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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

FIFTEENTH LOK SABHA

'PRODUCTION AND AVAILABILITY OF MEDICINES TO DEAL WITH SWINE FLU'

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

[Action Taken by the Government on Observations/ Recommendation contained in the Fifth Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2009-10) on 'Production and Availability of Medicines to deal with Swine Flu']

FOURTEENTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

August, 2011/ Sharvana 1933, (Saka)

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Presented to Lok Sabha on ***04 .08.2011***

Laid in Rajya Sabha on ***04 .08.2011***

LOK SABHA SECRETARIAT
NEW DELHI

August, 2011/ Sharvana 1933, (Saka)

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2.	Shri Ashok Sarin	-	Joint Secretary
3.	Shri C.S.Joon	-	Director
4.	Shri A.K. Srivastava	-	Additional Director

& NOMINATED W.E.F. 21.09.2010
# NOMINATED W.E.F. 04.10.2010

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2010-11) having been authorised by the Committee to present the Report on their behalf present this Fourteenth Report on Action Taken by the Government on recommendations contained in the Fifth Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2010-11) on 'Production and Availability of Medicines to deal with Swine Flu' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Fifth Report of the Committee was presented to Lok Sabha on 15 December, 2009. Action Taken Replies of the Government to all observations/ recommendations contained in the Report were received on 15 December 2009 and updated replies on 16 September, 2010. The Standing Committee on Chemicals and Fertilizers (2010-11) considered the updated Action Taken Replies received from the Government and adopted the Draft Action Taken Report thereon at their sitting held on 18 July 2011.

3. An analysis of the Action Taken by the Government on the recommendations contained in the Fourteenth Report (Fifteenth Lok Sabha) of the Committee is given in Appendix-II.

4. For facility of reference and convenience, the Comments of the Committee have been printed in bold letters in the body of the Report.

New Delhi;
28 July, 2011
6 Shravana, 1933 (Saka)

Gopinath Munde
Chairman,
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER - I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Fifth Report (Fifteenth Lok Sabha) of the Committee on 'Production and Availability of Medicines to deal with Swine Flu' of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 15 December, 2009. The Report contained 15 Observations/ Recommendations.

2. The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations/Recommendations contained in the Fifth Report within three months from the date of presentation of the Report, i.e., by 14 March 2010. The Action Taken Replies of the Government in respect of all the 15 Observations/Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals vide their O.M. No.5/57/2009-PI-I/III dated 29 March, 2010. However, in view of the recent onset of Swine Flu cases in the country, the Department were again requested to furnish updated Action Taken Replies as well as furnish the latest measures taken by them to control the Swine Flu through LSS Office Memoranda dated 16.08.2010, 27.08.2010 and 08.09.2010. They have furnished their updated Action Taken Replies on 16.09.2010 through their OM - F.No.35022/48/2010-PI-III. These have been categorized as follows :-

(i) Observations/Recommendations which have been accepted by the Government :-
Sl.Nos. 45, 47, 48, 49, 54, 56, 57 and 58 (Total = 8)
Chapter-II

(ii) Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply :-
Sl.No. 55 (Total = 1)
Chapter-III

(iii) Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration :-
Sl.Nos.44, 46 and 53 (Total = 3)
Chapter-IV

(iv) Observations/Recommendations in respect of which replies of the Government are of interim nature :-
Sl.Nos. 50, 51 and 52 (Total = 3)
Chapter-V

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I of this Report and the final replies in respect of the Observations / Recommendations for which only interim replies have been furnished by the Ministry should be furnished expeditiously.

4. The Committee will now deal with the action taken by the Government on some of their Observations/Recommendations which still require reiteration or merit comments.

A. ROLE OF DEPARTMENT OF PHARMACEUTICALS AND NATIONAL PAHARMACEUTICALS PRICING AUTHORITY FOR ENSURING EASY AVAILABILITY AND AFFORDABILITY OF THE MEDICINES FOR EFFECTIVE TREATMENT OF SWINE FLU

Recommendation (Sl.No.1, Para No.44)

5. The Committee in para 44 of their original Report had observed that the Department of Pharmaceuticals had been engaged in the production and availability of drugs for the treatment of Swine Flu. With the cooperation of the Ministry of Health and Family Welfare, they had been regularly monitoring the availability position of Shikimic Acid and Oseltamivir API which was used for the production of drug i.e. Oseltamivir or TamiFlu and Oseltamivir Capsules. The Ministry of Health and Family Welfare had also procured stocks of drugs at the instance of the Department of Pharmaceuticals. Six pharma companies had volunteered to maintain adequate quantity of drugs to deal with Swine Flu. The Ministry of Health and Family Welfare had also permitted the retail sale of Oseltamivir capsules, w.e.f., 19 September 2009. However, regarding the price control of the drug meant for the treatment of Swine Flu, the Committee had observed that the Pharmaceutical Companies had been given liberty to sell the medicine at a price decided by them though within a "reasonable limit". The Committee had felt that reasonable limit is too broad and vague a term which could be conveniently manipulated by the Pharmaceutical Companies for their own gain and at the cost of the common man. Further, chances of medicines for the treatment of Swine Flu becoming costlier could not be ruled out in view of the high volatility of the prices of raw material, especially when these were to be imported from China. Thus, in such a scenario, leaving the pharma industry to fix the price of the medicines on their own, albeit within a reasonable limit, did not seem to be an appropriate decision. While appreciating the initiatives taken by the Department in persuading the Ministry of Finance for exemption of Customs Duty on Oseltamivir and Shikimic Acid and Excise Duty on indigenously produced Oseltamivir API and capsules, the Committee had recommended that the Government should have

initiated immediate appropriate measures to ensure easy availability as well as affordability of the medicines for effective treatment of Swine Flu, particularly in view of increase in cases with the onset of winter.

6. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "Oseltamivir is a non-scheduled medicine and not covered under DPCO, 1995. In respect of drugs – not covered under the Drugs (Prices Control) Order, 1995, i.e., the non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government/NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities/packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of import, etc., As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of ORG IMS and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest . This is an ongoing process."

7. The Committee in their earlier Report had recommended that the Government should have initiated immediate appropriate measures to ensure easy availability as well as affordability of the medicines for effective treatment of Swine Flu. However, the Reply of the Government is silent about taking any initiative to ensure easy availability of the medicines, and, talks about the affordability factor only.

The Committee are unhappy to note that the Department has ignored the foremost part of their recommendation. They, therefore, advise the Department to stop furnishing incomplete and inconclusive replies which not only raise fingers on the functioning of the Department but also waste the precious time of the Committee in reiterating their earlier recommendation for the actual action to be taken by the Department on the ignored or missed out portion.

The Committee, therefore, reiterate that the Government should initiate immediate appropriate measures to ensure easy availability of the medicines for Swine Flu and expect the complete reply in this regard.

B. NEED TO SET UP SUFFICIENT NUMBER OF LABORATORIES IN SWINE FLU VULNERABLE STATES/ UTs

Recommendation (Sl.No.3, Para No.46)

8. The Committee in para 46 of their original Report had observed that they were highly concerned to note that although Maharashtra had reported maximum number of Swine Flu cases, it had only three Laboratories to detect such cases. In this regard, the Committee had found that Delhi which ranks number two in reported Swine Flu cases and Tamil Nadu which had reported fewer cases of Swine Flu had seven Laboratories each whereas other States had either one or two Laboratories. The Committee had felt that several cases of Swine Flu in various States might have remained undetected for want of adequate Laboratories/detection centres. They, therefore, had impressed upon the Ministry of Chemicals and Fertilisers to take up the matter at the appropriate level urgently so that sufficient number of Laboratories are set up especially in Swine Flu vulnerable States/UTs, for early detection and timely treatment of such pandemic disease. As some States had only one or two Laboratories, the Committee had recommended that Private Laboratories might be appropriately encouraged to supplement the efforts of the Government for detection of Swine Flu cases.

9. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

"Availability of testing laboratories comes under the purview of Ministry of Health and Family Welfare. They have informed that testing for pandemic inFluenza can only be done in Bio Safety Level (BSL) – 3 laboratory or a Bio Safety – 2 Laboratory with BSL-3 precautions. From the two testing laboratories (NCDC, Delhi and National Institute of Virology, Pune) available prior to July, 2009 the number of laboratories were expanded to 18. Subsequently, it was further expanded to 44. Among these 18 are in private sector."

10. The main crux of the original Recommendation of the Committee was that the Ministry of Chemicals and Fertilizers should take up the matter at the appropriate level urgently to ensure that sufficient number of labs are set up, especially, in Swine Flu vulnerable States/ Union Territories for early detection and timely treatment of Swine Flu. The Committee had also pointed out that Maharashtra was having maximum number of cases and having only three labs as compared to Delhi and Tamil Nadu which are at No. 2 and 3 places, respectively, having 7 labs in each State. However, the reply of the Government only mention about the existing number of labs as compared to number of labs available prior to July 2009 and does not mention about any efforts/ progress

made by the Ministry concerned, especially, after the Recommendation of the Committee was made to remove the disparity or imbalance in the number of reported cases of Swine Flu vis-à-vis number of labs available in a particular State/ UT.

