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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2009-10)

FIFTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

PRODUCTION AND AVAILABILITY OF MEDICINES TO DEAL WITH SWINE FLU

FIFTH REPORT

LOK SABHA SECRETARIAT

NEW DELHI

December, 2009/ Agrahayana 1931, (Saka)

CC&F No.5

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(FIFTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

PRODUCTION AND AVAILABILITY OF MEDICINES TO DEAL WITH SWINE FLU

Presented to Lok Sabha on ***15.12.2009***

Laid in Rajya Sabha on ***15.12.2009***

LOK SABHA SECRETARIAT
NEW DELHI

DECEMBER, 2009/ Agrahayana 1931(Saka)

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***Consequent upon nomination to the Committee on Information Technology Shri Tufani Saroj, MP (LS) ceased to be Member of the Committee w.e.f. 13.10.2009.**

#Vacancy arisen due to demise of Shri Mahendra Sahni, MP (RS) w.e.f. 6 November 2009.

SECRETARIAT

1. Shri N. K. Sapra - Additional Secretary
2. Shri Ashok Sarin - Joint Secretary
3. Shri A.K.Srivastava - Deputy Secretary

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2009-10) having been authorised by the Committee to submit the Report on their behalf present this Fifth Report on the subject 'Production and Availability of Medicines to deal with Swine Flu'.

2. The Committee examined the subject material furnished by the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals). The Committee were orally briefed by the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) and the Ministry of Health and Family Welfare at their sitting held on 16 September 2009.

3. The Committee considered and adopted the Report at their sitting held on 10 December 2009.

4. The Committee wish to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) and Ministry of Health and Family Welfare for furnishing the material and other information, which they desired in connection with the examination of the subject and briefing the Committee.

5. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

New Delhi;
10 December, 2009
19 Agrahayana, 1931 (Saka)

ANANTH KUMAR
Chairman,
Standing Committee on
Chemicals and Fertilizers.

REPORT

I INTRODUCTORY

The outbreak of Influenza pandemic dates back to the year 1918 which was known as “Spanish Flu”. The virus responsible for that pandemic was influenza A H1N1. An estimated 50 million deaths took place during that pandemic, including an estimated seven million deaths in India. About 25 per cent of the population was affected.

2 In India, the ‘Spanish Flu Pandemic” came in two waves. The first wave came in June-July 1918 was a mild wave. The second wave that came in September-October 1918 was much more lethal. There was a substantial requirement of hospital beds. Most of the affected countries established temporary hospitals in schools, stadiums, and other civic facilities. There were no proven drugs or vaccine available at that point of time. The mainstay of public health interventions used to be non pharmaceutical interventions at individual level (hand wash, covering mouth while coughing and sneezing and staying away) and at community level (social distancing measures such as closure of schools, colleges, work place etc; avoiding public gatherings and limitations of movements of public transport etc.).

3. Recently the influenza A H1N1 known as Swine Flu has assumed serious proportions all over the world after reportedly having originated from North America. Many countries including India have been seriously affected and Governments and WHO are keeping a close watch on the situation. The Ministry of Health & Family Welfare in the Government of India being the nodal Ministry to handle this issue is taking all the preventive and remedial steps. The Department of Pharmaceuticals (DoP) is responsible for production and availability of medicines including those used for management of Influenza A H1N1 commonly referred as Swine Flu.

4. As per the information received from Ministry of Health and Family Welfare, the Consolidated Status of Influenza A H1N1 cases as on 8 October 2009 is as under:-

Consolidated Status of Influenza A H1NI

(As on 8 October 2009)					
Sl	State	Lab confirmed cases reported on 8 October 2009	Lab confirmed cases cumulative	Death of Lab confirmed cases on 8 October 2009	Death of Lab confirmed cases cumulative
1	Delhi	44	2,941	0	15
2	Andhra Pradesh	9	698	0	38
3	Karnataka	13	1,179	1	106
4	Tamil Nadu	10	1,356	0	4
5	Maharashtra	35	3,187	3	153
6	Kerala	18	448	0	9

(As on 8 October 2009)					
Sl	State	Lab confirmed cases reported on 8 October 2009	Lab confirmed cases cumulative	Death of Lab confirmed cases on 8 October 2009	Death of Lab confirmed cases cumulative
7	Punjab	1	38	0	0
8	Haryana	12	645	0	4
9	Chandigarh (UT)	1	51	0	0
10	Goa	0	40	0	3
11	West Bengal	1	126	0	0
12	Uttarakhand	0	64	0	2
13	Himachal Pradesh	0	3	0	0
14	Jammu & Kashmir	0	41	0	0
15	Gujarat	0	203	0	36
16	Manipur	0	1	0	0
17	Meghalaya	0	6	0	0
18	Mizoram	0	3	0	0
19	Assam	0	45	0	0
20	Jharkhand	0	1	0	0
21	Rajasthan	1	32	0	1
22	Bihar	0	5	0	0
23	Uttar Pradesh	1	349	0	2
24	Puducherry	0	10	0	0
25	Chattishgarh	0	16	0	1
26	Madhya Pradesh	0	6	0	0
27	Daman & Diu	0	1	0	0
28	Orissa	0	3	0	0
29	Nagaland	0	2	0	0
30	Andaman & Nicobar	0	7	0	0
	Total	146	11,507	4	374

Notes

1. On 7 October 2009, 39,485 passengers have been screened at 22 Airports with 83 counters manned by 225 doctors and 172 paramedics. Total passengers screened till date are 6,869,505.
2. Till date, samples from 48,355 persons have been tested for Influenza A H1N1 in Government Laboratories and a few private Laboratories across the country and 11,507 (23.8%) of them have been found positive
3. Of the 146 cases reported on 8 October 2009, four are imported and the rest are indigenous cases
4. Four deaths have been reported on 8 October 2009 (Maharashtra 3, Karnataka 1)
5. Laboratory confirmation of 2 deaths from Maharashtra and 2 deaths from Karnataka have been received from the respective State Health departments, and are now reflected in the cumulative total
6. Andaman & Nicobar has reported 7 positive cases on 30 september 2009, and are now reflected in the cumulative total.

