Attorney from the product manufacturer.</td>
<td>Clearly unreasonable for all categories of applicants</td>
</tr>
<tr>
<td>4</td>
<td>Certificate of Manufacture issued by the competent health or regulatory authority in country of origin and authenticated by the Nigerian Mission in that country. Where there is no Nigerian Mission, The British High Commission or an ECOWAS country Mission will authenticate.</td>
<td>Probably unreasonable for all categories of applicants</td>
</tr>
<tr>
<td>5</td>
<td>If contract-manufactured, Contract Manufacturing Agreement, properly executed and notarized by a Notary Public in the country of manufacture.</td>
<td>Clearly unreasonable for all categories of applicants</td>
</tr>
<tr>
<td>6</td>
<td>Current World Health Organization Good Manufacturing Practice Certificate for the manufacturer, authenticated by the Nigerian Mission.</td>
<td>Clearly unreasonable for all categories of applicants</td>
</tr>
<tr>
<td>7</td>
<td>Certificate of Pharmaceutical Products (COOP) duly issued and authenticated.</td>
<td>Clearly unreasonable for all categories of applicants</td>
</tr>
<tr>
<td>8</td>
<td>Current Superintendent Pharmacists license to practice issued by the Pharmacists Council of Nigeria (PCN).</td>
<td>Only probably reasonable</td>
</tr>
<tr>
<td>S/No</td>
<td>Extra requirement</td>
<td>Remark</td>
</tr>
<tr>
<td>------</td>
<td>-------------------</td>
<td>--------</td>
</tr>
<tr>
<td>9</td>
<td>Premises Registration License from PCN</td>
<td>Only probably reasonable</td>
</tr>
<tr>
<td>10</td>
<td>Certificate of Registration of brand name with trademark registry in the Ministry of Commerce here in Nigeria; Letter of invitation from manufacturer to inspect factory abroad, stating full name and location of plant.</td>
<td>Probably unreasonable for all categories of applicants</td>
</tr>
<tr>
<td>11</td>
<td>The applicable fee payable only if documents are confirmed to be satisfactory</td>
<td>Likely to be abused if the amount is high. The fee should be a token amount paid by all applicants</td>
</tr>
<tr>
<td>12</td>
<td>Nutraceuticals, medical devices and other regulated drug products have similar requirements, with minor variations. Specific details can be obtained from NAFDAC.</td>
<td>A sketch of the minor variations should be provided in print no matter how brief. Any information provided by NAFDAC should be printable for sake of transparency</td>
</tr>
</tbody>
</table>

*The information on NAFDAC were drawn from leaflets and NAFDAC’s website (2010): www.nafdacnigeria.org/ The remarks are informed by current affairs and public perception of NAFDAC’s role and activities including the wholesale reorganization of its Management in 2000.

Table 3. NAFDAC’s extra requirements for registering herbal medicines.

3.4. A systematic review of the eight clauses of ISO 9001:2008 in relation to DRAs

3.4.1. A synopsis of the Mandate of DRAs and the eight clauses of ISO 9001:2008

ISO 9001:2008 is the most widely used QMS standard, with over a million certificates issued worldwide. Alas, it was revealed at the SON-NIPRD course in 2011, that only two public institutions in Nigeria have ISO 9001 certification! Yet, as stated earlier, ISO 9001:2008 defines the minimum requirements for a well managed organization. The standard is published by the International Organization for Standardization (ISO), Basle, Switzerland. National accreditation bodies like the Standards Organization of Nigeria (SON) provide accreditation to registrars who issue the ISO 9001 certificates to those they audit. ISO 9001:2008 is set out in eight clauses designated clauses 1 to 8. The structure and salient points/directing principles of the clauses are tabulated below. A copy of ISO 9001:2008 is a prerequisite for this study. Similarly required, is a grasp of the requirements for registering and regulation herbal drugs in a developed economy like Europe; and in a developing country like Nigeria, as depicted in Table 2. It is well known that herbal drugs are better regulated in the developed than in developing countries. Table 3 suggests that undue bureaucracy or needlessly cumbersome requirements can hinder efficient regulation. Tables 4-13 show the structure and salient points/directing principles of the 8 clauses.
Clause | Title and subtitles, with remarks | Salient points/ directing principles/ application to DRAs
--- | --- | ---
1 | 1. Scope | ISO 9001:2008 can be used to establish, and to update a DRA’s QMS. A DRA, like other parastatals or private organizations must consider its unique operational environment and the dynamics and risks associated therewith.
1.1 General |  
1.2 Application |  
2 | 2. Normative references | A normative reference implies, unless otherwise stated, that the most recent versions of the separate documents should be referenced. DRAs would benefit immensely from such key references and compendia such as the International Pharmacopoeia and others like the BP and USP, and the WHO manual on Quality Control Methods for Medicinal Plant Materials.
2.2.1 General - QMS documents must include: quality policy, quality objective, quality manual, documented procedures/ records specified by ISO 9001:2008, and documents/ records determined by the organization to be relevant for effective planning, operation and control of the QMS.
2.2.2 Quality manual – this should include the scope of the QMS, SOPs and a description of the QMS processes.
2.2.3 Control of documents - the documents required by the QMS must be established and controlled. This means that SOPs are to be established to define the controls needed.
2.2.4 Control of records – records are a special type of documents and must be established and controlled. Here too, SOPs are to be established to define the controls needed.
3 | 3. Terms and definitions | The term “product” may also mean “service”. “Legal requirements” means “statutory and regulatory requirements”. Most DRAs are service providers only, while others may produce and distribute certain specialized health products.
3.2.1 General |  
|  |  
|  |  
|  |  