The Committee, therefore, reiterate that the Ministry concerned should do the needful to remove the prevailing disparity or imbalance in the reported number of cases vis-à-vis number of available labs for detection of Swine Flu in each State/ UT at the earliest and apprise the Committee about the progress in this regard.

C. NEED TO ENSURE PROACTIVE MEDICATION OF THE CLOSE CONTACTS OF THE SWINE FLU AFFECTED INDIVIDUALS TO COUNTER THE SPREAD OF SWINE FLU

Recommendation (Sl.No.5, Para No.48)

11. The Committee in para 48 of their original Report had noted that Oseltamivir has also been given to family members who came into contact with patients affected by swine flu to break the transmission cycle and to provide protection to the individual. To effectively combat the menace of Swine Flu in the country, more so during the recent spurt of the disease in the national capital, the Committee had urged upon all the concerned agencies to ensure that the system of giving Oseltamivir to the close contacts of the Swine Flu affected individuals is encouraged proactively so that the transmission cycle of the H1N1 virus could be countered.

12. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "Ministry of Health & Family Welfare has informed that in order to stop the spread of H1N1 virus, Chemoprophylaxis was the strategic intervention followed by all States/ UT Administrations to delay community spread."

13. The Committee in the original Report had urged upon all the concerned agencies to ensure that the system of giving Oseltamivir to the close contacts of the Swine Flu affected individuals were encouraged proactively so that the transmission cycle of the H1N1 virus was countered.

The Committee find from the reply of the Government that the chemoprophylaxis was the strategic intervention followed by all the States/ UT Administrations to delay community spread. In order to know the success/ failure rate of this chemoprophylaxis intervention, the Committee would like to be apprised of the feedback which the concerned Ministries have been

gathering from all the States/ UTs Administration to determine the effectiveness of the same from the records that whether any close contacts/ family members coming in contact with the patient also got affected with the disease State/ UT - wise or there are no known cases of that kind of proliferation.

D. NEED TO PRODUCE OSELTAMIVIR FROM AN ALTERNATE/ NON-SHIKIMIC ROUTE TO AVOID DEPENDENCY ON CHINA FOR ITS RAW MATERIAL

Recommendation (Sl.No.6, Para No.49)

14. The Committee in para 49 of their original Report had noted that the medicine for the treatment of Swine Flu was being made from Shikimic Acid which was extracted from the seeds of Star Anise (illicium vernum) an evergreen Chinese plant. Besides Star Anise, Shikimic Acid was also produced from the leaves of Ginkgo Biloba tree. For Shikimic Acid India is dependent on China because plants from which Shikimic Acid was extracted, grow in China. Moreover, availability of Shikimic Acid depended upon the seasonal output of Star Anise crop. What had concerned the Committee was the fact that both the raw materials, i.e., Star Anise and leaves of Ginkgo Biloba tree were in short supplies, as had been admitted by the Department. However, they had drawn consolation from the Department's statement that some alternate and sustainable sources were being explored to produce medicines for the treatment of Swine Flu. As a result, ICMR had been conducting research to produce this drug in the country through non-Shikimic route. NIPER, Mohali had also submitted a Research proposal for producing Oseltamivir from an alternate route. The Committee had recommended that the Government should extend all possible help to these Research Organisations in their endeavour besides encouraging other similar premium institutions to follow suit so that any crisis in future regarding the availability of medicines for the treatment of Swine Flu could be averted.

15. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "ICMR has initiated steps to produce Shikimic Acid in India by exploring all options involving appropriate / competent groups which can do required R&D and develop production technology for manufacture of the compound. The Council invited proposals in the identified areas and has sanctioned 4 Projects.
>
> NIPER has reported that efforts are being made to look for alternative source of this Phyto-Chemical to meet this demand. In this direction two plant sources were explored as potential source of Shikimic Acid. The experimental design was planned around following two approaches :

1. Available plant source: The plants available in the nearby area were analyzed for the availability of Shikimic acid naturally. More than 50 plants were

screened by LC-MS for this purpose. The plant which was judged as the most economic source was selected on the basis of abundance in the region, availability of biomass throughout the year, easy harvesting and total Shikimic Acid contents. The selected plant was subjected for isolation of Shikimic Acid on lab scale that will be extended to pilot scale in coming days. The methods will be fine tuned to enhance the efficiency and economy for isolation of Shikimic Acid.

2. Intervention : The Shikimic Acid can be obtained from plant sources after intervention of Shikmic Acid pathway using a broad spectrum herbicide. A number of weedy plant species were screened and treated with the herbicide and Shikimic Acid content were analyzed by LC-MS. It was observed that the application of herbicide has enhanced Shikimic Acid contents.

The accumulation of Shikimic Acid varies depending upon the concentration of herbicide applied, days after application, stage of plant (vegetative or reproductive) and weather conditions (temperature, humidity of soil and air, etc). The method is being fine tuned on these lines so the plant material can be harvested year round."

16. In addition to the above reply, the Department have also stated through their updated reply, dated 16.09.2010 as under:

"The representative of ICMR has informed in the Task Force Meeting that four research projects have been initiated by them to evaluate the potential of indigenous manufacture of Shikimic acid in India.

1. Microbial fermentation method utilizing *Citrobacter* to produce Shikimic acid (Dept. of Microbiology, UDSC, New Delhi).
2. Isolation of Shikimic acid from Indian plants (*Araucaria excelsa* and *Calophyllum apetalum)* isolated from western ghats (NIPER, Chandigarh).
3. Hairy root culture of Indian plants to produce Shikimic acid through plant tissue culture in bioreactor (IIT, Delhi).
4. Isolation of Shikimic acid from other plants and biotransformation of Quinate to shikimate using enzymatic biotransformation (NCL, Pune).

ICMR is till exploring to fund research project to clone and express Shikimic acid pathways so that it can be produced in recombinant *E. coli system*.

The Progress on the above projects made so far as reported by ICMR is as under :

1. Microbial source has been explored at Dept. of Microbiology, Delhi University to produce Shikimic Acid. Citrobacter species have been identified and grown to produce Shikimic Acid through fermentation.

   A strain of Citrobacter sp. Which has been selected after an exhaustive screening produces 0.6 g/L of shikimic acid. The Production was estimated by TLC and HPLC procedures. Subsequently, for enhancing the production of shikimic acid one variable at a time approach was attempted, wherein, 1.8h/l of shikimic acid was achieved when the medium contained ammonium sulphate as a nitrogen source. Subsequently, when ammonium sulphate was replaced by aspraragine,

production enhanced to 4.3 g/L of shikimic acid. This study was attempted upto 2L flask. Furthermore, the produced shikimic acid was purified by crystallization process and the purity of crystals was confirmed by NMR. Scale up study was attempted on 10, 14,30 L bioreactors which resulted in 3.5 g/L of shikimic acid. Results are encouraging and further optimization will lead to successful shikimic acid production.

2. Optimization of extraction procedures are on at NIPER to extract Shikimic acid from Araucaria *excelsa* plant leaves.

3. Plant cell culture system has been established at IIT Delhi using Indigenous plant from western Ghats to produce Shikimic acid through in vitro tissue culture.

4. NCL Pune has started very actively in two areas : isolation of different plant sources to produce shikimic acid and isolation of microorganism to biotransformation quinate to Shichimic acid

They are analyzing concentration of shikimic acid in leaves and seeds of plant varieties common in India. Around 80 types of seeds and 20 types of leaves have been analyzed so far.

The Angiosperm seeds analyzed so far contain only traces of shikimic acid.
Dry leaves of Gymnosperms are found to contain 0.2 to 1.5% shikimic acid but some of the plants are grouped in “rare and endangered” species.
Dry pods of “Chakriful or Badalful or Bardana” (*Illicium* sp.) used in spices, available locally, have been found to contain around 5% shikimic acid.

They have also screened 55 microbial belonging to bacteria, yeast and fungi for biotransformation of quinic acid to shikimic acid but the results so far are negative.
The work on screening plant and microbial varieties is continuing.

Further, National Institute of Pharmaceutical Education and Research under Department of Pharmaceuticals has informed that they are working on the following two projects :

1. <u>Proposal to ascertain the commercial potential of the method for domestic production of “Shikimik Acid”.</u>

Under this project, an alternative domestic source for the shikimic acid is explored from the plants. The experiments are conducted on two fronts :

a. Available plant sources which accumulate the shikimic acid naturally in the aerial parts.
b. Intervention experiments for accumulation of shikimic acid by the use of broad spectrum herbicide.

2. <u>Production and Availability of Medicines to deal with Swine Flu</u>

In view of the Swine Flu outbreak in the country in 2009, NIPER has initiated a small research project titled “ Targetting Hemaglutinin of H1N1 Virus: Rational Design and Syntheses of Anti-influenza Molecules”.

17. The Committee in their original Report had observed that both the raw materials, namely, seeds of star Anise plant and leaves of Ginkgo Biloba tree from which Shikimic Acid was extracted for producing Oseltamivir medicine for the treatment of Swine Flu were in short supply from China, and, that some alternate and sustainable sources were being explored to produce medicines for the treatment of Swine Flu. As a result, Indian Council for Medical Research (ICMR) has been conducting research to produce this drug in the country through non-Shikimic route. National Institute of Pharmaceuticals Education and Research (NIPER), Mohali had also submitted a Research proposal for producing Oseltamivir from an alternate route. The Committee had recommended that the Government should extend all possible help to these Research Organisations in their endeavour besides encouraging other similar premium institutions to follow suit so that any crisis in future regarding the availability of medicines for the treatment of Swine Flu could be averted.

