that we come across in our working can be well imagined. I urge upon the Deputy Speaker also to ask the Minister to rectify such anomalies. I support this Bill and we are prepared to extend full co-operation to the Minister. But it is my humble request that the hon. Minister should bring forward a Bill on these lines in the days to come through which Members of Parliament may also get facilities and they may perform their duties with full efficiency.

SHRI VIRDHI CHANDER JAIN (Barmer): Mr. Deputy Speakar, Sir, I support the Governors (Emoluments, Allowances and Privileges) Amendment Bill, 1987. At the time our Constitution was framed, the Constitution makers had created the post of Governor after giving it due thought. Had the post of Governor not been created, it would have been difficult to conduct the affairs of different States in certain circumstances. Sometimes a vote of no-confidence is passed against a State Government and the Government falls, sometimes a State Government is dismissed. In these circumstances, only the Governor of a State conducts the affairs of that State till fresh elections are held. As such it must be noted that had the post of Governor not been there, the situation would have been volatile and it would have been difficult to conduct the affairs of the State. It is due to these reasons that the post of Governor is required. However, some qualification must be prescribed for appointment to the post of Governor. I have thoroughly studied the Constitution. In the Constitution, no qualifications have been prescribed except that the incumbent must be atleast 35 years old and he should not hold any office of profit. Except this the Constitution is silent about the qualifications of the Governor. If an illiterate person is appcinted as Governor, how he will discharge the duties of a Governor? The Governor, has to exercise his discretion in certain circumstances. Sometimes more than one parties have equal strength and in the circumstances the Governor has to decide as to which party should be asked to form the Government. The Governor has to take this decision at his own discretion. What I mean to say is that some qualifications must be prescribed for appointment to the post of Governor If it is not done, it will not be proper. Once Janata Government was also there. They had also appointed Governors. Communist party was also in power and it was extending its support to them. There were other parties also.

S. BUTA SINGH: They had also toppled the Governments.

SHRI VIRDHI CHANDER JAIN: What I mean to say is that they had also dismissed Governments. Government of Rajasthan was one of them. If at all, the office of Governor was ever misused, it was they who misused it. It is, therefore, imperative to ensure that the office of Governor is not misused.

[*English*]

MR. DEPUTY SPEAKER: You can continue tomorrow. We will take up half-an-hour discussion.

18.00 hrs.

HALF-AN-HOUR DISCUSSION

New Drug Policy

[*English*]

SHRI SHANTARAM NAIK (Panaji): Mr. Deputy Speaker, I stand here to initiate this discussion on New Drug Policy basically because this is a vital policy of the Government which is going to guide us at least for next four to five years. Therefore, the policy of the Government on this vital aspect of drugs tends to be very valuable.

At the outset, I would like to pinpoint a very preliminary thing, namely, in the document, which I have got here before me—Measures for rationalisation, quality control and growth of drugs and pharmaceuticals industry in India. It would have

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been apt and proper, if it had have been titled as the New Drug Policy of 1986 or whatever it is. Normally, we call this as New Drug Policy. You don't find this nomenclature anywhere, whereas on all the policies, whether on industry, health, labour, we find this nomenclature is correctly written on the cover. Therefore, I would like to know, as to why, this has been sought to be made that this is not a policy or something like that but some measures for rationalisation. If that is so and if something known as drug policy is coming forth, then I would like to know, whether the drug policy is coming or something titled as a drug policy is coming or whether these are only the rationalisation measures. I would like to have a clarificaiton from you in this regard.

Secondly, as per the contents of this policy, I have this title as "Measures for rationalisation, quality control, growth and Industry in India." The contains all the vital aspects of what a policy should contain. If this is not a policy, then what is the policy of the Government? That is what I would like to know. If this is not a policy and if the policy is to give the objectives, why the basic objectives, numbering four are given here wherein all the aspects which should be contained in a policy are mentioned. So, these are the basic things which you may explain to me.

Thirdly, as per this document of rationalisation, it is said that an impression has been created that, we still give scope for multi-nationals, in a sense that, if the multinationals dilute their policies to 40 per cent; they are practically treated on par with Indian companies. Whereas, it is said, in U.S.A., even companies with 10 per cent equity are called foreign companies and in Canada with 5 per cent equity, they are called as foreign companies. If it is so, then why that 40 per cent equity should be treated on par with Indian companies?