*The Table is to be studied side by side with the contents of ISO 9001:2008 and Table 2, which is on regulatory requirements of DRAs.

**Table 4.** Clauses 1-3 of ISO 9001:2008 in relation to DRAs.
Clause 5 Management Responsibility

5.1 Management commitment

5.2 Customer focus - the organization must ensure that its purpose/ focus (inclusive of customer/ stakeholder requirements) is understood and determined.

5.3 Quality policy - this should be:

1) appropriate to the purpose of the organization; 2) focused on meeting requirements and continual improvement; 3) used as a framework for quality objectives; 4) publicized and understood at appropriate levels; and 5) reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality Objectives

5.4.2 QMS Planning

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

5.5.2 Management Representative

5.5.3 Internal Communication - it is crucial that the organization ensures that appropriate communication processes regarding the effectiveness of the QMS are established and implemented.

5.6 Management Review

5.6.1 General

5.6.2 Review Input - includes audit results, public feedback, process performance, status of preventive/ corrective action, follow-up from previous management review.

The DRA must be committed to developing and implementing a QMS, as well as, a commitment to continually improve the effectiveness of the QMS. The DRA can do this by 1) communicating the importance of meeting “legal and customer requirements”; 2) establishing a quality policy and quality objectives; 3) conducting management reviews; and 4) by ensuring the availability of necessary resources. The “legal and customer requirements” of a DRA are implicit in its Mandate – which may be an act, law or decree. In planning, the DRA must 1) ensure that quality objectives are established at the relevant functions and levels within the Agency; 2) ensure that quality objectives are measurable and consistent with the quality policy; and 3) ensure that planning for the QMS meets the general requirements (clause 4.1) and quality objectives (clause 5.4.1), as well as, maintains the integrity of the QMS.

In as much as operations must be carried out the DRA must ensure that the responsibilities and authorities for such are defined and communicated appropriately. It is essential that a member of top management, irrespective of other duties, be appointed (as Quality Manager) and given the responsibility to: 1) ensure that the needed processes are established, implemented, and maintained; 2) report to top management on the performance of the QMS; 3) report to top management on any need for improvement; and 4) ensure the promotion of awareness of Agency’s Mandate. Most DRAs have a public relation office.

For a DRA to be effective it must review its QMS at planned intervals to: 1) ensure an effective QMS; 2) assess possible opportunities for improvement; 3) evaluate the need for any changes; and 4) consider the need for changes to the policy and objectives. The DRA must of course maintain records of reviews as per clause 4.2.4. For a DRA, the inputs for review must include information on: 1) results of audits; 2) feedback from government and the public, eg - incidences of counterfeit drugs; 3) status of preventive and corrective actions, eg - incidences of drug abuse; 4) follow-up actions from earlier reviews; 5) changes that can affect the QMS; and 6) recommendations for improvement.
3.4.2. The immediate historical antecedent of NAFDAC and the continuing relevance of ISO 9001