The Department in their reply have stated that ICMR has initiated steps to produce Shikimic Acid in India and has invited proposals in the identified areas and has sanctioned four projects while NIPER has explored two plant sources as potential source of Shikimic Acid and fine tuning the method to harvest the plant material year round.

The Committee appreciate the initiative and efforts being made by ICMR/ NIPER to look for alternate source(s) of this Phyto-chemical known as Shikimic Acid to meet its demand to produce medicine for the treatment of Swine Flu as desired by the Committee. However, it is not clear from the reply of the Government whether the Department has encouraged other premium institutions in Government and private sectors alike as recommended by the Committee or all the efforts are restricted to ICMR/ NIPER in this direction. The Committee would like to be apprised of the details such as funds allocated, tenure, Organizations/ Institutions involved, and the positive outcome of the 4 projects sanctioned by the Council as well as similar details about the efforts being done by NIPER in getting success in selected two plants for isolation of Shikimic Acid and fine tuning the methods to enhance the efficiency and feasibility for isolation of the same, through the further action taken reply of the Government in this regard.

E. NEED TO MAKE INDIA SELF-RELIANT FOR PRODUCING MEDICINE FOR SWINE FLU

Recommendation (Sl.No.7, Para No.50)

18. The Committee in para 50 of their original Report had observed that It was a matter of serious concern that the Department of Pharmaceuticals had not kept track of the means adopted by other countries like USA and Mexico to cope with the availability of Shikimic Acid or measures taken by them to find alternate route for production of Oseltamivir. As it had been established that the H1N1 virus had penetrated India from foreign land, it would have been prudent on the part of the Department to maintain appropriate international data with regard to their efforts towards availability/production of Oseltamiviror or alternatives thereto. However, even then, it was not too late. The Committee had impressed upon the Department to urgently initiate a study to gauge the dependency of other countries upon China for Shikimic Acid and the alternate route, if any, adopted by them to produce Oseltamivir. The Committee were confident that a comparative assessment would immensely help the Research Organisations like ICMR and NIPER in their endeavours towards making India self-sufficient in producing Oseltamivir medicine to counter Swine Flu.

19. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "The Department has written to three Research Agencies and has requested them to indicate their willingness or otherwise for conducting this study, the time required for completing this study and the fees chargeable for this. After getting the response from these Agencies, the suitable Agency for conducting the study will be selected.
>
> In the meantime, the Deputy Industrial Advisor in the Department has also been requested to conduct this study. He has submitted the report. He has reported that commercial production of Oseltamivir starts from the biomolecule Shikimic Acid harvested from Chinese star anise with a limited worldwide supply. Due to its limited supply searches for alternative synthetic routes preferably skipping Shikimic Acid are underway and to date several such routes have been published. In the total synthesis of Oseltamivir, control of Stereochemistry is important; the molecule has three stereo centers and the sought after isomer is only 1 of 8 stereoisomers.
>
> The current production method is based on research by Gilead Sciences starting from naturally occurring quinic acid and that of Hoffmann-La Roche starting from Shikimic Acid. The current production method include two reaction steps with potentially hazardous azides. A reported azide – free Roche synthesis of Tami Flu is given by Karpt/ Trussardi synthesis. Other reported routes published are:
>
> i) Corey synthesis
> ii) Shibasaki synthesis

iii) Fukuyama synthesis

Commercial production from alternative routes have not been reported in literature".

20. In addition to the above reply, the Department have also stated through their updated reply dated 16.09.2010 as under:-

"In order to get a study conducted to gauge the dependency of other countries upon China for Shikimic Acid and the alternate route, if any, adopted by them to produce Oseltamivir, based on information received from FICCI Department of Pharmaceuticals has written to three Research Agencies and has requested them to indicate their willingness or otherwise alongwith other terms and conditions for conducting this study. Reply from all the three agencies have not been received. The matter is being pursued with them. The Department has also written to two more research agencies and letters to WHO and Ministry of Health & Family Welfare have also been sent. "

21. The Committee in their original Recommendation had impressed upon the Department to urgently initiate a study to gauge the dependency of other countries upon China for Shikimic Acid and the alternate route, if any, adopted by them to produce Oseltamivir and had opined that a comparative assessment would immensely help the Research Organisations like ICMR and NIPER in their endeavours towards making India self-sufficient in producing Oseltamivir medicine to counter Swine Flu. The Department in their reply have stated that they have written to three Research Agencies and has requested them to indicate their willingness or otherwise along with other terms and conditions for conducting this study, the time required for completing this study and the fees chargeable for this. After getting the response from these Agencies, the suitable Agency for conducting the study would be selected. As per the updated information, the reply from all the three agencies have not been received and the matter is being pursued with them. The Department has also written to two more research agencies and letters to WHO and Ministry of Health & Family Welfare have also been sent.

As this matter is lingering on for quite a long period sans any positive results so far, the Committee desire that the whole process of selection of suitable agency for conducting the study as per the earlier recommendation of the Committee and completion of the study should be completed in stipulated time frame of six months and the Committee be apprised of the outcome in this regard.

F. NEED TO ESTABLISH BETTER COORDINATION AND COOPERATION AMONG MINISTRIES/ DEPARTMENTS DEALING WITH SWINE FLU

Recommendation (Sl.No.8, Para No.51)

22. The Committee in para 51 of their original Report had expressed their displeasure over the fact that details were reportedly not available with the Directorate General of Commercial Intelligence (DGCIS), Kolkata regarding the quality and value of medicines and Shikimic Acid imported on the plea that there was no specific code for Swine Flu in the classification system. They had also expressed their unhappiness since similar information which was also sought from the Department of Revenue by the Department of Pharmaceuticals had not been furnished. The Committee had pointed out that when so many Ministries/Departments had been entrusted with the responsibility to check the spread of Swine Flu, there must be a proper coordination and cooperation amongst themselves to perform the respective assigned task effectively. But, in the instant case, despite the efforts of the Department of Pharmaceuticals to get relevant information, the other concerned Ministries/Departments did not oblige. The Committee had taken a strong exception to the callouness on the part of the Department of Revenue on such an important issue and had recommended that henceforth any information sought by one Department from the other should invariably be furnished in a time bound manner in order to facilitate further follow up action for dealing with Swine Flu. The Committee had directed the Department of Revenue to institute an internal enquiry to fix the responsibility for this negligence and take punitive action against the erring officials. The Committee had advocated the need for a close coordination and cooperation at sufficiently high level amongst all the concerned Ministries/Departments and had desired the Department of Pharmaceuticals to play a proactive role in the process.

23. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "The observations of the Committee have been conveyed to Department of Revenue and Directorate General of Commercial Intelligence and Statistics, Kolkata. The recommendation of the Committee regarding proper coordination and cooperation amongst the Departments has been noted for compliance."

24. The Committee in their original recommendation had expressed their displeasure over the fact that details were reportedly not available with the Directorate General of Commercial Intelligence (DGCIS), Kolkata regarding the quality and value of medicines and Shikimic Acid imported on the plea that

there was no specific code for Swine Flu in the classification system. They had also expressed their unhappiness since similar information which was also sought from the Department of Revenue by the Department of Pharmaceuticals had not been furnished. The Committee had taken a strong exception to the callouness on the part of the Department of Revenue on such an important issue and had recommended that henceforth any information sought by one Department from the other should invariably be furnished in a time bound manner in order to facilitate further follow up action for dealing with Swine Flu. The Committee had directed the Department of Revenue to institute an internal enquiry to fix the responsibility for this negligence and take punitive action against the erring officials. The Committee had advocated the need for a close coordination and cooperation at sufficiently high level amongst all the concerned Ministries/Departments and desired the Department of Pharmaceuticals to play a proactive role in the process. The Department in their reply have stated that the observations of the Committee had been conveyed to Department of Revenue and Directorate General of Commercial Intelligence and Statistics, Kolkata. The recommendation of the Committee regarding proper coordination and cooperation amongst the Departments has been noted for compliance.

The Committee are pained to point out that mere conveying the relevant recommendation to the Department of Revenue and Directorate General of Commercial Intelligence (DGCIS), does not serve much purpose unless the responses/ replies of the concerned Department/ Directorate are obtained by the conveying Department and reported back to the Committee as feedback towards the befitting action the each one has taken and the outcome thereon. Moreover, the term "noted for compliance" is too vague and general phrase. The Committee are interested to know the actual progress/ outcome of their recommendation. The Committee hope that the Department would furnish their reply indicating the specific action taken on the recommendations of the Committee.