Then, I would like to take you to Para 3(2) of this document, which says, I quote:

> "With a view to exercise closer scrutiny over introduction of the new drugs in the country, the Drugs and Cosmetics rules will be amended to define clearly the new drugs and to give statutory basis to detailed guidelines which would be drawn up for the scrutiny and approval of the new drugs."

Normally, the definition part of anything is contained in the Act, and not in the rules. If some basic change is to be made with respect to policy, or if any measures are to be taken, the basic amendment has to be in the Act. Therefore, I would like to know whether, apart from any amendment to the Drugs and Pharmaceuticals Rules you may propose to make, you are going to amend the Act, or not. If the Act is not amended, there would not be any substantial change. You know very well that only minor details are provided for in the rules.

Secondly, is it true that under the new policy, 60% of the drugs will be outside the price control scheme, as against the earlier 14%? This is one of the criticisms that have been levelled. I would like to know whether it is correct.

Further, what are you going to do with respect to these generic names? In fact, it is a sound proposition to use generic names, rather than pharmaceutical names. I know there had been a problem. People have gone to the courts. I would like to know whether the policy of the Government stands; and if it stands, whether it stands with respect to single ingredient formulations, or also with respect to the multi-ingredient formulations. If the matter is in the court, what future measures are you going to take?

Incidentally, I would also like to know something with respect to taxation on drugs: They say that about 42% of the turnover is taken away by these taxes and octrois, as far as drugs are concerned. I

would like to cite an example, as far as my small territory of Goa is concerned. I would like to tell you that sales tax on drugs and medicines has been completely abolished in this budget, in my territory of Goa, because ultimately drugs and medicines are things which people require. We are having a goal of Health for All by 2,000 A.D. If we cannot attain such a health programme by that time, we can at least think of having tax-free medicines by 2,000 A.D. Can you assure us that?

THE MINISTER OF INDUSTRY (SHRI J. VENGALA RAO): Abolition of sales tax is a State subject.

SHRI SHANTA RAM NAIK: I am just saying how our Territory is coming forward to see that cheap medicines are made available to people. You, on your side, have to do something, or take appropriate steps, so that these drugs are available cheap in the market.

You are also contemplating this National Drugs and Pharmaceuticals Authority. It has been contemplated under paragraph 3(1). I would also like to know what exactly this machinery is going to do.

MR. DEPUTY-SPEAKER: Mr. Naik, you put the questions now.

SHRI SHANTARAM NAIK: Secondly, you have also, under paragraph 3.4, contemplated a Bank, known as the Central Information Bank. The paragraph says:

> "During the 6th five year Plan, central and peripheral units would be set up to monitor adverse drug reactions. It is also proposed to develop a Central Information Bank on the safety, efficacy, prescription and use of all drugs."

I would like to know whether, if this Authority viz. the National Drugs and Pharmaceuticals Authority was sought to be created, what was the need for this particular Authority. Cannot both these Authorities be combined, and work allotted to them? I would like to have a reply on these aspects.

Secondly, as far as quality control is concerned, are you going to entrust this job of quality control to private institutions, apart from the machinery of the Government? I think it will be very dangerous, unless you are very sure of the institutions which will be carrying out these jobs.

Regarding quality control, you know the things which are happening—the way people take medicines which are spurious and sub-standard. In some of these drugs, there are different qualities also. At this stage, if you are contemplating the entrusting of this quality control job to private institutions, I think you have to reconsider this aspect seriously.

As far as drug pricing is concerned, for six years, this matter was in the court. The Notification issued by you was challenged in the High Court, and after long five years, it was struck down by the High Court. Then you went to the Supreme Court. Now, fortunately, for the country and fortunately for your Ministry, we have won the matter in the Supreme Court. Therefore, what was the effect made during these years to convince the Supreme Court in such matters which are in the interest of the people. Should this expressly be decided? In fact, in the Supreme Court judgment, it has been said that the interest of the consumer and not the interest of the manufacturers should be the prime consideration; and the court has upheld the contention of the government in this regard. But, nevertheless, the fact remains that the matter in respect of prices, which was a good Notification of the government, remained in the courts for 5-6 years without the benefit of the Notification having gone to the People.