II ROLE OF DEPARTMENT OF PHARMACEUTICALS

5. The Department of Pharmaceuticals (DoP) is responsible for R&D, production and availability of drugs and pharmaceuticals including those used for management of H1N1 Flu, commonly referred as Swine Flu.

6 Management of Swine flu and treatment: As per available information, Swine flu is curable through:

(a) Antiviral medications: Following medicines are currently in the retail market:

(i) Tamiflu (Oseltamivir) capsules: This medicine produced/marketed by Roche and some other generic companies is used worldwide and is by far reportedly considered very effective. A very limited number of cases, with resistance to Oseltamivir capsules, have come to light worldwide. The Active Pharmaceutical Ingredient (API) for this formulation is Oseltamivir which in India is produced using Shikimic acid, that is imported mostly from China.

(ii) Zanamavir Rotacaps: This is reportedly being used in various countries as second line of treatment. Glaxo is selling this product as “Relenza”. So far they have not commenced its sale in India. M/s Cipla have recently launched its generic version “Virenza” in the form of packs of 20 rotacaps suitable for use @ 4 Rotacaps per day (for a 5 day course) alongwith an applicator (Revolizer).

(b) Vaccines: Efforts to develop vaccine for H1N1 Flu are underway and 1 MNC and few Indian companies are in the fray. First indigenously developed H1N1 Flu vaccine is expected to be in the market by April 2010. There are reports that vaccines are likely to be introduced in USA by December this year. The Ministry of Health and Family Welfare may resort to import the vaccine in case the post marketing reports of vaccines in USA are found satisfactory. It is also to be mentioned that before allowing marketing of imported vaccines by DCG(I), clinical evaluation is necessary.

(c) Diagnosis: The Kits being used to diagnose H1N1 Flu are currently imported and a few companies in India are trying to make indigenous kits.

7. Stocks of Oseltamivir capsules: Being responsible for healthcare delivery, Ministry of Health had initially made a stockpile of 10 million (mn) Oseltamivir capsules sufficient to treat nearly one million patients. Subsequently, in view of rising numbers of confirmed cases, the Ministry of Health has additionally procured over 20 million Oseltamivir capsules.

As pointed out above DoP is regularly monitoring the availability position of Shikimic acid, Oseltamivir API and Oseltamivir capsules in the country. It is monitoring the situation in close cooperation with the Ministry of Health & Family Welfare and has advised the Pharma Industry to be ready to meet the procurement targets of the Government. In view of serious situation, the Committee of Secretaries (COS) is regularly monitoring the matter.

8. Banking arrangement: Besides the stocks procured by Ministry of Health, at the instance of DoP all the 6 concerned Pharma companies volunteered to maintain a stockpile of 100 kg Oseltamivir API or equivalent number (one million) Oseltamivir capsules for supply to the Government as and when needed. Out of this stock, Roche recently donated half of this committed stock to the Ministry of Health. As on 13 October 2009, 700 kg Oseltamivir API and 0.55 mn Oseltamivir capsules were available under the banking arrangement.

9. Facilitation by DoP: In order to facilitate the production and availability of Oseltamivir capsules, the DoP took up the cause of the Industry at the Committee of Secretaries (CoS) and secured assistance to the concerned manufacturers of Oseltamivir capsules through various fiscal and non-fiscal measures. Such measures included restoration of regular power supply to M/s Hetero Drugs Ltd.–the single largest manufacturer of Oseltamivir capsules from basic stage of Shikimic acid and waiver of customs and excise duties applicable to the raw material or finished goods relevant for Oseltamivir capsules meant for banking arrangement in certain cases.

10. Retail sale of Oseltamivir capsules: The Ministry of Health has permitted retail sale of Oseltamivir capsules w.e.f. 19 September 2009. After permission by the Government only two companies; Natco Drugs & Hetero Drugs have launched their product in the market.

11. Price Control: Oseltamivir or its capsules are not covered under DPCO'1995. As such there is no price control for these products. The Government does not intend to intervene in the market at this stage. The Secretary (Pharma) has requested the Industry to act in a responsible manner by keeping the price-line of Oseltamivir capsules within a reasonable range.

12. On being asked as to what further action is contemplated by the Department in respect of production and availability of medicines, the Department in their reply submitted as under:-

> "Considering the comfortable availability situation for the time being the Department of Pharmaceuticals do not intend to take any specific action to augment the availability. However, in case Swine flu spreads further, production of Oseltamivir capsules by the Pharma PSUs may be considered. Depending upon the developments in retail market, price control on Oseltamivir Active Pharmaceutical Ingredient (API) & Oseltamivir capsules might be

considered in case the prices become unreasonably high. Development of alternate indigenous sources for getting Shikimic acid is also being explored. The DoP is regularly monitoring the availability position of medicines in the country."

13. The following suggestion has been furnished by the Department in their written note:-

"In order to ensure cheaper availability of medicine for H1N1 Flu, the DoP has taken up issue of Customs Duty exemption on Oseltamivir (both API & capsules) and Shikimic acid with the Ministry of Finance. At the same time excise duty exemption for indigenously produced Oseltamivir API and capsules has also been recommended to Ministry of Finance. The decisions in these matters are awaited."