G. NEED TO TAKE EFFECTIVE STEPS TO WARD OFF HOARDING OF SHIKIMIC ACID

Recommendation (Sl.No.9, Para No.52)

25. The Committee in para 52 of their original Report had observed that they were perturbed to note the self contradictory reply given by the Department of Pharmaceuticals in respect of the hoarding of Shikimic Acid by the traders. At one place it had been stated that the possibility of hoarding of Shikimic Acid could not be ruled out in view of it being under the Open General Licence (OGL) policy whereas, elsewhere it had been mentioned that the Open Licence Policy would prevent any monopolistic facilities such as hoarding. The two statements were needed to be reconciled. The Committee had desired that if according to the Department of Pharmaceuticals, there was any loophole in the existing OGL policy which might be taken advantage of by the traders to hoard Shikimic Acid, they should have taken up the matter with the Department of Commerce to revise the Licence Policy so as to make it transparent and foolproof in order to ward off any possibility of hoarding of Shikimic Acid.

26. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "DGFT has informed that domestic availability of Shikimic acid and Oseltamivir, was closely monitored through exports and imports of the above products. Even during the high phase of Swine Flu, no need of policy change on importability of these two products was felt except the need for close monitoring of imports and exports. Further, no instance of hoarding of these products was reported."

27. The Committee in their original recommendation had desired that if according to the Department of Pharmaceuticals, there was any loophole in the existing OGL policy which might be taken advantage of by the traders to hoard Shikimic Acid, they should have taken up the matter with the Department of Commerce to revise the Licence Policy so as to make it transparent and foolproof in order to ward off any possibility of hoarding of Shikimic Acid.

The Department in their reply have stated that Directorate General of Foreign Trade (DGFT) has informed that domestic availability of Shikimic acid and Oseltamivir, was closely monitored through exports and imports of the above products. Even during the high phase of Swine Flu, no need of policy change on importability of these two products was felt except the need for close monitoring of imports and exports. Further, no instance of hoarding of these products was reported.

The Committee also note from the reply that during high phase of Swine Flu, DGFT felt the need for close monitoring of imports and exports of Shikimic Acid and Oseltamivir in order to monitor domestic availability of these products. The Committee are also aware that Shikimic Acid is extracted from the seeds of Star Anise and also from the leaves of Ginkgo Biloba tree and both of these raw material are in short supplies as admitted by the Department. However, the Department is exploring the alternate non-shikimic Acid route to produce Oseltamivir domestically, sans any breakthrough, yet, in this direction.

The Committee are of the opinion that monitoring of domestic availability of Shikimic Acid and Oseltamivir through close monitoring of its imports and exports is an ongoing process and needs to be done regularly and, as and when the domestic availability of these two products are found to be affected, DGFT may restrict the exports of these two products till normalcy in domestic availability is restored/ regained or a real breakthrough in finding an alternate non-shikimic Acid route is achieved in India.

H. CENTRAL PUBLIC SECTOR UNDERTAKINGS IN PHARMA SECTOR SHOULD START PRODUCING SWINE FLU MEDICINE

Recommendation (Sl.No.10, Para No.53)

28. The Committee in para 53 of their original Report had noted that at present the Government do not have any plan to get into the production of Oseltamivir API through Central Public Sector Enterprises (CPSE) for the reason that they had not found it economically viable for the PSUs at this stage to enter into production of the drug. In this context, the Committee had found that six private Pharmaceutical Companies were engaged in the supply of Oseltamivir 75 mg capsules in the country. Four of these companies, viz. Hetero Drugs, Cipla, Ranbaxy and Strides Areolab have facilities for indigenous production of Oseltamivir from its raw material i.e. Shikimic Acid. Out of the remaining two Companies, Roche has no local production in India and is supplying Oseltamivir capsules by importing the same from their corporate set up. The other Company, viz. NATCO has only formulation capability of the capsules based on Oseltamivir API. The Committee had acknowledged the efforts made by the Private Sector in producing/supplying medicines for the treatment of Swine Flu. They were, however, disappointed to find that there was no move on the part of the Government to produce the Oseltamivir medicine through their PSUs on the plea of its being not economically viable. The Committee were not convinced by the Government's logic since production of one specific thing which has been commercially/economically viable for one Sector could not be otherwise for another

Sector, more so when the Private Sector does not opt for anything that is economically unviable. In Committee's view, cost alone could not be always the prime factor particularly when dealing with a pandemic situation like Swine Flu which had taken so many precious lives. Moreover, the Committee had dreaded a situation where the Private Sector, for some unforeseen circumstances, was not able to produce Oseltamivir at all or curtail its production and the Government had no contingency plan in place to deal with the situation. Prudence, therefore, had required the Government to gear up their preparedness to ensure availability of Oseltamivir medicine in any eventuality, notwithstanding the commercially viability factor. As it is life saving drug, the Department of Pharmaceuticals should have entrusted to one of its PSUs the job of production of Oseltamivir despite the same being unviable. Such company should be compensated suitably, if necessary, through budgetary grant.

29. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "PSU Division of the Department of Pharmaceuticals has informed that Oseltamivir is a patented drug. The pharma CPSUs do not have API manufacturing facilities to produce Oseltamivir. As such, it is not being manufactured by Pharma CPSUs. The CPSUs also do not have the generic composition to launch their own brand."

30. The Committee in their original recommendation had observed the efforts made by the Private Sector in producing/supplying medicines for the treatment of Swine Flu. They were, however, disappointed to find that there was no move on the part of the Government to produce the Oseltamivir medicine through their PSUs on the plea of it being not economically viable. The Committee were not convinced by the Government's logic since production of one specific thing which has been commercially/economically viable for one Sector could not be otherwise for another Sector, more so when the Private Sector did not opt for anything that was economically unviable.

The Committee had desired as Oseltamivir is life saving drug, the Department of Pharmaceuticals should entrust to one of its PSUs the job of production of Oseltamivir despite the same being unviable. Such company should be compensated suitably, if necessary, through budgetary grant.

The Department in their reply have stated that PSU Division of the Department of Pharmaceuticals has informed that Oseltamivir is a patented drug. The pharma CPSUs do not have API manufacturing facilities to produce Oseltamivir. As such, it is not being manufactured by Pharma CPSUs. The CPSUs also do not have the generic composition to launch their own brand.

The Committee are not convinced again with the reply of the Government that Oseltamivir is a patented drug. The pharma Central Public Sector Undertakings (CPSUs) do not have Active Pharmaceutical Ingredients (API) manufacturing facilities to produce Oseltamivir. They do not have the generic composition to launch their own brand and as such, it is not being manufactured by pharma CPSUs. The Committee would like to be apprised of the facts/ reasons when six private sector companies who volunteered for production and availability of Oseltamivir API and capsules could develop, acquire and create API manufacturing facilities/ generic composition to produce and launch Oseltamivir why CPSUs failed to respond positively and actively to fight the pandemic InFluenza and save their own countrymen by following the footsteps of these six companies, by overcoming the bottlenecks coming in the way to produce and make available life saving drug as a welfare measure and serving the cause of humanity for which the very same CPSUs were created and established in the country. The Committee, therefore, reiterate their earlier recommendation and expect the CPSUs to behave in a matured and seasoned way and come out with concrete plan of action to meet any contingency in this regard. This will allow the Department of Pharmaceuticals to honour its own earlier committed contemplation before the Committee that in case the Swine Flu spreads further, production of Oseltamivir capsules by the pharma PSUs may be considered.

I. NEED TO HAVE A JOINT TASK FORCE TO COMBAT SWINE FLU

Recommendation (Sl.No.15, Para No.58)

31. The Committee in para 58 of their original Report had been informed by the Department of Pharmaceuticals and the Department of Health and Family Welfare that Swine Flu cannot be combated in isolation as prevention and treatment of Swine Flu is a multidisciplinary approach. In this context, the Committee had found that while the Ministry of Health and Family Welfare has been closely associated with the prevention and treatment of Swine Flu, the production and the availability of Tami Flu has been the concern of the Department of Pharmaceuticals. The Ministries of Commerce and Industry and Finance have also been closely associated with the import and export of Shikimic Acid used for the finished product, i.e., Oseltamivir. Further, the Ministry of Human Resource Development had also been entrusted with the responsibility to ensure that the Guidelines issued by the Ministry of Health and Family Welfare in schools were properly implemented. The Committee had also noted

that the role of the Department of Animal Husbandry was also solicited to ward off any possibility of bird Flu being construed as Swine Flu. However, what had concerned the Committee was the admission of the Department of Pharmaceuticals that there was some overlapping in the allocation of the role and responsibilities to the different Ministries/Departments. The Committee had, therefore, reiterated that there should be proper coordination and cooperation among various Ministries/Departments while pursuing a common cause. The Committee had again liked the Government to ensure that all the concerned Ministries/Departments work in tandem so that the multidisciplinary task assigned to them to combat Swine Flu could be performed with utmost finesse. They had, therefore, recommended that a task force comprising senior representatives of all the concerned ministries / departments / organizations / research agencies should meet periodically and monitor such pandemic situation continuously to ensure easy and affordable medicines to all those who needed it. Appropriate urgent attention was also required with a view to taking suitable steps as there were reports of mutation of H1N1 virus.

32. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under:-

> "A Task force has been constituted under the Chairmanship of Joint Secretary, Department of Pharmaceuticals with representatives from various Ministries/ Departments as its members. The first meeting of the Task Force has been held on 12.3.2010."

