IN THE THIRD SESSION OF THE SIXTH PARLIAMENT OF THE FOURTH REPUBLIC OF GHANA

REPORT OF THE COMMITTEE ON HEALTH

ON THE

EBOLA VACCINATION TRIALS IN THE COUNTRY

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1.0 INTRODUCTION

Following a statement made by Hon. Emmanuel Kwasi Bedzrah on behalf of the Volta Caucus and a Statement by the Minister for Health, Hon. Alex Segbefia, on the on-going Ebola trials in the country, Rt. Hon. Speaker referred the matter to the Committee on Health in line with Order 178 for consideration and report

In considering the referral, the Committee met with the Minister for Health, Hon. Alex Segbefia, the Deputy Minister for Health, Hon. Victor Bampoe and the technical team from the Ministry of Health.

Other invitees were-

- The technical team from Food and Drugs Authority,
- Vice Chancellor, University of Health and Allied Sciences
- Noguchi Memorial Institute for Medical Research
- Ghana Health Service Ethics Review Committee
- Kintampo Health Research Unit, and
- The Ghana Academy of Arts and Sciences.

The Committee is most grateful to them.

2.0 REFERENCE DOCUMENTS

The Committee referred to the following documents

- The 1992 Constitution of Ghana
- The Public Health Act
- Document covering activities from the receipt of the application from the GSK and Johnson &Johnson
- Copies of communications with the GSK and Food and Drugs Authority
- Copies of communications with the Johnson &Johnson and Food and Drugs Authority
- Copies of communications with the Ethics committee of Ghana Health Service
- Reports from the Principal investigators on the status of approval on the GSK vaccine trial from Kintampo Health
- Brief report on what Noguchi memorial institute does and activities on the role of the institute in clinical trials
- Proposal from the University of Health and Allied Sciences on the processes and studies on the clinical trial
- Copy of Response to the Ghana Academy of Arts and Sciences
- Report of the Role of the Ethics Committee of the Ghana Health Service in the role in the Ebola Vaccine Trials in Ghana
- Report of the Ninth Meeting of the African Vaccine Regulatory Forum of the WHO
- Standard Operating Procedure (SOP) of the Ghana Health Ethics Review Committee

- Approval Letter of the Ghana Health Ethics Review Committee
- Report of a technical sub-committee proposed by the Sciences Section to advise council on news of an impending Ebola vaccine trial in Ghana
- Statement from the Academy of Arts and Sciences

3.0 OBJECT OF THE REFERRAL

The object of the referral was to ascertain:-

- Whether there is an on-going clinical Ebola Virus Disease (EVD)trial in the country
- If so, whether the candidate vaccines being used are safe and pose no risk to the citizenry

4.0 OBSERVATIONS

4.1 On-going clinical trials in Ghana

The Minister for Health, Hon. Alex Segbefia, upon attending to the Committee, reiterated his earlier statement in Parliament that no Ebola Clinical Trials was being carried out in the country as the processes toward undertaking the proposed clinical trials had been suspended. He said the Food and Drugs Authority (FDA) had earlier assured the Ministry that due diligence had been conducted and the Authority had followed the provisions of the Public Health Act, 2012 (Act 852) and that they were convinced of the safety of the vaccine. A directive for public education to be first done to dis-abuse the minds of the public was not obeyed. It was for this reason that the processes towards the trial had to be suspended to ensure that the public education is carried out.

4.2 Cooperation with other countries to find a cure to EVD

Mr Hudu Mogtari, the CEO of the FDA informed the Committee that the Clinical trials to be undertaken formed part of world efforts to find a cure for the deadly Ebola Virus Disease (EVD). In view of the urgency, it was resolved that joint reviews of clinical trials applications would be undertaken to reduce the time involved to develop an antidote. Towards this end, a number of countries worldwide were selected to review a number of candidate vaccines developed by some pharmaceutical companies.

Ghana was selected with four other countries namely Nigeria, Mali, Senegal and Cameroon to jointly review two of the candidate vaccines developed by GlaxoSmithKline (GSK) and Crucell BV of Janseen, a subsidiary of Johnson and Johnson.