14. Regarding the cost implications of the medicines to deal with Swine flu on account of production/ import/ import of raw materials it was stated by the Department in their written reply that considering the current level of indigenous production, availability of sizeable stockpile with the Ministry of Health, stockpile of over 7 mn capsules or equivalent API as banking arrangement for Department of Pharmaceuticals and competition between the local manufacturers, the cost level is expected to be within reasonable limits. It was also mentioned by them that the high volatility of the prices of raw material is an issue of concern.

III PREVENTIVE MEASURES TO CONTAIN THE SPREAD OF SWINE FLU

15. As per the written replies furnished by the Department of Pharmaceuticals, the following preventive measures have been taken by the Government to check the spread of Swine Flu.

(a) Screening at Airports

Entry screening of passengers from affected countries is a non pharmaceutical intervention for detecting cases at the point of entry, subsequent follow up, isolation and treatment. It has a limitation in that the passengers in the incubation period cannot be detected.

The Ministry of Health & Family Welfare, due to this limitation, decided to start entry screening at all its 22 international airports, sea ports and six international check points (border crossing). As on 8 October 2009 cumulative 68,69,505 passengers have been screened. Till the last week of July about 500 imported cases were detected directly/indirectly (follow up reporting) through entry screening. All of them were isolated and put on treatment and got cured. All these contacts (contacts sitting in close proximity in the aircraft; family contacts and social contacts) were traced and put on Chemoprophylaxis. By these concerted efforts the community spread of Pandemic influenza was delayed for almost three months.

(b) Early detection

As per World Health Organisation, the pandemic as of now is of mild to moderate severity implying the large number of cases exhibiting mild symptoms need only symptomatic treatment. Early detection and treatment would prevent complications and death. Analysis of about 150 deaths that took place in India showed that on an average, patients reported to the designated health facility after 5 days. On the other hand all the cases detected through airport screening, early in their illness, got cured with treatment. Hence, the Government of India in their guidelines have advocated opening of large number of screening and follow up of such patients.

(c) Quarantine

Quarantine is applied to healthy individuals who are suspected to be exposed to the ineffective agent. Individual quarantine of exposed individuals are recommended. Community-wise quarantine (quarantine of affected/exposed population) in defined geographical area has limited role for containment of the outbreak. Similarly, quarantine can be applied to international passengers at sea ports (maritime quarantine) at airports (airport quarantine). There is limited scientific evidence to support community based quarantine measures.

III PREPAREDNESS TO HANDLE THE SWINE FLU

16. The following measures have been taken up by the Government of India to handle the Swine Flu:

(a) Availability of laboratories – Proposal regarding new laboratories for screening the virus

Initially, there were two apex laboratories, National Institute of Virology, Pune and National Centre of Disease Control, Delhi. With the spread of the virus in the State of Maharashtra and Delhi there were increasing demands for laboratory testing of clinical samples. A number of laboratories were identified and strengthened. Of the 53 laboratories identified (31 in Government Sector and 22 in private sector), 35 are operational (23 in Government sector and 12 in private sector). Guidelines have been formulated and sent to all the States to identify laboratories fulfilling these norms. The list of operational laboratories is given at Appendix I.

(b) Preparedness of the hospitals in the country to handle the challenge

All the States with International Airports have identified isolation hospitals. The Minister of Health and Family Welfare has written to Chief Ministers of all the States to gear up their machinery and strengthen isolation facilities including critical care facilities at district level. Guidelines for setting up isolation facilities were issued. All States have since identified hospitals for isolation facility and are being strengthened. For better accessibility and to detect cases early, the States have been requested to open up a number of screening centres. Guidelines have been issued for categorization of cases during screening for home care, testing, treatment and hospitalization.

(c) Making available on the website the list of shops in various parts of the country from where medicines could be obtained

The Central Government has on 15 September 2009 issued a notification under Section 26B of the Drugs and Cosmetics Act for the regulated retail sale of Oseltamivir and Zananmivir. Both these drugs would henceforth be available with chemists holding schedule X license under the Drugs and Cosmetics Act. The State Governments have been advised to issue Schedule X licenses on fast track basis. The drug is available in some of the retail outlets and others would commence shortly. The list would be compiled and made available on the website as and when information is received from the State Governments.

(d) Need for launching awareness drive

A Task Force has been set up in Information and Broadcasting Ministry to fast track awareness campaign. Short term media campaign was started immediately when WHO declared the Pandemic. The materials prepared by the Ministry of Health and Family Welfare with assistance from United Nations Children's Emergency Fund (UNICEF), after approval of the Task Force are appearing in print and visual media. Travel advisory, Do's and Don'ts and simple public health measures required to prevent/mitigate the outbreak have been widely publicized in Hindi, English and various regional languages. Press briefing is being done by identified authority. Daily press releases are issued.

(e) Guidelines issued by the Government of India

The Government of India has issued various Guidelines to educational institutions, laboratories, hospitals etc., to prevent the spread of pandemic in the country. A copy each of these Guidelines is given at Appendix II.

