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GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department - Distribution of medicines in Health Care Institutions and for National Health Programmes - Recommendation of the State level committee - Orders issued

**HEALTH & FAMILY WELFARE (F) DEPARTMENT**

**G.O.(Rt)No.631/2020/H&FWD Dated,Thiruvananthapuram, 20/03/2020**

- Read 1 G.O(Rt)No. 572/2020/H&FWD dated 14/03/2020  
2 Report submitted by State Committee on 14/03/2020

ORDER

As per the Government order cited above, a committee was constituted for examining issues regarding the dispensing of medicines by Pharmacists. The Committee submitted the report and recommendations for clarifying the issue of drug distribution in various levels of health care.

Globally the Health sector is facing one of the biggest challenges in the form of pandemic COVID- 19 which affected more than 159 countries across the Globe. The situation demands quarantine of suspects and contacts at home, ensuring the care of their health, restricting the visit to hospitals for common conditions and ensuring serious cases get the treatment at Hospitals. This warrants the necessity of providing drugs and medications to the patients who are put on quarantine at their doorstep. In a state where prevalence of Hypertension, Diabetes, Cardiovascular diseases and other chronic diseases are very high, the chances of the infection getting severe is high and hence fall under high risk group. Therefore, it is the responsibility of the Government to ensure that all persons in home isolation and Quarantine are ensured of complying with the treatment for chronic diseases which they harbour. This has to be done by community level distribution of drugs at the doorsteps of each individual through community level workers.

Public Health is concerned with disease prevention and control at the population level, through organized efforts and informed choices of society, organizations, public and private communities and individuals. The practice of Public Health has been dynamic in India, and has witnessed achievements that impacted on the lives of the people of this country. Since independence, major public health problems like malaria, tuberculosis, leprosy, high maternal and child mortality and lately, human immunodeficiency virus (HIV) have been addressed through a concerted a, coupled with scientific advances and healthcare has led to a decrease in the mortality rates and birth rates. The role of Government by planning, programming and regulating is crucial for addressing these challenges and achieving health equity.

Government of India and State Government are implementing various health programmes to prevent the diseases and also to improve the health status of the population of the country. These programmes are being implemented in all States and Union Territories as per the guidelines issued by Government of India from time to time. The operational guidelines of the programmes is appended herewith.

The SCHEDULE K (Rule 23) of the Drugs and Cosmetic Act 1940 and the Rules 1945 deals with "Extent and Conditions of Exemption" Class 23 of Schedule K deals with exemption allowed in the case of medicine to be used for National or State Health Programme. Class 23 Schedule K provided exemption as follows:

**"23 Drug Supplied by:**

- **Multipurpose workers attached to Primary Health Centers/Sub Centers,**
- **Community Health Volunteers under the Rural Health**
- **Nurses ,Auxiliary Nurses, Midwives and Lady Health Visitors attached to Urban Family" Welfare Centers /Primary Health Centers/Sub Centers**
- **Anganwadi workers**

The above provisions in the Drugs and Cosmetic Act are important for the implementation of various National Health Programmes States in India. These programmes have made a tremendous impact on the public health side which is reflected in the declining mortality and morbidity rate in the country and in the state. **The state had achieved credible standards in public health care, which can be attributed to the concerted effort of the field level machinery and the effective public health delivery system run by the field level workers. The Infant Mortality rate (IMR- 10/1000 live birth), Maternal Mortality Rate (MMR- 42/100000 live birth), life Expectancy (75 years), low neonatal mortality, low Total Fertility Rate, etc are showcased as best health indicators often compared at par with developed nations.** These achievements are accomplished through the public health network, which had implemented the National Level Programmes through well oiled machinery of health workers, civil society and people. This included provision of vaccines, supplements, medicines and other consumables at the doorstep for penetrating in to the society.

The Public health history of Kerala has showcased many notable achievements which have changed the mortality and morbidity tables through the effective system of community based drug distribution system. All National and State level Public Health programmes and Public health emergency measures are implemented through the network of community level workers who are entrusted to distribute drugs as per the guidelines under the supervision of Medical Officers.

The service of the public health persons at field level was the crux of the success behind the implementation of public health programmes in preventing and controlling the epidemics and other public health hazards. In the floods which happened in 2018 and 2019 this was very evident in the fact that the occurrence of leptospirosis during the post flood period could be contained by **Doxycycline prophylaxis**. Leptospirosis is the dreaded complication expected in any flood situation due to contamination of water with leptospira – a spirochete, which is excreted through urine of Rodents and cattle. This

infection can be controlled by prophylactic use of doxycycline capsules. In 2018, the number of deaths due to leptospirosis in the post flood period was 212 where as in 2019, when Doxycycline prophylaxis by the multipurpose workers for the flood affected people was implemented, the incidence of mortality due to leptospirosis was brought down to 148. This shows the impact of drug distribution at the peripheral level.