Nigeria’s NAFDAC was created by decree in 1992/93 following the ethylene glycol disaster of 1991/92 in Langtang General Hospital, Plateau State, where ethylene glycol was used in the place of propylene glycol in preparing paracetamol elixir. The glycol had been purchased from a hitherto popular pharmacy shop located at Masalachin-Jumai Street, Jos. Prior to 1992/93, a department in the Federal Ministry of Health handled food and drug administration in Nigeria. Alas, in 2009 another ethylene glycol disaster occurred in Lagos. In this latter disaster a hitherto popular brand of paediatric mixture (“My Pikin”) was found to contain ethylene glycol that had been purchased from an unregulated source. It is important to note that whereas the glycol implicated in the Lantang disaster was purchased from pharmaceutically regulated source, the glycol in the case of the Lagos disaster was purchased from a company that dealt in industrial chemicals associated with automobiles and cooling systems. The occurrence of this kind of disaster within less than two decades is matter of concern that calls for a more efficient programme for regulating drugs and industrial chemicals in developing countries. The US-FDA after whose image and likeness NAFDAC was created is known for efficiency mostly because it is supported by proper laws and strong institutions. Better laws and stronger institutions, including DRAs, are required to avoid or minimize this kind of disaster as seen in Nigeria. It seems instructive to mention the “Tylenol case” in the US, and how that case led to a new legislation. Between late September and early October 1982, seven persons in Chicago died after taking capsules of Tylenol (a brand of paracetamol), to which cyanide crystals had been added. The crystals had apparently been introduced into the capsules by someone who had removed bottles of Tylenol from several drugstores and then replaced them on the shelves. It took an intensive investigation by a team of over 100 agents, including FDA staff, to discover the mischief, which led to a 1982-legislation that required all over-the-counter drugs and medicines sold in the county (and later elsewhere in the US and beyond) carry manufacturers’ seals which broken would be obvious. The rapid conclusion of the investigation led by the Illinois Attorney General himself (Tyrone C. Fahner) and the dispatch with which the new law was issued collectively testify to the inner workings of strong institutions – which developing nations lack.
6 Resource management
6.1 Provision of resources
6.2 Human resources
6.2.1 General
6.2.2 Competence, Training, and Awareness
6.3 Infrastructure
6.4 Work Environment

The DRA must determine and provide the resources needed: 1) to implement, maintain and continually improve the effectiveness of its QMS; and 2) to enhance the fulfillment of its Mandate. By virtue of its role as a highly specialized agency, the DRA must ensure that all staff irrespective of department whose work can impact DRA’s Mandate are competent based on appropriate education, skills, experience and abide by their professional ethics. This implies that the DRA must: 1) determine the competency of staff; 2) provide training as needed; 3) evaluate the effectiveness of the actions taken on training and skills acquisition; 4) inform staff of their relevance within the QMS; 5) ensure staff know their contributions to achieving quality objectives; and 6) maintain staff records of education, training, skill, and experience in accordance with clause 4.2.4. The DRA must, of course, provide appropriate work environment for all staff whose work is performed, and includes physical aspects like weather and noise pollution.

*The Table is to be studied side by side with contents of ISO 9001:2008 and Table 2, which is on regulatory requirements of DRAs.

Table 7. Clause 6 of ISO 9001:2008 in relation to DRAs.

3.4.3. The making of stronger DRAs and the need for clearer demarcation of responsibilities

In most countries where DRAs are not a department of the Ministry of Health, they exist as a parastatal or as a special department within the Ministry (as in Japan), with conditions of service being slightly more favourable than in the rest of the Ministry. The idea is to give special incentives to the staff on account of hazards perceived to be peculiar to the job. In Nigeria, NAFDAC is well housed both at the federal and state levels and the staff earn about the same remuneration as the universities and research institutes. In most countries the DRAs have well equipped offices and laboratories, and those DRAs that produce and distribute goods are equipped with the necessary plant and storage facilities.

3.4.4. The inevitability of confusion in the absence of regulatory standardization

In Nigeria, NAFDAC previously handled certain aspects of manufacture/distribution of vaccines until certain developments (or rather controversies over quality/effectiveness of polio vaccines during the late 1990s/early 2000s) led, first to the creation of a National Programme on Immunization (NPI); and latter to the transfer of the same functions from NPI back to the Federal Ministry of Health. It is obvious from the foregoing that institutions like NAFDAC and NPI would have performed better had they been certified. It seems also that one of the keys to ending the cycle of poverty and underdevelopment in some countries is to ensure that elite institutions like the DRAs are certified to appropriate ISO standards. Certifications of agencies like the Health Insurance Scheme and the Pension Commission will definitely reduce perceive current levels of corruption in such institution.
Clause Title and subtitles, with remark