The vaccines were the GSK's ChAd3 from GlaxoSmithKline (GSK) and Jansen Ad26 ZEBOV plus MVA-BN-Filo Boost from Crucell BV of Janseen, a subsidiary of Johnson and Johnson.

The Committee was informed that the National Medicine Regulatory Agencies of the selected countries met and proposed a joint review of the two candidate vaccines. Just like the others, Ghana then started the review of the vaccines.

4.3 Approval Process for the EVD Vaccine trials

Mr Mogtari, the CEO of FDA informed the Committee that the approval process for clinical trials generally took time normally in view of the relevant documentation that the

company is required to produce. He however indicated that in the case of these two vaccines and the traumatizing effect of the EVD, a fast track and stringent process approach for the review of the applications facilitated by the World Health Organisation (WHO) was adopted by the participating countries.

He intimated that for the FDA to carry this through, the Authority co-opted other experts to assist the Expert Technical Advisory Committee of the FDA made up of twelve experts to execute the review.

The approach adopted included:-

- In-country review of submitted protocols
- WHO joint review process
- Review by the Expert Technical Advisory Committee (TAC)on Clinical Trials
- Special Joint TAC meetings with expect TAC on safety to discuss emerging issues on the proposed trials
- Separate Ebola-specific TAC Clinical Trial meetings
- Pre-Trial site inspections to ascertain capacity and preparedness of sites selected
- Customised on-site GCP training for selected trials sites

The CEO of the FDA informed the Committee that the GSK clinical Trial involved Phase 2 clinical development phase with safety and immunogenicity as its main objective in health humans in EVD free countries. When the vaccine is injected into healthy human, it is expected to produce antibodies against the Ebola virus in the human.

With respect to the Janssen Ebola Vaccine, he said it is a combination of two vaccines namely the prime vaccine and the boost vaccine. The prime vaccine is an Ebola glycoprotein gene inserted into adenovirus serotype 26 vector. This is designed to immunize against single specie of the Ebola virus. It is also expected that when the vaccine is injected into healthy humans, antibodies would be produced against that specie of Ebola virus. The Booster vaccine is effective against multiple strains of the Ebola virus. He said like the GSK vaccine, it is expected that it would produce antibodies against Ebola in humans.

He informed the Committee that unlike the GSK vaccine, the Johnson Ebola Vaccine has been approved for clinical trials in the country. The GSK vaccine is currently under review for approval.

4.3.1 Presentation by the Ghana Health Service Ethics Review Committee (GHS ERC)

The Ethics Review Committee informed the Committee that it had only granted ethical approval for Janssen Ebola Vaccine after it met all the requirements and is still in the process of reviewing other applications before it.

4.4 Presentation by the Ghana Academy of Arts and Sciences (GAAS)

Prof. Akilagpa Sawyerr of the GAAS informed the Committee that prior to appearing before the Committee, the Academy had a number of concerns. These concerns are captured in their press release, a copy of which was submitted to the Committee.

Subsequent to the press release, Prof Sawyerr informed the Committee that the Academy had been appraised on some concerns which they had raised.

He however indicated that there were few outstanding questions to be addressed and they include

- The cloud of uncertainty surrounding the origin of the Ebola Disease,
- The nature of the construct (the wild type Zaire Ebola virus GSK Vaccine formulation) and whether the Ebola virus would not escape or shed itself, and
- The procedures and processes leading to the approval of the trials.
- Lack of information about the processes

4.5 Structure of the Vaccine (Construct)

The Committee observed that one of the concerns of Members of Parliament and Ghanaians as a whole was whether the vaccine to be used for the trials carried Ebola virus.

Mr Mogtari, the CEO of FDA, explained to the Committee that the vaccine does not carry the Ebola Virus. He reiterated his earlier comments that the vaccine is basically made up of the adenovirus of the Chimpanzees but a glycoprotein of the Ebola virus DNA has been inserted into it. The vaccine is therefore a vector carrying vaccine and not a virus based vaccine

Prof Fred Binka, Vice Chancellor of the University of Health and Allied Sciences, Ho explained that a glycoprotein of the Ebola Virus DNA is not a replicating organism. He explained that the glycoprotein was inserted to enable the adenovirus mimic the behaviour of the Ebola Virus in order to challenge humans to produce antibodies.