33. In addition to the above reply, the Department have also stated through their updated reply dated 16.09.2010 as under:-

> "As per the recommendation of the Standing Committee, a Task force has been constituted in the Department of Pharmaceuticals under the chairmanship of Joint Secretary, Department of Pharmaceuticals with senior representatives of concerned Ministries/ Departments and organizations as its members. Periodic meetings of the Task Force are held to monitor the pandemic situation so as to ensure the easy and affordable availability of medicines to all those who need it.
>
> Six meetings of the Task Force have been held so far. As per information provided by the Indian Council of Medical Research (ICMR) during these meetings, they have initiated steps to produce Shikimic acid in India by exploring possible options involving appropriate/ competent groups which can do required R&D and develop production technology for commercially viable manufacture of the compound. ICMR had invited proposals for the purpose and has sanctioned 4 projects. These projects are presently in the research mode.
>
> As per the information provided by Drug Controller General (India), Ministry of Health has allowed Retail sale of Oseltamivir and Zanamivir Capsules under certain specific conditions specified under Schedule 'X' to Drugs & Cosmetics Rules. This medicine was introduced in major outlets of schedule 'X' Licensed shops .

The representative of M/s Zydus Cadila has informed the Task Force that H1N1 vaccine manufactured by them is a single dose vaccine in injectible form which gives protection for one year. It has already been launched in the Indian market on 3rd June, 2010. He has also informed that they have sufficient stock ready with them.

The representative of M/s Panacea has informed that they have completed clinical trials for their H1N1 vaccine and their vaccine is safe for all age groups. They are going to submit the report to Drug Controller shortly.

The representative of M/s Serum Institute has informed that their Intranasal H1N1 vaccine has been licensed and is available in the market. Clinical trials for their Inactivated H1N1 vaccine have been successfully completed and the company has got the Marketing Authorization and Manufacturing License from DCG(I)."

34. The Committee in their original recommendation had desired the Government to ensure that all the concerned Ministries/Departments work in tandem so that the multidisciplinary task assigned to them to combat Swine Flu could be performed with utmost finesse. They, therefore, had recommended that a task force comprising senior representatives of all the concerned ministries / departments / organizations / research agencies should meet periodically and monitor such pandemic situation continuously to ensure easy and affordable medicines to all those who need it. Appropriate urgent attention was also required with a view to taking suitable steps as there were reports of mutation of H1N1 virus.

The Committee note from the reply of the Government that a Task Force comprising senior representatives of all the concerned Ministries/ Departments and Organizations as its members, have been constituted under the Chairmanship of Joint Secretary, Department of Pharmaceuticals and till 16.09.2010, six meetings of the Task Force have been held so far. However, it is not clear from the reply whether concerned organizations/ research agencies involved with the issues related to prevention/ treatment of Swine Flu have been given due inclusion/ representation in the Task Force as has been recommended by the Committee or it has been ignored by the Department.

The Committee would like to be apprised of the above mentioned point as well as the complete list / Composition of the Task Force, scheduled periodicity of meetings, if any, alongwith the details of six meetings held so far, such as, dates, venue and duration of each of the six meetings, representatives who attended/ did not attend each of the meeting, and contributions/ suggestions made by them, summary of things discussed, etc.

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CHAPTER - II

OBSERVATIONS/RECOMMENDATIONS THAT HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation

The Committee note that three types of preventive measures have been taken by the Government to check the spread of Swine flu. These are

i) screening at Airports , sea ports and six international check points.

ii) Early detection – issuing guidelines for opening large number of screening centers and

iii) Quarantine measures. However, most of the centers/ agencies which are supposed to implement the above measures fall under the purview of the Ministry of Health and Family Welfare . The role of the Department of Pharmaceuticals in this regard is confined only to make available medicine for quarantine purpose. Thus , the overall responsibility of the Ministry of Health and Family Welfare increases manifold to ensure meaningful and effective implementation of the measures adopted to prevent the spread of Swine flu. Nevertheless, the role and responsibilities of the Department of Pharmaceuticals in this regard are no less important as they have been entrusted with the task of making available medicines for quarantine purpose which is meant for the medical and para- medical staff who are prone to be affected by the H1N1 virus. Needless to say , both the Ministries should, therefore, act in unison so that the objectives of the measures initiated to contain the spread of Swine flu are truly achieved.

(Para No. 45)

Reply of the Department

Ministry of Health & Family Welfare has informed that an Inter Ministerial Task Force (IMTF) has been constituted in that Ministry. In this Task Force, Department of Pharmaceuticals is represented by its Secretary. All inter sectoral issues are discussed in IMTF.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee note that the Ministry of Health and Family Welfare have issued Guidelines to the educational institutions, laboratories and hospitals to take adequate preventive measures against the spread of Swine flu pandemic in the country, the moot point is whether such Guidelines are being followed in letter and spirit. The Committee are apprehensive of their proper adherence since the Ministry have nowhere mentioned any mechanism to

monitor effective implementation of the Guidelines . They are,therefore, of the view that mere issuance of Guidelines will serve no purpose unless a system is developed to get appropriate feedback on the implementation aspect based on which further follow up action can be taken . Since there has been a rapid increase in Swine flu cases recently, the Committee would like the Ministry of Health to examine whether the issued Guidelines need a revision. For instance, instead of discouraging people not affected with the H1N1 virus to visit crowded places like Cinema Halls and Shopping Malls appeal could be made to the people affected with or having symptoms of Swine flu to exercise self – restraint in not visiting crowded places/ offices/ schools / colleges in the interest of their fellow citizens.

(Para No. 47)

Reply of the Department

Ministry of Health & Family Welfare has informed that Joint Monitoring Group under the Chairmanship of DGHS, Government of India monitored the outbreak and revised the guidelines as and when necessary. There have been constant interaction by Ministry of Health with the States for implementing the guidelines. Officers of the rank of Additional Secretary/Joint Secretary and also technical officers from DGHS visited the States to identify the gaps and fill them.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee note that Oseltamivir is also given to family members who come into contact with a patient to break the transmission cycle and to provide protection to the individual. To effectively combat the menace of Swine flu in the country, more so during the recent spurt of the disease in the national capital, the Committee would urge upon all the concerned agencies to ensure that the system of giving Oseltamivir to the close contacts of the Swine flu affected individuals is encouraged proactively so that the transmission cycle of the H1N1 virus is countered.

(Para No. 48)

Reply of the Department

Ministry of Health & Family Welfare has informed that in order to stop the spread of H1N1 virus, Chemoprophylaxis was the strategic intervention followed by all States /UT Administrations to delay community spread.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee note that the medicine for the treatment of Swine flu is made from Shikimic Acid which is extracted from the seeds of Star Anise (illicium Vernum) an ever green Chinese plant. Besides Star Anise , Shikimic Acid is also produced from the leaves of Ginkgo Biloba tree. For Shikimic acid India is dependent on China because plants from which Shikimic acid is extracted grow in China. Moreover, availability of Shikimic acid depends upon the seasonal output of Star Anise Crop. What concerns the Committee is the fact that both the raw material ie. Star Anise and leaves of Ginkgo Biloba tree are in short supplies , as admitted by the Department. However, they draw consolation from the Department's statement that some alternate and sustainable sources are being explored to produce medicines for the treatment of Swine flu. As a result , ICMR is conducting research to produce this drug in the country through non- Shikimic route. NIPER , Mohali has also submitted a Research Proposal for producing Oseltamivir from an alternate route. The committee recommend that the Government should extend all possible help to these Research Organizations in their endeavor besides encouraging other similar premium institutions to follow suit so that any crisis in future regarding the availability of medicine for the treatment of Swine flu is averted.

(Para No. 49)

Reply of the Department

ICMR has initiated steps to produce Shikimic Acid in India by exploring all options involving appropriate / competent groups which can do required R&D and develop production technology for manufacture of the compound. The Council invited proposals in the identified areas and has sanctioned 4 Projects.

NIPER has reported that efforts are being made to look for alternative source of this Phyto- Chemical to meet this demand. In this direction two plant sources were explored as potential source of Shikimic acid. The experimental design was planned around following two approaches :

1. Availability plant source: The plants available in the nearby area were analyzed for the availability of Shikimic acid naturally. More than 50 plants were screened by LC-MS for this purpose. The plant which was judged as the most economic source was selected on the basis of abundance in the region, availability of biomass throughout the year, easy harvesting and total shikimic acid contents.
The selected plant was subjected for isolation of Shikimic acid on lab scale that will be extended to pilot scale an coming days. The methods will be fine tuned to enhance the efficiency and economic for isolation of Shikimic acid.

2. Intervention : The Shikimic acid can be obtained from plant sources after intervention of Shikmic acid pathway using a broad spectrum herbicide. A number of weedy plant species were screened and treated with the herbicide and Shikimic acid content were analyzed by LC-MS. It was observed that the application of herbicide has enhanced Shikimic acid contents.

The accumulation of Shikimic acid varies depending upon the concentration of herbicide applied, days after application, stage of plant (Vegetative or reproductive) and weather conditions (temperature, humidity of soil and air etc). The method is being fine tuned on these lines so the plant material can be harvested year round."

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The representative of ICMR has informed in the Task Force Meeting that four research projects have been initiated by them to evaluate the potential of indigenous manufacture of Shikimic acid in India.