IV PRODUCTION AND IMPORT OF OSELTAMIVIR API (TAMIFLU)

17 As per the brief note furnished by the Department, the production of Oseltamivir is only possible through Shikimic acid route which is currently available only from China. As such, the prices of Shikimic acid have been highly volatile and have moved between $ 45 and $ 475 per kg. The present price is $ 400 per kg. The possibility of ban on export of Shikimic acid from China has also been apprehended. Regarding the strategy of Government of India to obtain Shikimic acid from China in future for its continuous uninterrupted supply the Department in their written reply stated as under:-

> "At present the Government do not have any plan to get into the production of Oseltamivir API through Central Public Sector Enterprises (CPSEs). This issue has been examined by the Department of Pharmaceuticals and certain central public sector enterprises and it was decided that it may not be economically viable for Public Sector Undertakings (PSUs) at this stage to enter into production. Being dependant on the agricultural resource, the availability of Shikimic Acid depends upon the seasonal output of star anise crop. Considering limited usage of Shikimic Acid any long term commitment in the matter need to be taken based upon various factors including the actual production and requirement of oseltamivir as also the spread of H1 N1 Flu pendamic. At the same time, the Government is exploring the possibility of development of alternate sources of getting Shikimic Acid or Oseltamivir API. Department of Pharmaceuticals is closely monitoring the availability position of Shikmic Acid and Oseltamvir API."

18. On being asked whether any other source of production of Oseltamivir in addition to Shikimic acid route has been explored by NIPER or any other research institution or the pharmaceutical industry, the Department in their written reply submitted as under:-

> " Oseltamivir (Tamiflu) is produced in India by several manufacturers, for which shikimic acid serves as a starting material that is extracted from the seeds of Star anise *(Illicium vernum)*, an evergreen Chinese plant. Besides Star anise, Shikimic acid is also produced form the leaves of *Ginkgo biloba* tree. Since both raw materials are in short supplies, an alternate and sustainable source is being explored and ICMR is conducting a research to produce this drug in the country indigenously through non – Shikmic Acid route. This includes exploration of other sources for production of Shikimic acid viz. microbial fermentation process, identification of Indian plants and optimization of extraction process, use of plant tissue/hairy root culture, development of enzymatic biotransformation process, production of Shikimic acid using recombinant *E. Coli* as host. Research proposal entailing the above processes/sources for production of Oseltamivir are being evaluated by Indian Council of Medical Research (ICMR) for financial support, including one proposal from NIPER, Mohali. Proposals have been technically approved and are being processed for release of grant".

19. Regarding other chemical routes available for production of Oseltamivir, the Department in their written note stated that there are more than one chemical routes available for production of Oseltamivir. The patent holder Roche has licensed the production to Hetero Drugs based on use of Shikimic acid. Details of producers in USA & Mexico are not readily available with them.

20 As per brief note furnished by the Department, Shikimic acid is under Open General Licence (OGL) and, therefore, the possibility of hoarding by traders in India and elsewhere cannot be denied. On being asked as to why no restriction has been made on its import in view of its possible hoarding, the Department has stated as under:-

> "The Department of Pharmaceuticals is regularly monitoring the stock of Shikimic acid in the country. It is also trying to gather details of traders if any in the country that are engaged in trading of Shikimic acid. Based on the position reviewed in the department, the Directorate General of Foreign Trade (DGFT) has been advised to have closer monitoring of the import of this commodity. Government of India has no control, if hoarding of Shikimic acid is done outside India. Once an item is under OGL, all importers willing to import may do so. This open policy, prima facie, will prevent any monopolistic practice such as hoarding. Any restriction on import may, in fact, lead to hoarding and monopoly by the license holder".

21. The Department further added that the retail sale of Tamiflu has already been allowed and the hoarders, if any, may get benefitted due to volatility of the prices and availability of this medicine and there are provisions in the existing Foreign Trade Policy to impose anti-dumping, duties etc. in appropriate cases.

22. During briefing by the representatives of Department of Pharmaceuticals, the Committee were informed that Shikimic acid is a plant based material produced in laboratory. The plant is grown in China. On being enquired whether Department of Pharmaceuticals has taken up the issue with Ministry of Agriculture / Indian Botanical Research Institute so that the plant from which Shikimic acid is derived, can be grown in the country the Department stated in a written reply that they had not taken up this issue with Indian Botanical Research Institute so far.

23. Further in their written reply furnished by the Department of Pharmaceuticals it has been mentioned that there is no specific code for Swine Flu in the classification system, as such no details are available indicating the quantity and value of medicines and Shikimic acid imported/ available with Directorate General of Commercial Intelligence and Statistics (DGCIS), Kolkata. It was also informed by the Department that efforts were made to collect import data form DGCIS, Kolkata, for the period 1.4.08 to 31.3.09 and 1.4.09 to 31.7.09. E-mails were also sent to Commissioner (Imports), Mumbai Ports and Chennai Ports requesting them to furnish the import data for the above period. Further, e-mail was also sent to Commissioner

(Cus.& EP), CBEC, DOR, New Delhi for sending import data for the period 1.5.09 to 9.9.09. However, no import data has been received from any of the above offices so far.

24. Regarding indigenous production of different medicines to deal with Swine Flu, the Department in their written reply stated that there are six Pharma companies engaged in supply of Oseltamivir 75 mg capsules in the country. Four of these (namely Hetero Drugs, Cipla, Ranbaxy and Strides Arcolab) have facilities for indigenous production of Oseltamivir from its raw material: Shikimic acid. Roche has no local production in India and is supplying Oseltamivir capsules by importing from their corporate set up. The remaining Indian company NATCO has only formulation capability for the capsule based on Oseltamivir API.