Salient points / directing principles / application to DRAs

7 Product realization

7.1 Planning of product realization

Product realization typically means that manufacturers need to plan and develop the QMS processes required for product realization; keep the planning consistent with other requirements of the QMS; document the plan in a suitable form; and determine through the planning, the following: a) quality objectives and product requirements; b) need for processes, documents, and resources; c) verification (establishment of truth/confirmatory evidence), validation (formal registration/obtaining of official sanction), monitoring, measurement, inspection, and test activities; d) criteria for product acceptance; and e) records providing evidence that the processes and resulting product meet requirements. Since DRAs regulate manufacturers they must be acquainted with clause 7. NOTE 1: Recall that "quality plan" (2.4.8 of this article) is a document specifying the processes, and the resources to be applied to a specific product, project, or contract.

NOTE 2: An organization can apply the requirements of sub-clause 7.3 (vide infra) to the development of product realization processes.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

7.2.2 Review of Requirements Related to the Product

7.2.3 Customer Communication

The intensity and scope of communication depends on the product and the associated mandate. Thus the DRA must determine and implement the necessary arrangements for communicating with stakeholders on aspects like 1) product information; 2) inquiries and contracts; 3) customer/stakeholder feedbacks - positive or negative.

Some DRAs produce/ store/ distribute specialized and non-profit products like vaccines and orphan drugs. For such, all aspects of clause 7 apply. The DRAs of developed economies concentrate on regulating manufacturers, distributors and use of products. Different processes are involved in drug regulation but these often have some aspects in common. For example, the process of registering a manufacturer and that of registering a product are essentially the same, but they differ in their aims, point of action, who by, and so on. Some of the processes involved in "planning of service realization", which is the core business of a typical DRA, require a wide range of differing concepts, technicalities, approaches, specializations, and so on. For example, although the technical aspects of producing tablets of aspirin, diazepam, B-complex, erythromycin, and orphan drugs may be similar, the modes of their regulation and distribution are different. Given the involved Mandate of DRAs, different strategies must be developed to grapple with the differing nuances and intricacies associated with the regulation of the five products. Typically, questions that have answer buried in culture/society rather than the lab do arise in drug regulation. Why, for example, despite the similarities between NAFDAC and EMEA, it is impossible to buy erythromycin or diazepam over-the-counter in Europe but not in Nigeria? To what extent do political, social environments? It well known that regulatory strategies that work in Europe often fail to work outside despite obvious legislative similarities between nations. The customers/ stakeholders of a typical DRA are the general public, manufacturers, suppliers and the government. DRAs that engage in production and distribution must determine customer requirements, which invariably include specified and unspecified but desirable attributes. Such DRAs must also determine the legal requirements applicable to the product. Other desirable requirements, including post-delivery activities like maintenance services, may be considered. DRAs that produce or distribute would normally review the product requirements before committing to supply in order to: 1) ensure that product requirements are defined; 2) resolve any requirements differing from those previously expressed; and 3) ensure its ability to meet the requirements. In the same vein when a DRA plans a regulatory strategy or legislation the plan should be graduated and made reasonable to its purpose and scope and with reference to the operating socioeconomic environment. The DRA must maintain the results of reviews, and any subsequent follow up actions in accordance with 4.2.4. When the requirements are not documented, they must be confirmed before acceptance. But if product requirements are changed, the DRA must ensure relevant documents are amended and relevant personnel are made aware of the changed requirements.

NOTE: In some situations a formal review is impractical for each order. In such cases reviews can cover relevant product information such as catalogues or adverts.

*The Table is to be studied side by side with contents of ISO 9001:2008 and Table 2, which is on the regulatory requirements of DRAs.

Table 8. Clause 7 of ISO 9001 in relation to DRAs (Product planning and Customer-Related processes).
Table 9. Clause 7 of ISO 9001:2008 in relation to DRAs (Design and Development).
3.4.5. **Some causes and signs of a malfunctioning DRA**

Once the staff recruitment system can be skewed to favour persons, a serious non-compliance exists. Once the purchase processes can be demonstrated to have vested interest, a serious flaw exists in the QMS. Once there is a convincing evidence of maladministration, arbitrary treatment of personnel or executive high handed, a serious condition against performance exists.