1. Microbial fermentation method utilizing *Citrobacter* to produce Shikimic acid (Dept. of Microbiology, UDSC, New Delhi).
2. Isolation of Shikimic acid from Indian plants (*Araucaria excelsa* and *Calophyllum apetalum)* isolated from western ghats (NIPER, Chandigarh).
3. Hairy root culture of Indian plants to produce Shikimic acid through plant tissue culture in bioreactor (IIT, Delhi).
4. Isolation of Shikimic acid from other plants and biotransformation of Quinate to shikimate using enzymatic biotransformation (NCL, Pune).

ICMR is till exploring to fund research project to clone and express Shikimic acid pathways so that it can be produced in recombinant *E. coli system*.

The Progress so far of the above projects as reported by ICMR is as under :

1. Microbial source has been explored at Dept. of Microbiology, Delhi University to produce Shikimic Acid. Citrobacter species have been identified and grown to produce Shikimic Acid through fermentation. A strain of Citrobacter sp. Which has been selected after an exhaustive screening produces 0.6 g/L of shikimic acid. The Production was estimated by TLC and HPLC procedures. Subsequently, for enhancing the production of shikimic acid one variable at a time approach was attempted, wherein, 1.8h/l of shikimic acid was achieved when the medium contained ammonium sulphate as a nitrogen source. Subsequently, when ammonium sulphate was replaced by aspraragine, producton enhanced to 4.3 g/L of shikimic acid. This study was attempted upto 2L flask. Furthermore, the produced shikimic acid was purified by crystallization process and the purity of crystals was confirmed by NMR. Scale up study was attempted on 10, 14,30 L bioreactors which resulted in 3.5 g/L of shikimic acid. Results are encouraging and further optimization will lead to successful shikimic acid production.

2. Optimization of extraction procedures are on at NIPER to extract Shikimic acid from Araucaria *excelsa* plant leaves.

3. Plant cell culture system has been established at IIT Delhi using Indigenous plant from western Ghats to produce Shikimic acid through in vitro tissue culture.

4. *NCL Pune has started very actively in two areas : isolation of different plant sources to produce shikimic acid and isolation of microorganism to biotransformation quinate to Shichimic acid*

They are analyzing concentration of shikimic acid in leaves and seeds of plant varieties common in India. Around 80 types of seeds and 20 types of leaves have been analyzed so far.

The Angiosperm seeds analyzed so far contain only traces of shikimic acid.
Dry leaves of Gymnosperms are found to contain 0.2 to 1.5% shikimic acid but some of the plants are grouped in "rare and endangered" species.
Dry pods of "Chakriful or Badalful or Bardana" (*Illicium* sp.) used in spices, available locally, have been found to contain around 5% shikimic acid.
They have also screened 55 microbial belonging to bacteria, yeast and fungi for biotransformation of quinic acid to shikimic acid but the results so far are negative.
The work on screening plant and microbial varieties is continuing.

Further, National Institute of Pharmaceutical Education and Research under Department of Pharmaceuticals has informed that they are working on the following two projects :

1. Proposal to ascertain the commercial potential of the method for domestic production of "Shikimik Acid".

Under this project, an alternative domestic source for the shikimic acid is explored from the plants. The experiments are conducted on two fronts :

a. Available plant sources which accumulate the shikimic acid naturally in the aerial parts.
b. Intervention experiments for accumulation of shikimic acid by the use of broad spectrum herbicide.

2. Production and Availability of Medicines to deal with Swine Flu

In view of the Swine Flu outbreak in the country in 2009, NIPER has initiated a small research project titled " Targetting Hemaglutinin of H1N1 Virus: Rational Design and Syntheses of Anti-influenza Molecules.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee note that sufficient quantities of the Tami flu drug have been given to the State Governments to ensure its availability in all the treatment centers and there is reportedly no gap in the demand and supply of the medicine. However, in view of the rare nature of the raw material used to produce Tami flu, the Committee would like the Department of Pharmaceuticals to initiate a survey on their own to assess the situation instead of waiting for the State Government to bring to the Department's notice any gap in the demand and supply of Tami flu. This is all the more necessary to avert the wastage of the precious medicine in view of having adequate buffer stock in anticipation .

(Para No. 54)

Reply of the Department

Ministry of Health & Family Welfare is responsible to ensure that sufficient quantities of Tamiflu drug have been given to the State Governments to ensure its

availability in all the treatment centres and there is reportedly no gap in the demand and supply of the medicine. If at all the situation is required to be assessed, it can be taken up in the Task Force meeting which has been constituted under Department of Pharmaceuticals with representatives from various Ministries/ Departments

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee observe that the NPPA have issued an order under the Essential Commodities Act directing the six known manufacturers and any other company providing Oseltamivir based formulation packs, to furnish a daily report on the quantitative details of Oseltamivir API and Oseltamivir based formulation packs to which the manufacturers are complying. The Committee wish that this order is being complied with in letter and spirit. While India is not only stated to be self sufficient in the production of Oseltimivir capsule but also exporting the same to various developing countries as well as to France, a developed country. According to the Department of Pharmaceuticals, the Directorate General of Foreign Trade monitors the export of medicines on weekly basis. The Committee, however, would like the Government to ensure that the export of such vital medicine does not affect the easily availability for indigenous consumption.

(Para No. 56)

Reply of the Department

As per the decision taken in the Inter Ministerial Task Force on Avian and Pandemic Influenza, the Department of Pharmaceuticals have been asked to request the domestic manufacturers of Oseltimivir API to keep a stock of 100 kgs. at their disposal all the time. This stock would be used only as per the directions of Department of Pharmaceuticals. Whenever, any shortage has been reported from any part of the country, the Government has seen that required quantity of medicines used for the treatment of HINI have been sent to that area.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee understand that an indigenous vaccine for prevention of Swine Flu is likely to be introduced in the market by March 2010 . Before that some international manufacturing companies may launch their own vaccines for which the Government are in dialogue with all the international manufacturing companies for procuring interim quota for front line health workers to protect them against Swine Flu. The Committee are of the considered view that the steps taken by the Department of Health Research and ICMR for indigenous production of vaccine as well as procuring ad hoc quota with the international manufacturers especially for front line health workers are measures in the right direction and should be expeditiously persisted with. The committee, further desire that the Department of Pharmaceuticals, the Department of Health Research, ICMR and Department of Biotechnology should make concerted efforts to make the indigenous production of Swine Flu vaccine a big success to nip the disease in the bud.

(Para No. 57)

Reply of the Department

The directions of the Committee have been noted for compliance. DCG(I) has informed that Swine Flu vaccine manufactured by Sanofi Aventis will be available by the end of March, 2010 to targeted/selected population in the country.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The representative of M/s Zydus Cadila has informed the Task Force that H1N1 vaccine manufactured by them is a single dose vaccine in injectible form which gives protection for one year. It has already been launched in the Indian market on 3rd June, 2010. He has also informed that they have sufficient stock ready with them.

The representative of M/s Serum Institute has informed that their Intranasal H1N1 vaccine has been licensed and is available in the market. Clinical trials for their Inactivated H1N1 vaccine have been successfully completed and the company has got the Marketing Authorization and Manufacturing License from DCG(I) and this vaccine is also available in the market.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee have been informed by the Department of Pharmaceuticals and the Department of Health and Family Welfare that Swine Flu cannot be combated in isolation as prevention and treatment of Swine flu is a multi disciplinary approach. In this context , the committee find that while the Ministry of Health and Family welfare are closely associated with the prevention and treatment of Swine Flu, the production and the availability of Tami flu is the concern of the Department of Pharmaceuticals. The Ministries of Commerce and Industry and Finance are also closely associated with the import and export of Shikimic Acid used for the finished product, i.e oseltamivir . Further, the Ministry of Human Resource Development have also been entrusted with the

responsibility to ensure that the Guidelines issued by the Ministry of Health and Family Welfare in Schools are properly implemented. The Committee also note that the role of the Department of Animal Husbandry is also solicited to ward off any possibility of bird flu being construed as Swine Flu. However, what concerns the Committee is the admission of the Department of Pharmaceuticals that there is some overlapping in the allocation of the role and responsibilities to the different Ministries/ Departments. The Committee, therefore, reiterate that there should be proper coordination and cooperation among various Ministries / Departments while pursuing a common cause. The Committee would again like the Government to ensure that all the concerned Ministries/Departments work in tandem so that the multidisciplinary task assigned to them to combat Swine Flu are performed with utmost finesse. They, therefore, recommend that a task force comprising senior representatives of all the concerned ministries/ departments/organizations/ research agencies should meet periodically and monitor such pandemic situation continuously to ensure easy and affordable medicines to all those who need it. Appropriate urgent attention is also required with a view to taking suitable steps as there are reports of mutation of H1N1 virus.

(Para No. 58)

Reply of the Department

A Task force has been constituted under the Chairmanship of Joint Secretary, Department of Pharmaceuticals with representatives from various Ministries/Departments as its members. The first meeting of the Task Force has been held on 12.3.2010.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

As per the recommendation of the Standing Committee, a Task force has been constituted in the Department of Pharmaceuticals under the chairmanship of Joint Secretary, Department of Pharmaceuticals with senior representatives of concerned Ministries/ Departments and organizations as its members. Periodic meetings of the Task Force are held to monitor the pandemic situation so as to ensure the easy and affordable availability of medicines to all those who need it.