The Department in their Brief note submitted as under:-

> "Influenza A H1N1 is treated through antiviral medications. One particular remedy, used worldwide, is Tamiflu (Oseltamivir Phosphate) 75/45/30 mg capsules. Supplied by Roche, is considered very effective against the disease. Oseltamivir/Tamiflu is the most preferred treatment and Prophylaxis globally as well as in India.
>
> Other anti-viral medicine Zanamivir sold by GSK globally as "Relenza" is also in the market as second line of treatment. Cipla has also recently launched its generic version "Viranja" in the form of packs of 20 capsules suitable for use @ 4 Rotacaps per day (for a 5 day course) alongwith an applicator (Rotahaler)."

25. On being asked whether the Department of Pharmaceuticals intend to promote all the medicines at equal footing, the Department in their written reply submitted as under:-

> "At present only Oseltamivir capsules are permitted for sale in the country by Drug Controller General of India (DCGI). As soon as other medicines are approved, the DoP would render all possible assistance to the Pharma Industry to go ahead with the production/ supply of the same".

26. On being asked about the efficacy of the medicines other than Tamiflu (Oseltamivir), the Department in their written reply submitted as under :-

> "Relenza & Virenza are based on the API: Zanamivir. This medicine is reportedly not as effective as Tamiflu and it is reportedly used as second line treatment. According to Cipla company who have launched their product recently, the response has not been very encouraging. Globally, Tamiflu (Oseltamivir) is considered as the most effective medicine".

27. It has also been submitted by the Department of Pharmaceuticals that neither the Department nor the National Institute of Pharmaceutical Education Research (NIPER) has made any study to develop any Swine Flu medicine with the Private Sector.

V STOCK, DISTRIBUTION AND SALE OF MEDICINE TO DEAL WITH SWINE FLU

28. During the briefing, the representatives of Department of Health submitted before the Committee that they are maintaining a stockpile of four crore capsules of Oseltamivir and four lakh bottles of pediatric syrup out of which one crore has been distributed to all States and Union territories to ensure that there is a stockpile available in each district. When asked whether stockpile is commensurate with the demand, the Department in their written reply stated that ten thousand capsules of Oseltamivir have been provided to each district. (Maharashtra, Karnataka, and Delhi) which are reporting community spread including rural community have been provided additional quantity as per demand.

29. The Department in their written note also submitted that sufficient quantities of the drug have been given to the State Government to ensure its availability in all treatment centres.

30. As regards State-wise database indicating the probable availability of medicines the Department informed that the Ministry of Health and Family Welfare are having enough quantity of medicines to meet any eventualities and till date no shortage has been reported from any part of the company for treatment of this disease.

31. When asked as to how the unused drugs should be utilized, the Department in their written note stated that "The drug Oseltamivir has a shelf life of five years. Apart from this pandemic, the drug could be used for avian influenza and seasonal Influenza."

32. Stock position of Oseltamivir Formulation, Oseltamivir API and Shikimic Acid under voluntary banking arrangement made by Department of Pharmaceuticals as on 13.10.2009 is as under:

Sl. No.	Name of Company	Latest committed stocks to DoP under Banking Arrangment	Total stocks available					Comments
			API (Kgs)	Shikimic Acid (Kgs)	Shikimic acid (under process) 2-3 weeks reqd.	Capsules Nos. in Million	Total (Equivalent to million Capsules)	
1	Hetero	200 kg. + 100 kg 85 kg.	1640	20 t (Eq.to 5t API)	NIL	1.70	71.1	Total stocks including 200 Kgs committed for DoP plus 85 kgs on behalf of NATCO(*) and 100 kg on behalf of Roche.
2	Cipla	100 kg.	279.50	Nil	Nil	7.19	10.98	
3	Ranbaxy	100 kg.	183	750 t (Eq.to 187.5 Kg. API)	1950 Kg. (equivalent to 487.5 kg API)	NIL	9.57	
4	Roche	5,52,660 capsules.	--	--			0.55	
5.	Strides	100 kg.	704	NIL	Nil	2.34	10.38	
6.	Natco	15 Kg. + 85 Kg.	85	--		*0.39*	2.24	**M/s Hetero

Sl. No.	Name of Company	Latest committed stocks to DoP under Banking Arrangment	Total stocks available					Comments
			API (Kgs)	Shikimic Acid (Kgs)	Shikimic acid (under process) 2-3 weeks reqd.	Capsules Nos. in Million	Total (Equivalent to million Capsules)	
		of API*						Drugs have committed to keep Buffer stock of 85 kgs. on behalf of Natco Pharma
Total		**700 Kg. API + 0.55 million Caps**	**2891.5**	***5187.5 Kg API Eq.***	***487.5 Kg.***	***11.62***	**104.82**	

33. It has also been mentioned by the Department that Hospitals in private Sector identified by the State Governments are being provided Oseltamivir by the concerned State Governments and as a public health intervention. Oseltamivir is also given to close contacts of a patient, then it not only breaks the transmission cycle, but also provides protection to the individual till such time he takes Oseltamivir (Chemoprophylaxis) thereby preventing its further spread. This intervention is only done through the public health system using the tool of contact tracing. As regards the purchase of medicine from open market, that can only be purchased on the basis of a doctor's prescription.

34. When asked whether the Department of Pharmaceuticals has made any study to evaluate the number of patients affected by H1N1 and the requisite quantity of Tamiflu and other medicines for the treatment of disease, the Department informed the Committee that healthcare delivery is within the purview of Ministry of Health & Family Welfare, which regularly studies the H1 N1 Flu cases to evaluate the demand and availability of Tamiflu. They also informed that no gap in demand and supply has come to the notice of Department of Pharmaceuticals.