4.6 Process and Procedure for approval

The Minister for Health, Hon Segbefia informed the Committee that under the law, it is the Food and Drugs Authority that is mandated to review and give clinical approval for all clinical trials. He said when the issue of clinical trials came up, the Ministry referred to its technical Agency which had the mandate to review and advice accordingly.

He told the Committee that he is aware that the Food and Drugs Authority had followed all the relevant procedures and processes consistent with the WHO and the existing law and that it was important that the right processes and procedures were followed to handle issues such as Ebola.

The technical team informed the Committee that Ghana was adhering strictly to International Conference on Harmonisation protocol (ICH) guidelines to ensure that the integrity of the data collected did not become questionable. The Protocol is reviewed locally by the Food and Drugs Authority and at the international level through a joint review by the African Vaccine Regulatory Forum (AVAREF)

4.7 Safety of the vaccine

The CEO of the Authority indicated that both vaccines cannot cause an EVD as the constructs cannot be replicated in humans, as indicated earlier. The replicating gene of the EVD is not part of the glycoprotein of the EVD that is contained in the vector to be used for the trials and therefore they are replication deficient.

He explained that the adenovirus construct is highly characterized from the current vaccinology technology. Before the adenovirus vaccine trial material (the vector vaccine) was released for use, it was subjected to checks to ensure that there were no replication competent adenoviruses or other replicating contaminants in it. None was detected and from current knowledge, it is highly unlikely that vector vaccine would cause a disease.

He stated that in order to assess the safety and immunogenicity in humans, GSK conducted phase 1 trials with different dosages of the wild type Zaire Ebola virus GSK Vaccine formulation (GSK vaccine) in different countries. These include the National Institute of Health-Maryland, USA with 10 volunteers and Oxford University, UK with 80 volunteers and the Center for Vaccine Development, Mali with over 80 volunteers. In all these trials no safety issues relating to the candidate vaccines had so far been recorded.

On the Janssen Ebola Candidate Vaccine, he said that the Phase I (first in Man) clinical trials had also been conducted in two countries namely the United Kingdom and the United States of America. Again, no issues regarding the safety of the drug had been recorded to date.

Side effects and adverse effects observed during the trials of both vaccines included injection site pain, swelling and redness, myalgia, headache and mild fever. These effects are normally associated with vaccination exercises.

4.8 Public Education

The Minister for Health, Hon Segbefia conceded that public education on the proposed clinical trials was inadequate. He explained that the usual practice had been that it was only after an approval was granted that funds are made available for public education. The import was that if approval is not given, there would be no need for public education.

He however acknowledged that with these emerging issues such as Ebola, there is the need to take a second look at some of the procedures. He agreed that due to lack of education, the general public became worried. He informed the Committee that the Ministry had learnt a lesson from this Ebola issue and was looking into its existing procedures. He informed the Committee that he had directed the Ministry to kick start public education on the clinical trials whilst other processes go on.

Prof Binka also informed the Committee that in line with the Ministry's directive, some sensitisation is currently on-going especially in areas where the exercise would be carried. The team had met with various groups in parts of Hohoe and Kintampo. There was also on-going education through the media using newspaper articles and flyers educate people on the trials especially on its safety.

4.8 Capacity of the FDA to supervise the trial

The Committee was informed that the FDA, which is responsible for approving all clinical trials in the country, is equipped to employ well competent and trained staff in its clinical trials. Other professional training from well acclaimed international bodies and institutions had also been designed to train FDA employees on continuous basis to ensure that they are abreast with international standards.

The CEO intimated to the Committee that some of Authority staff serve on International Committees engaged in the activities of advanced clinical research and development.

He said that since November 2004, the FDA has received 54 clinical trial applications and had approved 43 of them. The eleven trials not approved were due to insufficient evidence of safety and efficacy.