Six meetings of the Task Force have been held so far. As per information provided by the Indian Council of Medical Research (ICMR) during these meetings, they have initiated steps to produce Shikimic acid in India by exploring possible options involving appropriate/ competent groups which can do required R&D and develop production technology for commercially viable manufacture of the compound. ICMR had invited proposals for the purpose and has sanctioned 4 projects. These projects are presently in the research mode.

As per the information provided by Drug Controller General (India), Ministry of Health has allowed Retail sale of Oseltamivir and Zanamivir Capsules under certain specific conditions specified under Schedule 'X' to Drugs & Cosmetics Rules. This medicine was introduced in major outlets of schedule 'X' Licensed shops .

The representative of M/s Zydus Cadila has informed the Task Force that H1N1 vaccine manufactured by them is a single dose vaccine in injectible form which gives protection for one year. It has already been launched in the Indian market on

3rd June, 2010. He has also informed that they have sufficient stock ready with them.

The representative of M/s Panacea has informed that they have completed clinical trials for their H1N1 vaccine and their vaccine is safe for all age groups. They are going to submit the report to Drug Controller shortly.

The representative of M/s Serum Institute has informed that their Intranasal H1N1 vaccine has been licensed and is available in the market. Clinical trials for their Inactivated H1N1 vaccine have been successfully completed and the company has got the Marketing Authorization and Manufacturing License from DCG(I).

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

CHAPTER - III

OBSERVATIONS/RECOMMENDATIONS WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

Recommendation

The Committee have been given to understand that the medicine(Tami flu) can also be used for the treatment of avian/ seasonal influenza/ flu. Hence, the possibility of Tami flu drug being administered to the patients having Swine flu like symptoms without waiting for the confirmation of the presence of the H1N1 virus in them cannot be entirely ruled out. In such a situation , onus lies with the Department of Pharmaceuticals and the Ministry of Health and Family Welfare to take suitable measures to ensure that the drug meant for the treatment of Swine flu is used appropriately only after confirming the presence of H1N1 virus in the flu/ influenza affected people.

(Para No. 55)

Reply of the Department

Ministry of Health & Family Welfare has informed that the guidelines issued by them recommend treatment with Oseltamivir (Tamiflu) after clinical assessment. The mild cases are not treated with the drug but followed up. Moderate cases and those with co-morbid conditions are put on Oseltamivir treatment without testing.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

CHAPTER - IV

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE

Recommendation

The Committee note that the Department of Pharmaceuticals are engaged in the production and availability of drugs for the treatment of Swine flu. With the cooperation of the Ministry of Health and Family Welfare, they are regularly monitoring the availability of position of Shikimic acid and Oseltamivir API which are used for the production of drug ie. Oseltamivir or Tamiflu and Oseltamivir Capsules. The Ministry of Health and Family Welfare have also procured stocks of drugs at the instance of the Department of Pharmaceuticals. Six Pharma companies have volunteered to maintain adequate quantity of drugs to deal with Swine flu. The Ministry of Health and Family Welfare have also permitted the retail sale of Oseltamivir capsules w.e.f 19 September 2009. However, regarding the price control of the drug meant for the treatment of Swine flu, the committee observe that the Pharmaceutical Companies have been given liberty to sell the medicine at a price decided by them though within a "reasonable limit". The Committee feel that reasonable limit is too broad and vague a term which could be conveniently manipulated by the Pharmaceutical Companies for their own gains and at the cost of the common man. Further, chances of medicines of the treatment of Swine flu becoming costlier can not be ruled out in view of the high volatility of the prices of raw material, especially when these are imported from China . Thus in such a scenario, leaving the pharma industry to fix the price of the medicine on their own , albeit within , a reasonable limit, does not seem to be an appropriate decision. While appreciating the initiatives taken by the Department in persuading the Ministry of Finance for exemption of Customs Duty on Oseltamivir and Shikimic acid and Excise Duty on indigenously produced Oseltamivir and Shikimic acid and Excise Duty on indigenously produced Oseltamivir API and capsules, the Committee recommends that the Government should initiate immediate appropriate measures to ensure easy availability as well as affordability of the medicines for effective treatment of Swine flu. Particularly in view of increase in case with the onset of winter.

(Para No. 44)

Reply of the Department

Oseltamivir is a non-scheduled medicine and not covered under DPCO, 1995. In respect of drugs – not covered under the Drugs (Prices Control) Order, 1995 i.e. the non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government/NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities/packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of import etc. As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of ORG IMS and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest . This is an ongoing process.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee are highly concerned to note that although Maharashtra has reported maximum number of Swine flu cases, it has only three Laboratories to detect such cases. In this regard the Committee find that Delhi which ranks number two in reported Swine flu cases and Tamil Nadu which has reported fewer cases of Swine flu has seven Laboratories each whereas other states have either one or two Laboratories . The Committee feel that several cases of Swine flu in various states might have remained undetected for want of adequate Laboratories / detection centers . They,therefore, impress upon the Ministry of Chemicals and Fertilizers to take up the matter at the appropriate level urgently so that sufficient number of Laboratories are set up especially in Swine flu vulnerable states/UTs, for early detection and timely treatment of such pandemic disease. As some states have only one or two Laboratories , the Committee recommend that Private Laboratories may be appropriately encouraged to supplement the efforts of Government for detection of Swine flu cases.

(Para No. 46)

Reply of the Department

Availability of testing laboratories comes under the purview of Ministry of Health and Family Welfare. They have informed that testing for pandemic influenza can only be done in Bio safety level (BSL) – 3 laboratory or a Bio Safety – 2 Laboratory with BSL-3 precautions. From the two testing laboratories (NCDC, Delhi and National Institute of Virology, Pune) available prior to July, 2009 the number of laboratories were expanded to 18. Subsequently, it was further expanded to 44. Among these 18 are in private sector.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee note that at present the Government do not have any plan to get into the production of Oseltamivir API through Central Public Sector Enterprise (CPSE) for the reason that they have not found it economically viable for PSUs at this stage to enter into production of the drug. In this context, the Committee find that six private Pharmaceutical Companies are engaged in the supply of Oseltamivir 75 mg Capsules in the country. Four of these companies,

viz. Hetero Drugs, Cipla, Ranbaxy and Strides Areolab have facilities for indigenous production of Oseltamivir form its raw material i.e. Shikimic Acid. Out of the remaining two Companies, Roche has no local production in India and is supplying Oseltamivir Capsules by importing the same from their corporate set up. The other company, viz . NATCO has only formulation capability of the capsules based on Oseltamivir API. The Committee acknowledge the efforts made by the Private Sector in producing / supplying medicines for the treatment of Swine flu. They are, however, disappointed to find that there is no move on the part of the Government to produce the Oseltamivir medicine through their PSUs on the plea of it being not economically viable. The Committee are not convinced by the Government's, logic since production of one specific thing which is Commercially/ economically viable for one sector cannot be otherwise for other sector , more so when the private sector does not opt for anything that is economically un-viable . In Committee's view cost alone cannot be always the prime factor particularly when the dealing with a pandemic situation like Swine flu which has taken so many precious lives. Moreover, the Committee dread a situation where the Private Sector, for some unforeseen circumstances, is not able to produce Oseltamivir at all curtail its production and the Government have no contingency plan in place to deal with the situation. Prudence, therefore, requires the Government to gear up their preparedness to ensure availability of Oseltamivir medicine in any eventuality , notwithstanding the Commercially viability factor. As it is life saving drug, the Department of Pharmaceuticals should entrust to one of its PSUs the job of production of Oselltamivir despite the same being unviable. Such company should be compensated suitably, if necessary, through budgetary grant.

(Para No. 53)

Reply of the Department

PSU Division of the Department of Pharmaceuticals has informed that Oseltamivir is a patented drug. The pharma CPSUs do not have API manufacturing facilities to produce Oseltamivir. As such, it is not being manufactured by Pharma CPSUs. The CPSUs also do not have the generic composition to launch their own brand.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2011 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

CHAPTER - V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH FINAL REPLIES OF THE GOVERNMENT ARE STILL AWAITED

Recommendation

It is a matter of serious concern that the Department of Pharmaceuticals has not kept track of the means adopted by other countries like USA and Mexico to cope with the availability of Shikimic Acid or measures taken by them to find alternate route for production of Oseltamivir. As it has been established that the H1N1 virus has penetrated India from foreign land, it would have been prudent on the part of the Department to maintain appropriate international data with regard to their efforts towards availability/ production of Oseltamivir or alternatives thereto. However, even now it is not too late. The Committee impress upon the Department to urgently initiate a study to gauge the dependency of other countries upon China for Shikimic Acid and the alternate route , if any, adopted by them to produce Oseltamivir. The Committee are confident that a comparative assessment would immensely help the Research Organizations like ICMR and NIPER in their endeavors towards making India self – sufficient in producing Oseltamivir medicine to counter Swine flu.