VI MONITORING BY THE DEPARTMENT OF PHARMACEUTICALS AND ROLE OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY ON THE AVAILABILITY OF MEDICINE

35. During the presentation made by the Department before the Committee on 16 September 2009, it was informed that as a proactive step, the following measures have been initiated by Department of Pharmaceuticals:-

- Daily Compulsory reporting of Stock position to NPPA under EC Act - Introduced by Department of Pharmaceuticals
- Weekly reporting of exports also introduced.
- Weekly meeting by Secretary, Department of Pharmaceuticals with the manufacturers to assess stocks, assist Industry in their manufacturing/ supply problems & monitor relevant parameters.
- Voluntary stockpile of API equivalent to 7.57 million capsules created with the companies at no cost to Government of India.
- Stockpile replenished subsequently to compensate supplies to Government procurement.
- Secured import duty exemption for import for banking arrangements.
- Interventions made for issues relating to supplies/ production of medicines.
- Assessment of preparedness of CPSUs to undertake manufacture of Oseltamivir formulation if required.

36. The Department in their written reply submitted that on the advice of the Department of Pharmaceuticals, NPPA has issued an order under the Essential Commodities Act directing the six known manufacturers and any other company providing Oseltamivir based formulation packs, to provide a daily report on the quantitative details of Oseltamivir API and Oseltamivir based formulation packs covering opening/closing stocks/purchases/sales of Oseltamivir API and formulations. The six companies are:

1. M/s Hetero Drugs Private Limited
2. M/s Cipla Limited
3. M/s Ranbaxy Limited
4. M/s Roche
5. M/s Strides Arcolab Limited
6. M/s Natco Pharma Limited

The six known manufacturers are keeping a buffer stock of 100 kg/each of API on behalf of the Department of Pharmaceuticals. This stock is committed to the Department of Pharmaceuticals irrespective of their other commitments.

NPPA is receiving daily reports from the six manufacturers since the date of issue of order, i.e. 11 May 2009. The weekly reports regarding exports are being received in the Office of DGFT.

As per the the reports received upto 7 October 2009, M/s Hetero Drugs has put 5 million capsules and M/s Natco has put 2,42,960 capsules for sale in the retail market.

As per latest report dated 21.10.2009, the six manufacturers are maintaining the buffer stock committed by them.

37. It has been stated in the note furnished by the Department of Pharmaceuticals that Director General of Foreign Trade (DGFT) is regularly monitoring on weekly basis the exports of medicines being carried out by the manufacturers. The imports are being made as per existing Foreign Trade Policy. At present DGFT and DoP are closely monitoring the export/production/availability position of Oseltamivir API, formulation and Shikimic Acid. Indian companies are exporting Oseltamvir formulations & API to countries like Guyana, Honduras, Panama, Peru, Colombia, South Africa, Ecuador, Korea, South Africa, Maldives, Venezuela, France, Netherlands, Mauritius, Iran, Uruguay, Guyana, Korea, Cuba, Yemen, Afghanistan, Nicaragua, Cost Rica, Bangaladesh, etc.

VII VACCINE FOR PREVENTION OF SWINE FLU

38. During the course of oral evidence, a representative of the Ministry of Health and Family Welfare informed the Committee that a vaccine for prevention from swine flu shall be introduced in the market soon. In India, three companies, viz. Serum Institute, Panacea Bio Tech and Bharat Bio-Tech have been identified to promote indigenously manufactured vaccine. He also informed that the vaccine would be available in the market by March 2010. Before that international manufacturing companies may launch their vaccine. The Government of India is in dialogue with all the international manufacturing companies for procuring interim quota for our front line health workers. WHO may also render some assistance in this regard. The latest position is given at Appendix III.

39. The Department of Pharmaceuticals has further informed that as per the information received from Ministry of Health and Family Welfare vaccine would only be introduced after the laid down protocol of clinical trial and approval of the regulatory authority.

VIII STRATEGY FOR FUTURE AND CO-ORDINATION WITH OTHER MINISTRIES/ DEPARTMENTS

40. During the course of briefing the representative of the Ministry of Health and Family Welfare expressed his apprehension over the possibility of mutations of H1N1 virus in the coming winter season. He was of the opinion that if virus mutates, the current American Vaccine will also become useless and the current Indian Vaccine would also become useless.

41. On being asked whether any study has been done by ICMR/ Ministry of Health and Family Welfare on the possibility of mutation of H1N1 Virus in the coming winter and whether any preventive measures/ strategy has been adopted by Department of Pharmaceuticals to meet such a contingency in case H1N1 Virus mutate in the coming months, the Department in their written reply stated that studies to see mutation of H1N1 virus are being conducted by ICMR's National Institute of Virology (NIV), Pune. Whole genome sequencing has been carried out for eight isolates. So far, no mutation has been noted. The information on preventive measures/strategy to meet such a contingency in case H1N1 virus mutates in coming months would be available with the EMR, Division of DGHS, Ministry of Health and Family Welfare.

The Department of Health Research is conducting virological surveillance and studying the character of the virus to detect possible mutations.

42. During briefing, the representative of the Ministry of Health and Family Welfare expressed apprehensions of a possible combination of Swine Flu virus and Bird Flu Virus. On being enquired about the preventive measures proposed to be taken by the Ministry of Health and Family Welfare to ward off catastrophe which may happen in case virus of Bird Flu (H5N1) which has mortality rate of more than 50 per cent mix with Swine Flu (H1N1) virus, the following submission was made by the Department in their written reply :-

> "If there is a possible combination of swine flu virus and bird flu virus, constant monitoring of this has to be done in collaboration with Department of Animal Husbandry, Ministry of Agriculture. Preventive measures are required to be taken to ward off catastrophe which may happen in case virus of Bird Flu(H5N1) which has mortality rate of more than 50 per cent mix with Swine flu (H1N1) virus.
>
> There is a possibility of the Avian and Human virus combining to form a novel virus. This could be prevented by stamping out Avian Influenza out breaks and minimizing contact of humans with infected birds. Department of Animal Husbandry is keeping a watch through ongoing surveillance to detect outbreaks in birds early to contain them".