In the fight for the Malaria elimination in the state, a progressive decrease in the number of cases was observed due to the impact of medicine distribution at the field level by multipurpose workers. In 2013, the prevalence was 1636 cases which showed a decline to just 57 cases in 2019-2020 through drug distribution at community level and now State is moving towards elimination of Indigenous Malaria.

As per the National Vector Borne Disease Control Programme, Malaria, Lymphatic Filariasis and Kala-azar are the three diseases under elimination (Sustainable Development Goal) by 2020-2025. The first and foremost strategy for the elimination of malaria is early diagnosis and complete treatment. In Kerala, *Plasmodium vivax* malaria is the commonest which contributes to 70% of the total malaria. As per 2013, malaria drug policy, Chloroquine for 3 days and Primaquine for 14 days is the treatment. For *Plasmodium falciparum* malaria, Artesunate combination therapy for 3 days and for mixed malaria (Pv and Pf), Artesunate combination therapy for 3 days and Primaquine for 14 days to be given. The treatment is given as per the direction of the treating doctor. The rest of the treatment for 13 days is given as directly observed by the Junior Health Inspectors in the patient's doorstep. This 14 days treatment is essential to prevent relapse. Due to the earnest efforts of the peripheral health workers, the incidence of indigenous malaria burden also reduced to less than half of 2015. If anti malarial drugs are not given by the field staff, the patient needs to come to the PHCs/hospitals everyday which may cause non-compliance and thereby drug resistance with complications including death.

#### Malaria Cases from 2015-2019

Year	No. of cases
2015	1549
2016	1547
2017	1192
2018	908
2019	656

As part of elimination of Lymphatic Filariasis, the two important strategies coined by WHO is, one to reduce the transmission of Lymphatic Filariasis and second to prevent the morbidity and disability of already affected people with lymphoedema and hydrocele. In the Sustainable Development Goals, Lymphatic Filariasis is targeted for elimination by 2020 globally. As part of that, the state is conducting Annual Mass Drug Administration Programme since 2004. Both DEC and Albendazole are being given to all the eligible people (Except children under 2 years, Pregnant women and seriously ill patients) on the same day. The drug is administered by trained volunteers like ASHA/Anganwady workers under the supervision of field health workers through out the country. By doing annual MDA since 2004 the state would be able to achieve reduction of Lymphatic Filariasis transmission in 9 out of 11 endemic districts. Currently MDA is being done in Palakkad and Malappuram districts. In addition to this, migrant screening is an important activity in all districts that have completed MDA programme, to prevent

resurgence of Lymphatic Filariasis. This is being done by the District Vector Control unit staff and PHC teams. They will conduct night blood smear examinations of these migrants and if anyone found positive for microfilaria, DEC tablets are being given for 12 days along with single dose of Albendazole as part of treatment. This is being given by the field health workers as it is difficult to bring these migrant workers to the treating facilities and the compliance also will be affected. Such missed out cases will be the reservoir of infection that may lead to resurgence of the disease in the country.

As per the guidelines issued by Ministry of Health & Family Welfare; Government of India, National Deworming Day is being implemented in all the States. On the Deworming Day Albendazole Tablet is given to children through Schools and Anganawadies.

**ORS** is distributed through Health care institutions like CHC, PHC, Major Hospitals, subcentres, Anganawadies and through ASHA's in the State. As per the Government of India guidelines, one ORS depot is mandatory for every 1000 populations. Patients and their relatives shall collect ORS from ORS depot, Subcentres, Anganawadies and also through ASHA's for their immediate use. As per the Government of India guidelines, the Zinc tablet is also need to be supplied along with ORS as it will reduce duration of the diarrhoea and also increase the absorption of water and electrolyte. It also improves the immunity and reduces the chance of diarrhoeal attack for 2 to 3 months. ORS is the best and cheapest available treatment for the control of diarrhoea and it is the most lifesaving drugs for diarrhoea.