<table>
<thead>
<tr>
<th>Clause</th>
<th>Title and subtitles, with remarks</th>
<th>Salient points/ directing principles/ application to DRAs</th>
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<tbody>
<tr>
<td>7</td>
<td>7.4 Purchasing</td>
<td>Whether a DRA produces/distributes it will have cause to purchase various items of commerce hence QMS requirements for purchases are required. Like other organizations a DRA would require and ensure the adequacy of the specifications of items to be purchased before communicating the purchasing information to the supplier. Typically a DRA would establish the specified purchase requirements. If a DRA or its customers/stakeholders propose to verify a good or service at the supplier’s location, the intended verification arrangements/method must be stated in the purchasing information.</td>
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<tr>
<td></td>
<td>7.4.1 Purchasing Process</td>
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<td>7.4.2 Purchasing Information</td>
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<td>All organizations irrespective of type of business will have cause to purchase a multitude of goods for the business. If and implement inspection or other necessary activities for ensuring that purchased goods meet the specified purchase requirements. If a DRA or its customers/stakeholders propose to verify a good or service at the supplier’s location, the intended verification arrangements/method must be stated in the purchasing information.</td>
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<td></td>
<td>7.4.3 Verification of Purchased Product</td>
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<td></td>
<td>7.5 Production and Service Provision</td>
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<tr>
<td></td>
<td>7.5.1 Control of Production and Service Provision</td>
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<td></td>
<td>7.5.2 Validation of Processes for Production and Service Provision</td>
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<td></td>
<td>7.5.3 Identification and Traceability</td>
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<td>7.5.4 Customer Property</td>
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As a standard practice, a DRA would: 1) assess and record the validity of prior results if the equipment/method are found not to conform to requirements; 2) maintain records of the results of calibration and verification; and 3) confirm or re-confirm the ability of any software or programme used for monitoring or measurement before its initial use. To ensure the validity of results, a DRA would normally:

1. Calibrate and/or verify the measuring equipment at specified intervals or prior to use.
### Clause Title and subtitles, with remarks

<table>
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<tr>
<td>7.5.5</td>
<td>Preservation of Product</td>
<td>2. Calibrate the equipment to national or international standards (or record other appropriate actions).</td>
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<td>3. Adjust or re-adjust as necessary.</td>
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<td>4. Identify the measuring equipment in order to determine its calibration status.</td>
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<td>5. Safeguard equipment from improper adjustments.</td>
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<td>6. Protect equipment from damage and deterioration.</td>
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<td>7.6</td>
<td>Control of Measuring and Monitoring Equipment</td>
<td>As may be applicable, a DRA would:</td>
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<td></td>
<td>1) Determine the type of monitoring and measurements to be made, and the equipment/method to be used in providing evidence of conformity.</td>
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<td></td>
<td></td>
<td>2) Use and control the monitoring and measuring devices in order to ensure that measurement capability is consistent with monitoring and measurement requirements.</td>
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</table>

*The Table is to be studied side by side with contents of ISO 9001:2008 and Table 2, which is on the regulatory requirements of DRAs.

<table>
<thead>
<tr>
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<tr>
<td>8</td>
<td>Measurement, analysis and</td>
<td>Given the overwhelming importance of measurement, analysis and improvement to the Mandate of DRAs, a DRA would typically want to be sure, thorough and effective in the application of clause 8. To ensure effectiveness therefore, the DRA would routinely, or as may be necessary, determine through planning the need for, use of, and extent of use of applicable methods, including statistical techniques. DRAs should view customer/stakeholder perception as a key performance measurement of its QMS. For producing and/or distributing DRAs especially, monitoring customer/stakeholder perception can be obtained from: 1) customer/stakeholder satisfaction surveys; 2) customer data on delivered product quality; 3) user opinion surveys; 4) lost business analysis; 5) compliments; 6) warranty claims; and 7) dealer reports.</td>
</tr>
<tr>
<td>8.1</td>
<td>General</td>
<td>A producing/distributing DRA would plan and implement the monitoring, measurement, analysis, and improvement methods, including statistical techniques. DRAs should view customer/stakeholder perception as a key performance measurement of its QMS. For producing and/or distributing DRAs especially, monitoring customer/stakeholder perception can be obtained from: 1) customer/stakeholder satisfaction surveys; 2) customer data on delivered product quality; 3) user opinion surveys; 4) lost business analysis; 5) compliments; 6) warranty claims; and 7) dealer reports.</td>
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<td></td>
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<td>For thoroughness and effectiveness a producing/distributing DRA must: 1) plan the audit program; 2) consider the status and importance of the audited areas; 3) consider the results of prior audits; 4) define the audit criteria, scope, frequency, and methods; and 5) select and use impartial and objective auditors. Non-producing/distributing DRAs must have the ability to ensure that manufacturers/distributors comply.</td>
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<td></td>
<td>To institute thoroughness and effectiveness, producing/distributing DRAs must: 1. Maintain records of the audits and their results. 2. Ensure control of the audited areas. 3. Take actions without undue delay to eliminate detected nonconformities and their causes. 4. Verify through follow-up actions.</td>
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</table>