43. As regards coordination with other Ministries/ Departments, the Department of Pharmaceuticals in their written note stated that as on date the healthcare system to

deal with pandemic disease of Swine Flu has multiplicity of stakeholders. These include Ministry of Health & Family Welfare (responsible for medical education including healthcare delivery and regulation of medicines), Department of Pharmaceuticals (responsible for R&D, production and availability of medicines), DGFT (for import and export of medicines), etc. In spite of above cited different roles, there is some overlapping in the allocation of subjects. On being asked about the mechanism presently available in the Government to interact and co-ordinate various activities in the matter of production and availability of Swine flu, the Department stated that considering the gravity of the current Swine Flu pandemic, effective coordination is being done through regular meetings of the Committee of Secretaries under the Chairmanship of Cabinet Secretary. The Departments also interact amongst each other for coordination and follow up.

44. 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 position of Shikimic acid and Oseltamivir API which are used for the production of drug i.e. 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 gain and at the cost of the common man. Further, chances of medicines for 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 medicines 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 API and capsules, the Committee recommend 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 cases with the onset of winter.

(Recommendation No.1)

45. 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 centres and (iii) Quarantine measures. However, most of the centres/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 medicines 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.

(Recommendation No.2)

46. 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 centres. They, therefore, impress 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 have only one or two Laboratories, the Committee recommend that Private Laboratories may be appropriately encouraged to supplement the efforts of the Government for detection of Swine flu cases.

(Recommendation No.3)

47. The Committee note that though 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.

(Recommendation No.4)

48. 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 flue affected individuals is encouraged proactively so that the transmission cycle of the H1N1 virus is countered.

(Recommendation No.5)

49. 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 evergreen 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 materials i.e. 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 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 is averted.

(Recommendation No.6)

50. 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 Oseltamiviror 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 Organisations like ICMR and NIPER in their endeavours towards making India self-sufficient in producing Oseltamivir medicine to counter Swine flu.

(Recommendation No.7)

51. 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 medicines 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/Departments did not oblige. The Committee take a strong exception to the callouness 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/Departments and desire the Department of Pharmaceuticals to play a proactive role in the process.

(Recommendation No.8)

52. 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.

(Recommendation No.9)

53. 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 Enterprises (CPSE) for the reason that they have not found it economically viable for the 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 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 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 another 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 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 or 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 Oseltamivir despite the same being unviable. Such company should be compensated suitably, if necessary, through budgetary grant.

(Recommendation No.10)

54. The Committee note that sufficient quantities of the 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. However, in view of the rare nature of the raw material used to produce Tamiflu, 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 governments to bring to the Department's notice any gap in the demand and supply of Tamiflu. This is all the more necessary to avert the wastage of the precious medicine in view of having adequate buffer stock in anticipation.

(Recommendation No.11)

55. The Committee have been given to understand that the medicine (Tamiflu) can also be used for the treatment of avian/seasonal influenza/flu. Hence, the possibility of Tamiflu 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 flue is used appropriately only after confirming the presence of H1N1 virus in the flu/influenza affected people.

(Recommendation No.12)

56. 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.

(Recommendation No.13)

57. 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 for 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.

(Recommendation No.14)

58. 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 multidisciplinary 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 Tamiflu 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 contrued 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.

(Recommendation No.15)

New Delhi;
10 December 2009
19 Agrahayana, 1931 (Saka)

ANANTH KUMAR
Chairman,
Standing Committee on
Chemicals & Fertilizers.

APPENDIX-IV

EXTRACT OF MINUTES

SECOND SITTING

(16.09.2009)

The Committee sat from 1430 hours to 1700 hours.

Present

Shri Ananth Kumar - Chairman

MEMBERS

LOK SABHA

2. Smt. Sushmita Bauri
3. Shri Prabhatsinh P. Chauhan
4. Shri K. D. Deshmukh
5. Shri Ganeshrao Nagorao Dudhgaonkar
6. Shri Madhu Koda
7. Shri N. Peethambara Kurup
8. Shri Baidyanath Prasad Mahato
9. Shri Ponnam Prabhakar
10. Shri Ashok Kumar Rawat
11. Shri Tufani Saroj
12. Shri Suresh Kumar Shetkar
13. Shri N. Cheluvaraya Swamy
14. Shri Narendra Singh Tomar

RAJYA SABHA

15. Shri J. D. Seelam
16. Shri Raghunandan Sharma
17. Dr. C. P. Thakur
18. Shri Brijlal Khabri
19. Shri Mahendra Sahni
20. Shri Raj Mohinder Singh Majitha
21. Shri Biswajit Daimary

SECRETARIAT

1.	Shri N. K. Sapra	-	Additional Secretary
2.	Shri P. Sreedharan	-	Joint Secretary
3.	Shri C. S. Joon	-	Director
4.	Shri A.K. Srivastava	-	Deputy Secretary
5.	Smt. Balwant Kaur Saimbhi	-	Deputy Secretary

I. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1. Shri Ashok Kumar, Secretary
2. Shri Mathew C. Kunnumkal, Additional Secretary & Financial Adviser
3. Shri Devendra Chaudhry, Joint Secretary
4. Shri Arun Jha, Joint Secretary