(Para No. 50)

Reply of the Department

The Department has written to three Research Agencies and has requested them to indicate their willingness or otherwise for conducting this study, the time required for completing this study and the fees chargeable for this. After getting the response from these Agencies, the suitable Agency for conducting the study will be selected.

In the meantime, the Deputy Industrial Advisor in the Department has also been requested to conduct this study. He has submitted the report. He has reported that commercial production of Oseltamivir starts from the biomolecule Shikimic acid harvested from Chinese star anise with a limited worldwide supply. Due to its limited supply searches for alternative synthetic routes preferably skipping Shikimic acid are underway and to date several such routes have been published. In the total synthesis of Oseltamivir, control of Stereochemistry is important; the molecule has three stereo centers and the sought after isomer is only 1 of 8 streoismers.

The current production method is based on research by Gilead Scinces starting from naturally occurring quinic acid and that of Hoffmann- La Roche starting from Shikimic acid. The current production method include two reaction steps with potentially hazardous azides. A reported azide – free Roche synthesis of Tami flu is given by Karpt/ Trussardi synthesis . Other reported routes published are:

(I) Corey synthesis
(II) Shibasaki synthesis
(III) Fukuyama synthesis

Commercial production from alternative routes have not been reported in literature.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

In order to get a study conducted to gauge the dependency of other countries upon China for Shikimic Acid and the alternate route, if any, adopted by them to produce Oseltamivir, based on information received from FICCI Department of Pharmaceuticals has written to three Research Agencies and has requested them to indicate their willingness or otherwise alongwith other terms and conditions for conducting this study. Reply from all the three agencies have not been received. The matter is being pursued with them. The Department has also written to two more research agencies and letters to WHO and Ministry of Health & Family Welfare have also been sent.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee express their displeasure over the fact that details are reportedly not available with the Directorate General of Commercial Intelligence (DGCIS), Kolkata regarding the quality and value of medicine and Shikimic Acid imported on the plea that there is no specific code for Swine flu in the classification system. They also express their unhappiness since similar information which was also sought from the Department of Revenue by the Department of Pharmaceuticals has not been furnished. The Committee would like to point out that when so many Ministries / Departments have been entrusted with the responsibility to check the spread of swine flu, there must be a proper coordination and cooperation amongst themselves to perform the respective assigned task effectively. But in the instant case, despite the efforts of the Department of Pharmaceuticals to get relevant information, the other concerned Ministries/ Department did not oblige. The Committee take a strong exception to the callousness on the part of the Department of Revenue on such an important issue and recommend that henceforth any information sought by one Department from the other should invariably be furnished in a time bound manner in order to facilitate further follow up action for dealing with Swine Flu. The Committee direct the Department of Revenue to institute an internal enquiry to fix the responsibility for this negligence and take punitive action against the erring officials. The Committee advocate the need for a close coordination and cooperation at sufficiently high level amongst all the Concerned Ministries/ Department and desire the Department of Pharmaceuticals to play a proactive role in the process.

(Para No. 51)

Reply of the Department

The observations of the Committee have been conveyed to Department of Revenue and Directorate General of Commercial Intelligence and Statistics, Kolkata. The recommendation of the Committee regarding proper coordination and cooperation amongst the Departments has been noted for compliance.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

Recommendation

The Committee are perturbed to note the self contradictory reply given by the Department of Pharmaceuticals in respect of the hoarding of Shikimic Acid by the traders. At one place it has been stated that the possibility of hoarding of Shikimic Acid cannot be ruled out in view of it being under the Open General Licence (OGL) policy whereas, elsewhere it has been mentioned that the Open Licence policy would prevent any monopolistic facilities such as hoarding. The two statements need to be reconciled. The Committee desire that if according to the Department of Pharmaceuticals, there is any loophole in the existing OGL policy which might be taken advantage of by the traders to hoard Shikimic Acid, they should take up the matter with the Department of Commerce to revise the Licence Policy so as to make it transparent and foolproof in order to ward off any possibility of hoarding of Shikimic Acid.

(Para No. 52)

Reply of the Department

DGFT has informed that domestic availability of Shikimic acid and Oseltamivir, was closely monitored through exports and imports of the above products. Even during the high phase of Swine flu, no need of policy change on importability of these two products was felt except the need for close monitoring of imports and exports. Further no instance of hoarding of these products was reported.

(Department of Pharmaceuticals O.M. No.5/57/2009-PI-I/III dated 29.3.2010)

Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 16 September 2010 has stated 'No Change'.

(Department of Pharmaceuticals O.M. No.35022/48/2010/PI-I/III dated 16.9.2010)

New Delhi;
28 July, 2011
6 Shravana, 1933 (Saka)

Gopinath Munde
Chairman,
Standing Committee on Chemicals and Fertilizers

Appendix – I

MINUTES OF THE TENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

The Committee sat on Tuesday, the 31 May, 2011 from 1500 hrs. to 1630 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

Present

Dr. Manda Jagannath - *Acting Chairman*

Members

Lok Sabha

2.	Smt. Susmita Bauri
3.	Shri Prabhatsinh P. Chauhan
4.	Smt. Santosh Chowdhary
5.	Adv. Ganeshrao Nagorao Dudhgaonkar
6.	Shri T.K.S. Elangovan
7.	Shri N. Peethambara Kurup
8.	Shri Baidya Nath Prasad Mahato
9.	Shri Jagdambika Pal
10.	Shri Tapas Paul
11.	Shri Ponnam Prabhakar
12.	Shri Ashok Kumar Rawat
13.	Shri Narendra Singh Tomar
RAJYA SABHA	
14.	Shri A.A. Jinnah
15.	Prof. Anil Kumar Sahani
16.	Shri Raghunandan Sharma
17.	Shri Parshottam Khodabhai Rupala
18.	Shri Abani Roy
19.	Shri Biswajit Daimary

Secretariat

1. Shri Ashok Sarin - Joint Secretary
2. Shri C. S. Joon - Director
3. Shri A.K. Srivastava - Additional Director

2. As the Chairman could not attend the sitting due to pre-occupation, the members chose Dr. Manda Jagannath, a member of the Committee, to act as the Chairman. The Acting Chairman welcomed the members to the sitting of the Committee.

3. The Committee thereafter took up for consideration and adoption the following draft Action Taken Reports :

(i) Report on Action Taken by the Government on the recommendations contained in the Fifth Report (15th Lok Sabha) on 'Production and Availability of Medicines to deal with Swine Flu' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

(ii) *** *** *** ***

(iii) *** *** *** ***

(iv) *** *** *** ***

4. After some deliberation the adoption/ consideration of the above mentioned Reports was deferred to a later date.

The Committee then adjourned.

*** ***Matters not related to this Report.***

Appendix – II

MINUTES

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

THIRTEENTH SITTING (18.07.2011)

The Committee sat on Monday from 1500 hours to 1600 hours.

Present

Shri Gopinath Munde - Chairman

Members

Lok Sabha

2. Smt. Susmita Bauri
3. Shri Prabhatsinh P. Chauhan
4. Smt. Santosh Chowdhary
5. Shri K.D. Deshmukh
6. Adv. Ganeshrao Nagorao Dudhgaonkar
7. Shri Baidya Nath Prasad Mahato
8. Shri Jagdambika Pal
9. Shri Tapas Paul
10. Shri Ashok Kumar Rawat
11. Shri N. Chaluvaraya Swamy

Rajya Sabha

12. Shri Silvius Condpan
13. Shri Brijlal Khabri
14. Prof. Anil Kumar Sahani
15. Shri Raghunandan Sharma
16. Shri Parshottam Khodabhai Rupala
17. Shri Abani Roy

Secretariat

1.	Shri N.K. Sapra	-	Secretary
2.	Shri Ashok Sarin	-	Joint Secretary
3.	Shri C. S. Joon	-	Director
4.	Shri A.K. Srivastava	-	Additional Director

2. At the outset, Hon'ble Chairman welcomed the members to the sitting of the Committee.

3. The Committee thereafter took up for consideration the following draft Reports:

(i) Draft Report on Action Taken by the Government on the recommendations contained in the Fifth Report (15th Lok Sabha) on 'Production and Availability of Medicines to deal with Swine Flu' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals);

(ii), (iii), (iv), (v), (vi) and (vii) *** *** *** ***

4. The Committee adopted the draft reports with minor amendments and authorized the Chairman to present the same to both the Houses of Parliament.

The Committee then adjourned.

*** ***Matters not related to this Report.***

Appendix – III

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FIFTH REPORT (FIFTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2009-10) ON 'PRODUCTION AND AVAILABILITY OF MEDICINES TO DEAL WITH SWINE FLU' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	15
II	Observations / Recommendations which have been accepted by the Government:- (*Vide* Recommendation at Sl.Nos.45, 47, 48, 49, 54, 56, 57 and 58)	08
	Percentage of Total	53%
III	Observation / Recommendation which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation at Sl.No.55)	01
	Percentage of Total	7%
IV	Observation / Recommendation in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation at Sl.Nos.44, 46 and 53)	03
	Percentage of Total	20%
V	Observations / Recommendations in respect of which replies of the Government are of interim nature:- (*Vide* Recommendations at Sl.Nos.50, 51 and 52)	03
	Percentage of Total	20%