**After the introduction of ORS therapy, diarrhoea and death due to diarrhoea are reduced. Still coverage of ORS, is improved 26% to 56% all over the India and a coverage of Zinc tablet improved from 0.3%-20.3%. However coverage of ORS & Zinc needs to improve by 90% by 2025 as per the Indian action plan for pneumonia and diarrhoeal diseases (IAPPD).**

As per the guidelines issued by the Ministry of Health and Family Welfare, Government of India **Anaemia Mukh Bharath** is initiated in the state for Anaemia Control among 6 Months onwards Population. India is one of the countries with very high prevalence of anaemia in the world. Nutritional anaemia is a major public health problem in India and is primarily due to iron deficiency.

The National Family Health Survey 2015-16 (NFHS-4), in Kerala, 35.7% of Children ages 6-59 months are anaemic, 34.3% of women (age between 15 and 49 yrs) are anaemic. Out of this, anaemia % of Pregnant and Non- Pregnant women are 22.6% and 34.7% respectively. In young children, iron deficiency is due to increased iron requirement during periods of rapid growth. In addition, infant and toddler diets are often poor in bio available iron, particularly post weaning. Children who suffer from anaemia have delayed psychomotor development and impaired performance; in addition they have 5-10 point deficits in intelligence quotient. Iron deficiency can cause significant central nervous system (CNS) damage even in the absence of anaemia.

**The state has achieved low MMR and low IMR due to the control of Anaemia in the community by the distribution of Iron Folicacid Tablets by multipurpose workers at sub centre level.**

Family Planning programme is an important programme of country. By implementing the Family Planning programme, the TFR of Kerala is reduced to 1.8 and India to 2.2. The Family Planning programme not only envisages population stabilization goals, but also promote reproductive health to reduce maternal, infant & child mortality and morbidity.

As per the **Reference Manual for Oral Contraceptive Pills** published by Family Planning Division Ministry of Health and Family Welfare Government of India, Oral Contraceptive Pills should be available as a contraceptive choice in all public health facilities. Oral pills available under the National Family Planning Program are - Combined Oral Contraceptives, Progestin Only Pills, Centchroman and Emergency Contraceptive Pills.

As per the guideline of Government of India ANMs and ASHAs are specifically responsible for the receiving and storing contraceptives in the health center according to recommended storage guidelines and issuing products to service providers according to FEFO (First-to-Expire, First Out) system of distribution. Under the scheme for 'Home Delivery of Contraceptives', ASHAs distribute the Oral pills and condoms at the doorstep of the beneficiary. This ensures the advocacy with user and their compliance to family planning programme all over the country.

**District Mental Health Programme** is being implemented in all districts of Kerala according to the National Mental Health programme guidelines. The team members include psychiatrist, clinical psychologist, psychiatric social worker, staff nurse and attenders. **Kerala is the only state which has a mental health programme at all districts and at present 21000 patients receiving medicines at the field level through the programme.**

The team conducts fixed day clinics monthly in community health centres; where mentally ill patients are seen and medicines are distributed for specific duration. The medicines are to be given uninterrupted or else the patient may go in for relapses. DMHP team is doing follow up of all patients in the line list available with district team. Issues have come up that only pharmacist can give medicines. If it happens in the District Mental Health Programme the whole activity will suffer and may adversely affects the patient with mental health problems.

**Non Communicable Diseases** like Diabetics, Hypertension, Heart Diseases and Cancer are posing great threat to the population of Kerala as studies quote that more than 52% of deaths occurring between the productive age group of 30 and 60 are due to one or other cause of NCD. Studies (PURE) show that 27% of Kerala adult males are having Diabetes Mellitus compared to 15% national average. 19% of adult female population is diabetic compared to 11% national average. Genetic predisposition, dietary habits and sedentary lifestyle are considered to be the reason for this phenomenon. 40.6% of adult males and 38.5% of adult females are hypertensive compared to 30.7% and 31.9% national average. Incidents of obesity, hyper lipedemia, heart attack and stroke are also high. Cancer mortality is extremely high in males in Kerala compared to national average.

In the recent survey conducted by Achutha Menon Centre for Health Science Studies, the NCD scenario in the state has further worsened with the results pointing that one out of three has Hypertension and one out of five have diabetes. The study also revealed that the level of normalcy attained for blood sugar and blood pressure even after early detection and management is significantly low compared to the standards.

Through the NCD control programme early diagnosis of disease and distribution of medicines were done free of cost at peripheral level through Primary Health Centres and Community Health Centres.