II. MINISTRY OF HEALTH AND FAMILY WELFARE

1. Sh. Vineet Chaudhry, Joint Secretary

III. REPRESENTATIVES OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

1. Shri A.K. Banerjee, Chairman
2. Shri Om Prakash, Member Secretary
3. Sh. A.K Singhal, Adviser (Pricing)
4. Shri P. V. Rajeev Sebastian, Economic Adviser
5. Dr. A. K. Vishandass, Deputy Director General

IV. REPRESENTATIVES OF PSUs / AUTONOMOUS INSTITUTION

1. Shri T. K. Ranganathan, Managing Director, Hindustan Antibiotics Ltd.
2. Dr. Ms. Jayshree Gupta, Chairman & Mg. Director, Indian Drugs & Pharmaceuticals Ltd.
3. Shri S. Kundu, Managing Director, Bengal Chemicals & Pharmaceuticals Ltd.
4. Shri R. K. Vashistha, Managing Director, Rajasthan Drugs & Pharmaceuticals Ltd.
5. Shri S.L. Phadke, Chairman & Mg. Director, Karnataka Antibiotics & Pharmaceuticals Ltd.
6. Dr. P. Ramarao, Director, National Institute of Pharmaceuticals Education & Research

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

3. Thereafter, he called the officials of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), the Ministry of Health & Family Welfare and the Public Sector Undertakings and invited their attention to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

4. Then the officials of the Ministries and the PSUs introduced themselves. Thereafter, the Joint Secretaries of the Department of Pharmaceuticals gave audio-visual presentations on Demands for Grants (2009-10) as well as on the subject `Production and availability of medicines to deal with Swine Flu'. During the audio-visual presentations, the Chairman raised certain queries which were replied to by the Secretary and other officials of the Department of Pharmaceuticals.

5. Subsequent to the power-point presentations, the Chairman and members of the Committee raised some questions which were answered by the Secretary (Department of Pharmaceuticals), Joint Secretary (M/O Health & Family Welfare) and Chairman (NPPA). They also promised to furnish the requisite information in writing which was not readily available with them. Apart from various aspects concerning Swine Flu, the following issues related to the Department of Pharmaceuticals were discussed :-

XX XX XX

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6. XX XX XX

XX XX XX

7. A verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

XX Matters not related to this Report

EXTRACT OF MINUTES

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2009-10)

TENTH SITTING
(10.12.2009)

The Committee sat from 1500 hours to 1600 hours.

Shri Ananth Kumar - Chairman

MEMBERS

LOK SABHA

2. Smt. Sushmita Bauri
3. Shri Ganeshrao Nagorao Dudhgaonkar
4. Shri N. Peethambara Kurup
5. Shri Poonam Prabhakar
6. Shri Suresh Kumar Shetkar

Rajya Sabha

7. Shri Biswajit Daimary

SECRETARIAT

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

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

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

(i) xxx xxx xxx xxx xxx

(ii) Production and Availability of Medicines to deal with Swine Flue.

4. The draft Reports were adopted by the Committee with minor amendments.

5. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Reports by the Ministry of Chemicals and Fertilizers xxx xxx xxx and (Department of Pharmaceuticals) and present the same to both the Houses of Parliament.

The Committee then adjourned.

APPENDIX-VI

STATEMENT OF RECOMMENDATIONS/ OBSERVATIONS OF THE COMMITTEE

Reco. No.	Para No.	Recommendations/ observations
1	44	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 position of Shikimic acid and Oseltamivir API which are used for the production of drug i.e. 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 gain and at the cost of the common man. Further, chances of medicines for 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 medicines 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 API and capsules, the Committee recommend 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 cases with the onset of winter.
2	45	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 centres and (iii) Quarantine measures. However, most of the centres/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 medicines 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.
3	46	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 centres. They, therefore, impress 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 have only one or two Laboratories, the Committee recommend that Private Laboratories may be appropriately encouraged to supplement the efforts of the Government for detection of Swine flu cases.
4	47	The Committee note that though 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.
5	48	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 flue affected individuals is encouraged proactively so that the transmission cycle of the H1N1 virus is countered.
6	49	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 evergreen 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 materials i.e. 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 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 is averted.
7	50	. 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 Oseltamiviror 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 Organisations like ICMR and NIPER in their endeavours towards making India self-sufficient in producing Oseltamivir medicine to counter Swine flu.
8	51	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 medicines 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/Departments did not oblige. The Committee take a strong exception to the callouness 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/Departments and desire the Department of Pharmaceuticals to play a proactive role in the process.

9	52	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.
10	53	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 Enterprises (CPSE) for the reason that they have not found it economically viable for the 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 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 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 another 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 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 or 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 Oseltamivir despite the same being unviable. Such company should be compensated suitably, if necessary, through budgetary grant.
11	54	The Committee note that sufficient quantities of the 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. However, in view of the rare nature of the raw material used to produce Tamiflu, 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 governments to bring to the Department's notice any gap in the demand and supply of Tamiflu. This is all the more necessary to avert the wastage of the precious medicine in view of having adequate buffer stock in anticipation.
12	55	The Committee have been given to understand that the medicine (Tamiflu) can also be used for the treatment of avian/seasonal influenza/flu. Hence, the possibility of Tamiflu 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 flue is used appropriately only after confirming the presence of H1N1 virus in the flu/influenza affected people.
13	56	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.
14	57	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 for 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.
15	58	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 multidisciplinary 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 Tamiflu 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 contrued 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.

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