### Table 10. Clause 7 of ISO 9001:2008 in relation to DRAs (Purchasing/Production/Control of Equipment).
Internal audits must be conducted at planned intervals so that DRAs can determine if their QMS: 1) conforms to requirements of ISO 9001:2008; 2) conforms to planned arrangements as per sub-clause 7.1; and 3) is effectively implemented and maintained. In order to thoroughly address staff responsibilities and the requirements to be met by the audit exercise, DRAs must establish: 1) a documented procedure for planning audit; 2) a documented procedure for conducting audits; and 3) a documented procedure for recording and reporting audit results.

Again, non-producing/distributing DRAs must have the ability to ensure that manufacturers/distributors comply.

NOTE: ISO 19011 (Audit guidance) should be consulted for further enlightenment quality auditing.

*The Table is to be studied side by side with contents of ISO 9001:2008 and Table 2, which is on the regulatory requirements of DRAs.

### Table 11. Clause 8 of ISO 9001:2008 in relation to DRAs (Monitoring and measurement).

#### 3.4.6. Remediation of a malfunctioning DRA

A national or regional DRA is a critical factor in socioeconomic development and wellbeing in at least two ways: i) by “guaranteeing the health of the nation” (as trumpeted in NAFDAC’s adverts); and by supporting the emergence of responsible manufacturers of regulated products. It is well known that the US-FDA more than any US organization has made the US the world leader in manufacture of health products. The prominence of India and China in world drug trade owes much to the vibrancy and relative efficiency of their DRAs. There is therefore a critical need for DRAs to be vibrant and responsible. The gravity with which China views the role of her DRA can be gauged by the death sentence passed on the Director General in 2007 for accepting a bribe [15].

### Clause Title and subtitles, with remarks

<table>
<thead>
<tr>
<th>Clause</th>
<th>Salient points/ directing principles/ application to DRAs</th>
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<tbody>
<tr>
<td>8</td>
<td>Producing/distributing DRAs need to 1) apply suitable methods for monitoring and measuring QMS processes; and 2) confirm through these methods the continuing ability of each process to satisfy its intended purpose.</td>
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<tr>
<td>8.2.3</td>
<td>Non-producing/distributing DRAs must have the ability to ensure that manufacturers/distributors comply.</td>
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<tr>
<td>Measurement of Processes</td>
<td>NOTE: When determining “suitable” methods, consideration is given to the type and extent of monitoring or measurement for each process in relation to its impact on product conformity and on the effectiveness of the QMS.</td>
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<tr>
<td>1) Apply suitable methods to monitor and, where applicable, measure the QMS processes.</td>
<td>To better fulfill their Mandate producing/distributing DRAs must 1) monitor and measure product characteristics so as to verify if product requirements are being met; 2) carry out the monitoring and measurements at the appropriate stages of product realization in accordance with planned arrangements; and 3) maintain evidence of conformity with the acceptance criteria.</td>
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<tr>
<td>2) Confirm through these methods the continuing ability of each process to satisfy its intended purpose.</td>
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<tr>
<td>3) When the planned results are not achieved, take correction and corrective action, as appropriate.</td>
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</table>
1) Monitor and measure product characteristics to verify if product requirements are being met.
2) Carry out the monitoring and measuring at the appropriate stages of product realization in accordance with planned arrangements (see 7.1).
3) Maintain evidence of conformity with the acceptance criteria.
4) Record the person responsible for authorizing release of product for delivery to the customer.