The Committee was informed that the FDA currently is designated as a Regional Centre for Regulatory Excellence with oversight responsibility for clinical trials as well as Medicines Evaluation and Registration in the sub-region.

4.9 Proposal to pay GH¢200 and a mobile phone to volunteers

The ERC informed the Committee that the issue of honorarium for volunteers was also before them and that no decision had been agreed upon and that any information relating to payment of GH¢200 and a mobile phone was false. Volunteers were not to be induced but rather compensated for taking part in the study for the loss of time and transport each time they come to the clinic.

The Committee was informed that the guide to be used in determining the amount to be paid to volunteers was to ensure that the amount was not too small to exploit the volunteers and not too big to coerce the volunteers. When a decision is reached, it would be appropriately communicated. The Committee was assured that insurance for volunteers has been provided.

4.10 Selection of Volunteers

Prof. Fred Binka, the Vice Chancellor of the University of Health and Allied Sciences informed the Committee that potential volunteers would be required to fill application forms out of which a strict selection process would be employed to select the would be volunteers.

He explained that it was an academic exercise and therefore there was the need to ensure that people don't use money as the motivating factor to engage in the exercise.

4.11 Why Ghana was selected

The Committee was informed that Ghana and the other four countries namely Nigeria, Senegal, Cameroon and Mali selected for the trial, share a common border with the affected countries of the Ebola disease in the West Africa sub-region. The rational was that should the vaccine prove efficacious, it would be deployed immediately to help stop any possible spread of the disease.

The technical team from the Ministry of Health reiterated that Ghana has so far not recorded any case of Ebola. Ghana is however located close to countries who have recorded cases of the Ebola Virus Diseases.

Another reason canvased was that residents in countries with recorded cases of the Ebola Virus Disease may have developed some form of antibodies that would affect the outcome of the trial. The standard practice is to undertake the trial in a country with no track record of the disease.

The technical team indicated that the reasons behind the selection of the Oncho Research Centre in Hohoe and the Kintampo Health Research Centre for the trial were that the two were centres with well-equipped clinical trial facilities of international standards and well-recognised qualified biomedical scientists and clinical vaccine studies.

4.13 Benefits of the clinical trials to Ghana

The Committee was assured that the current processes underway to develop an Ebola vaccine are similar to other processes performed to develop vaccines globally. Through these trials, Ghana stands at an advantage to develop its own capacity to undertake similar trials on the efficacy of locally manufactured products especially herbal drugs.

Further, without the test, there would be only experimental drugs available to combat EVD whose efficacy cannot be guaranteed.

The technical team informed the Committee that the location of the country to Ebola prone locations make it susceptible to an EVD. In the event of any outbreak, the impact could be disastrous. There is therefore the need for the country to hold itself in readiness especially if it can help find a cure in any eventuality.

5.0 CONCLUSION

After interaction with key stakeholders, the Committee was persuaded that there had been no Ebola clinical trials going on in the country. However, the FDA has approved a vaccine, namely the Johnson Ebola vaccine for clinical trials as part of an international effort to find a cure to the deadly Ebola Virus Disease. A second vaccine, the GSK vaccine is currently been considered for approval.

The Committee was convinced that the vaccine approved for clinical trial is safe and that most of the concerns about the vaccine can only be answered after the clinical trials have been undertaken. Indeed it is because of these concerns that this scientific exercise is being undertaken with the view of coming out with a cure for the dreaded EVD. The trials are to be conducted with strictest adherence to national regulations and international standards. There is also a constant review mechanism both at the national and international levels.

The Committee, cognisant of the fact that approval has been given in order for the trial to be carried out, recommends to the House to urge the Minister for Health to intensify education on the clinical trials. The Committee also resolved to undertake follow ups on all the processes involved with these scientific exercises.

The Committee thus urge the House to adopt this report on the Ebola vaccination trials in the country.

Respectfully submitted

HON. JOSEPH YIELEH CHIREH
CHAIRMAN

ASANTE AMOAKO-ATTA
CLERK TO THE COMMITTEE

Wednesday, 08 July 2015