As the drugs were ceased to be provided at the periphery level institutions like sub centres, there was a huge attrition of patients especially the elderly people with limited mobility as they had to travel long distances to reach their concerned PHC's for getting

medicines. The Primary Health Centre caters to a population of 25 to 35 thousand and may be located in any corner of the geographical area of a Panchayat. People living in distant wards of the Panchayat often find it difficult to access these centres frequently resulting in dependency on private Pharmacies and Clinics. The attendance at the NCD clinics showed a steady decline in the sub centres which acted as the strong pillars of the program due to non availability of drugs at the sub centre. **The control rates of Hypertension dipped to 13% and that of Diabetes mellitus dipped to 16% in this period.** This had resulted in heavy out of pocket expenditure which is against the objectives of the National Programme and the interest of the Government. **Government of India in its guidelines have clearly directed to distribute medicines for NCD control through sub centre**

The state of Kerala is having a low prevalence of HIV cases amongst the states in India. This was due to an effective network of ART providers at all levels of health care which had ensured compliance to treatment by the patients. Also all the high risk behaviour groups like Commercial sex workers, homosexuals, injecting drug abusers and migrants were provided STI care through field functionaries in targeted interventions. The impact of this programme helped in reducing the number of deaths and morbidity due to the disease and also helped in lowering the prevalence of virus in the community.

**Revised National Tuberculosis Control programme**, which is renamed as National Tuberculosis Elimination Programme, is the cardinal public health management programme envisaged to eliminate Tuberculosis from the society. The programme functions through the distribution of anti Tuberculosis drugs to the patients directly by the field level providers, which includes multipurpose workers, ASHA workers, Kudumbasree Workers and even the close contacts of the patients who are acting as treatment supporters. This approach named as **Directly observed treatment schedule (DOTS)** done through such field workers created a platform to eliminate TB in our country and the state, which is lauded by all globally. Through this network of drug distributions at community level, the management of Tuberculosis in the State found profound success by ensuring treatment compliance and there by the prevalence of Tuberculosis coming down drastically in the state to the level of total elimination.

Nurse based home care is the back bone of **palliative care** in the state. There are many home care services under LSGD, palliative care units under NGO's, social service agencies etc and under hospitals including cancer centres. Many patients under home based palliative care are terminally ill cancer patients. Pain management is one of the major management of terminally ill cancer patients. Intolerable pain is a major concern for this group of patients. These patients are managed well by home care nurses who provide pain medicines prescribed by doctors. If the system is deranged, it will have a huge impact on the management of cancer patients and palliative patients. If the optimal pain management is affected.

A) Terminally ill patients will be required to bring the patients to hospitals which adds to their woes and the transportation of patients to hospitals may lead to physical difficulties

B) The fear of intolerable pain itself inflicts major mental distress to patients and their close relatives

Pain management through pharmacological means required monitoring of its side effects through clinical examination. This is best managed by nurses as they are trained in clinical medicine.

Manpower requirement for current home care services is a trained nurse/ nurses and palliative care volunteers. Under the present situation, it will be require adding pharmacist to the team which has no benefit to the patient except creation of additional posts. This will add to the cost of the services and the financial implications will be huge. The possibility of cessation of such services is a potential grave threat which shall affects thousands of terminally ill patients in the state. **More than 48,000 persons are being benefited through Home Care every month, the service rendered through community level workers through home visits.**

**Kerala has given the unique model of pain and palliative care, which is well acclaimed by the Health sector experts all over the world.**

The health care delivery system of the state delivers preventive, promotive, curative and rehabilitative health care services to the community with the help of different professionals like doctors, nurses, pharmacists, lab technician, radiographer etc. There are different acts pertaining to different professions like Medical Council act 2019 (to ensure transparency, accountability and quality in the governance of medical education in the country) Indian nursing council act 1947 (to establish a uniform standard of training of nurses, midwives and health visitors) and Pharmacy act 1948(to regulate the profession of pharmacy) and the rules related to that.

The state has the responsibility of organizing the system to ensure proper delivery of the services to the population/community in an organized, responsible way utilizing these professionals who are trained and regulated by above mentioned acts. The aim of the Government is to ensure safe, prompt, economical and efficient delivery of the services and national programme to the community through these professionals and supporting staff and achieve the stated objective of the Welfare State.

The Government has recognized the fact that the Doctors who are registered under IMC, the Nurses registered with the nursing council has underwent the stipulated training programme envisaged by the Act in their curriculum and they have the necessary knowledge and skill in eliciting and interpreting clinical signs , understanding the drug dosage, drugs interactions, clinical implications of drug treatment and monitoring its side effects. The JPHNs involved in the national programme also have a full fledged training about the drugs they distribute through the national programme under the supervision of a doctor.