8.3 Control of nonconforming product

DRAs must: 1) Ensure any nonconforming product is identified and controlled to prevent its unintended use or delivery.
2) Establish a documented procedure to define the controls and related responsibilities and authorities for dealing with nonconforming product.
3) Maintain records of the nature of the nonconformity, and any subsequent actions, (including any concessions). When the nonconformity is corrected, DRAs must re-verify it to prove or show evidence of conformity.
4) Where applicable, DRAs must deal with the nonconforming product by one or more of the following ways:
   1. Take action to eliminate the detected nonconformity.
   2. Authorize its use, release, or acceptance by concession.
   3. Take action to preclude its original intended use or application.
   4. Take action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

To better fulfill their Mandate, DRAs must: 1) Ensure that any nonconforming product is identified and controlled to prevent its unintended use or delivery. 2) Establish a documented procedure to define the controls and related responsibilities and authorities for dealing with nonconforming product.

The Table is to be studied side by side with contents of ISO 9001:2008 and Table 2, which is on the regulatory requirements of DRAs. Although a DRA may not possess certain facilities for measurements and monitoring, it should possess the ability or the means necessary to ensure that manufacturers/ distributors possess and use them in accordance with approved QMS guidelines.

Table 12. Clause 8 of ISO 9001 in relation to DRAs (Product characteristics/ Control of nonconformities).

In Nigeria, the entire NAFDAC Management was sacked on alleged acts of corruption in 2000. It seems to us that the following are essential for a DRA to perform optimally:

1. The laws creating/ amending a DRA should be well articulated as is the case with the US-FDA.
2. DRAs should be so well funded as not to rely on a plethora of frivolous fees as with NAFDAC.
3. Staffing of DRAs must be transparent - competence and integrity must be the decisive criteria.
4. DRAs should be audited frequently, at least yearly or twice yearly.
5. DRAs should have a Board of Governors to whom the Management reports.
6. Parliamentary health committees should view DRAs as critical to socioeconomic well-being of the nation.

<table>
<thead>
<tr>
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<th>Salient points/ directing principles/ application to DRAs</th>
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<tbody>
<tr>
<td>8.4</td>
<td>Analysis of data</td>
<td>DRAs should as a matter of practice:</td>
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<td></td>
<td>Whether producing/ distributing or not, as a rule; DRAs must determine, collect, and analyze appropriate relevant sources in their analyses.</td>
<td>1. Include the primary data generated by monitoring and measuring activities, and from other data to demonstrate the suitability and effectiveness of their QMS, as well as, evaluate where continual improvement of the QMS can be made.</td>
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<td></td>
<td>DRAs cannot enforce compliance among manufacturers/ distributors in an aspect of quality management in which they are themselves deficient.</td>
<td>b. Conformity to product requirements as per 8.2.4.</td>
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<tr>
<td></td>
<td></td>
<td>c. Characteristics and trends of processes and products, including opportunities for preventive action as per 8.2.3, 8.2.4, and 8.5.3.</td>
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<tr>
<td>8.5</td>
<td>Improvement</td>
<td>DRAs are to continually improve the effectiveness of their QMS through:</td>
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<tr>
<td>8.5.1</td>
<td>Continual Improvement</td>
<td>1. Quality policy</td>
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<td>8.5.2</td>
<td>Corrective Action</td>
<td>2. Quality objectives</td>
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<td>The standard practice for organizations is that:</td>
<td>3. Audit results</td>
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<td></td>
<td>1. Wherever a nonconformity or breach is detected, corrective action must be taken to eliminate the cause of the nonconformity and to prevent its recurrence.</td>
<td>4. Analysis of data</td>
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<td></td>
<td>2. Wherever corrective action is taken by an organization, such action must be such as is appropriate to the effects of the problem caused by the nonconformity or breach.</td>
<td>5. Corrective and preventive action</td>
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<tr>
<td>8.5.3</td>
<td>Preventive Action</td>
<td>6. Management review</td>
</tr>
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<td></td>
<td>Organizations must:</td>
<td>For thoroughness and effectiveness, DRAs must establish a documented procedure (SOP) for corrective action. Such a procedure must define requirements to:</td>
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<tr>
<td></td>
<td>1. Determine in advance the action that needs to be taken to eliminate the causes of potential non-conformity, in order to prevent its occurrence.</td>
<td>1. Review nonconformities (including customer complaints).</td>
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<td></td>
<td>2. Ensure that preventive actions are appropriate to the anticipated effects of the potential problem.</td>
<td>2. Determine the causes of nonconformities.</td>
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<td></td>
<td>For thoroughness and effectiveness, DRAs must establish a documented procedure for preventive action. Such a procedure must define requirements to:</td>
<td>3. Evaluate the need for actions to prevent recurrence.</td>
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<tr>
<td></td>
<td>1. Determine potential nonconformities and their causes.</td>
<td>4. Determine and implementing the needed action.</td>
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<td>2. Evaluate the need for actions to prevent occurrence.</td>
<td>Maintain records of the results of the action taken.</td>
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<td></td>
<td>3. Determine and implementing the needed action.</td>
<td>6. Review the effectiveness of corrective action taken</td>
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<tr>
<td></td>
<td>4. Maintain records of the results of the action taken.</td>
<td>Review the effectiveness of preventive action taken</td>
</tr>
</tbody>
</table>