The post of Pharmacist is available in all 848 Primary Health Centres, 227 Community Health Centres and other major hospitals. Presently a total of 1792 posts of Pharmacists are existing in Health service department. Temporary appointment of Pharmacists is also done in hospitals/Family Health Centres through HMC/NHM/LSG as per the demand requirement. The Government cannot afford to add additional human resources below the level of Primary Health Centres like sub centres and also to retain a buffer category for managing unforeseen shortages. It is the prerogative of the sovereign government to examine all aspects of the system and to take appropriate decision on creation of post depending on various aspects prevalent from time to time in all the Departments involved in governance.

As per the available statistics, only 35 % of the population is depending on the health services for their medical care. But the achievement for national programmes implemented in the state varies between 90 to 100% depending on type of programme making it evident that the success rate is much higher when the service is provided at the grass root level. Therefore, it is important to sustain the national programmes and its grass root level distribution of drugs as exempted in Drugs and Cosmetics act, for the

control/elimination of diseases of public health importance to progress and maintain the achievements the State had in the past decades.

The evidences from around the world shows that the medical management including distribution of medicines by nurse practitioners have yielded rich results in containment of public health emergencies. The National Health Services, UK, Thailand and all developed nations have adopted community oriented medical management utilizing the service of staff nurses for better distribution of public health services. Government of India through Ayushman Bharath scheme also envisages nurse practitioner based management at Health and Wellness centres.

Government has examined the recommendations in detail and while understanding the responsibility of the Pharmacy Wing in handling and dispensing of medicines at the Pharmacy Counters, the role of community level distribution of medicines for public health programmes in controlling major health issues as evidenced in the past in controlling the outbreaks of Leptospirosis, Malaria and in the recent context of global pandemic COVID19 where home isolation is mandated is also considered with importance. The responsibility of the health system in delivering preventive, promotive and curative services, especially at time of public health emergencies is also taken into consideration.

It is the bounded duty of the welfare state to ensure appropriate care of patients, implementation of various national health programmes and also managing public health emergencies. Considering the above mentioned facts and its implications on Public Health which has already been established through various studies and documented evidences reported in various Literature, the Government are pleased to issue the following orders;

1. The medical officers are empowered to manage drugs and consumables distribution at various levels of Health care in his/her jurisdiction utilizing the available Human resources for providing uninterrupted service to the public as being done throughout the country.
2. This provision is applicable for managing all National/State level health programmes and public health emergencies, as advised in respective Guidelines and Advisories.
3. All Health Department functionarie's primary responsibility is to ensure providing efficient health care, seamlessly through available resources
4. The Medical Officers are empowered to do appropriate arrangements regarding giving of drugs and consumables which are readily available in blister packs and labelled containers ; as practised all over the country as per the national Health program guidelines.

(By order of the Governor)  
**RAJAN NAMDEV KHOBRADE**  
**PRINCIPAL SECRETARY**

To:  
State Mission Director, National Health Mission, Thiruvananthapuram



Director of Health Services, Thiruvananthapuram  
 Drugs Controller, Thiruvananthapuram  
 Director of Medical Education, Thiruvananthapuram  
 Director, Sri Chitra Tirunal Institute for Medical Sciences & Technology,  
 Thiruvananthapuram  
 Director Regional Cancer Centre, Thiruvananthapuram  
 Director Malabar Cancer Centre, Kannur  
 Director Cochin Cancer Research Centre, Kochi  
 Director of Indian Institute of Diabetics, Thiruvananthapuram  
 Director, Child Development Centre, Thiruvananthapuram  
 Director of IMHANS, Kozhikode  
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 Section Officer

മേലുദ്ദേശ്യാർക്കു നം. 03 & എം.4 - 21735/20/DHS നീ 05/05/2020.

സർക്കാർ ഉത്തരവ് നം. G.O (RT) No. 631/2020/  
 H & FWD തീയതി, തിരുവനന്തപുരം, 20/03/2020 മേൽ  
 നടപടികൾ കോലി അയക്കുന്നു.

*(Signature)*  
 5/5/20  
 ആരോഗ്യ വകുപ്പ് ഡയറക്ടർക്കു  
 വേണ്ടി.  
*(Signature)*  
 5/5/20.

പകർപ്പ്: To DHS website

- To. 1) Asst. Director (Pharmacy) For U.S.P  
 2) DH Section 6/5/20  
 3) MSA Section 6/5/20  
 4) MSP & 6/5/20