*The Table is to be studied side by side with contents of ISO 9001:2008 and Table 2, which is on the regulatory requirements of DRAs. It must be stressed once again that if DRAs are to persuade manufacturers/ distributors to comply with the provisions of this and other clauses of ISO 9001:2008 industrial standard, they too must be conversant with and adept in them.

Table 13. Clause 8 of ISO 9001:2008 in relation to DRAs (Analysis of data/ Improvement).
3.4.7. Further remarks on clauses 7 and 8 of ISO 9001:2008

Although the principles of clauses 7 and 8 apply to all organizations, they are strictly speaking, the deeds and stuff intended for high profile institutions with elaborate concern and facilities for design and R&D, and with tall entrepreneurial ambition. Such organizations include the most successful pharmaceutical and biotechnology companies of the US, Europe, Japan and India; NASA, aircraft manufacturers, international airlines and 5-star hospitality concerns. However, in as much as DRAs must regulate the work and product of advanced pharmaceutical manufacturers, the onus is upon the DRAs themselves to be conversant with the entire provisions of these clauses and be as intellectually equipped as the manufacturer. This explains why it is often desirable that regulators have a stint in both academia and industry. In many countries, especially the US and India, top rate biomedical facilities/institutions and personnel are to be found in the following four circles: i) the DRAs (eg: US-FDA); ii) health research institutions (eg: NIH); iii) the universities/ R&D institutions patronized by the DRAs; and iv) big transnational drug manufacturers (eg: Pfizer). We once again refer to the Nigeria polio vaccine controversy of the late 1990s/early 2000s mentioned earlier, and ask the following question: When a DRA produces or distributes product as is the case in many developing economies, who regulates the DRA? Can subsequent revisions of ISO 9001 or some other ISO standard provide an answer?

4. Conclusions

It is evident from the foregoing that all the eight clauses of ISO 9001:2008 apply to the Mandate of DRAs. However, most of what appears in clauses 7 and 8, the lengthiest of the clauses, relates more pertinently to high stake pharmaceutical manufacturers that have elaborate R&D than they do to the average DRA, which nevertheless should be thoroughly acquainted with the clauses. Some DRAs like the US-FDA and EMEA that have advance laboratories or access to such or that heavily fund R&D must be guided by the rigorous provisions of clauses 7 and 8. Needless to say, those DRAs that produce/distribute products must be similarly guided to the extent of their relevance to the scope and size of their operations. The US-FDA, Japan’s Ministry of Health and Social Services and EMEA are certified to appropriate performance standards and are known for their efficiency. By contrast NAFDAC and other developing national DRAs are not similarly certified and are less well known for efficiency, considering the rampancy of counterfeit drugs and other ills in their drug delivery systems. The DRAs of China, India and Southeast Asian countries compare quite well in many aspects with those of Europe, Canada and the US, and are by far more efficient than those of many African and South American countries. From the foregoing, and in view of the historical and international dimensions of phytotherapy, especially its galloping global patronage in recent times [1,2,11,12], it is necessary that there to be a minimum global standard to which DRAs should be certified. We propose ISO 9001 because of its global popularity, applicability and suitability. The standard provides the general climate for DRAs to efficiently discharge their Mandate. We project that a carefully planned application of ISO 9001 to herbal drug regulation will improve the production, distribution and usage of herbal drugs.
It will also boost the economy of developing economies that rely to a large extent on herbal
drugs. But since the DRAs of many developing economies produce/distribute certain prod-
cucts, there is a need for subsequent revisions of ISO 9001 to take cognisance of the question
of who regulates the regulator that produces/distributes? In the meantime we recommend
that the Minister/Secretary of Health and/or the Parliamentary Committees of Health take
note of this significant lacuna.

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