Regarding formulations, the Supreme Court in the judgment also have quoted Dr. N.H. Antia; they said, what is the need of the 6000 formulations spending Rs. 2,500 crores when hardly a few formulations

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would do as per the recommendation of the WHO. Are you going to do something in the matter of reducing formulations or not so that the limited number of formulations as suggested by the WHO are marketed and produced so that people get good formulations in the market.

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETRO-CHEMICALS IN THE MINISTRY OF INDUSTRY (SHRI R.K. JAICHANDRA SINGH): The first question which was raised by the hon. member is about the title of the documents as to why we have called this measure for rationalisation, measure for quality control and measure for growth of drugs and pharmaceutical industry. As I have said on various occassions in this House and on the Floor of the other House that this is not a new policy document. The 1978 policy still stands to the extent that we have brought in these measures; to that extent, the old policy stands amended. But there are many other areas which we have not mentioned. For example about the role of the small scale sector, we still have reservations for them. We have not mentioned some of the items here and those items which are not mentioned here, they are still there; and they stand; the old policy of 1978 stands to the extent; and to the extent these new measures suggest, the old policy stands amended. That is why we have called it a measure for rationalisation, for quality control and for growth of the drugs and pharmaceutical industry.

Another point which the hon. member has mentioned is about the role of the multi-national companies. Why is it that we are treating them with 40 per cent or less equity—their equity being diluted. Why are we treating all these multi-national companies alongwith wholly Indian sector that is those of the companies which are wholly indigenous? This is not the exclusive jurisdiction or parameter of this department, but the multi-national companies; to the extent that they have diluted upto '40 per cent or less, this concerns the entire industry; not only the Ministry of Industry, or the Department of Chemicals and Petro-Chemicals but even industries in other sector like energy or in other area. Perhaps, there has been a lot of write up; it has also been mentioned by the hon. members in this House and also in the other House that the Government of India should perhaps re-examine this, because in some other countries the equity participation of the multi-national companies is much less. But this is something which the Government of India will have to take up at an appropriate time. This is not the time we can discuss this, because this spans not only this Department or the Ministry of Industry, but it also concerns the other departments and other Ministries as well.

About the amendment of the Cosmetic Rules, if it is necessary that we have to amend the Cosmetic Act we will do it. We have mentioned that, about the introduction of the new drugs in the country it will be sufficient if we amend the rules. It will be sufficient to give a statutory basis to the detailed guidelines and if necessary we could examine the position about the amendment of the Cosmetics Act also but this will have to be taken up by the Health Ministry because the administrative Ministry is the Health Ministry and not the Industry Ministry. But we could pass on this information to them.

Then another provision mentioned by the hon. Member is that 60 per cent of the entire gamut of the drugs would be outside the price control. It is a little premature for me to react at this stage because we have still not got the list of Category I and Category II. Category I would include the drugs to be used in the National Health Programme, the diseases the eradication of which has been in the National Health Programme, by the Health Ministry. The Health Ministry has been asked to draw up a list of drugs which they are going to use for the eradication of these diseases, in the implementation of the National Health Pol-

icy. That list should be forthcoming from the Health Ministry and we would go by that list. That is category I.

And Category II is, as you know, we have appointed a committee headed by the Chairman of the BICP and we are expecting the report on that either by the end of this month or by the beginning of June and as soon as the list of both the categories is available then we would be able to say how many drugs it will be within the price control and how much will be outside.

Another point which is mentioned is about the generic names. As you know, the view of the Government on this is very clear. But our hands are tied to the extent, that the matter is still in the Supreme Court and since it is *sub judice* we will not be able to comment, but the Government's intention is very clear, that we have taken a decision to have a display of the generic names twice the size of the brand names but because the Supreme Court case is still pending we are not able to say either this way or that way but that Government's view as of now is that the display of the generic names should be double the size of the brand names.

The hon. Member has mentioned about Sales Tax abolition in Goa. It is a very good step. I think it is a very positive step. This is a matter pertaining to the State Governments; we would be very happy if the other State Governments follow the pattern initiated by the Goa Government. Because this pertains to the States may be we could also perhaps write to them that they should examine this particular aspect and they should abolish sales tax at least on those items which are essential or may belong to Category I and Category II, or we can write to them but as I said it, this matter is absolutely within the jurisdiction of the State Governments.

The creation of the NDPA, this is going to be a very important institution because it is on this institution that the success of most of the meausres that we have initiated will depend How far the implementation will be successful will depend on this NDPA. We have given ourselves one full year to set up this authority. I would briefly mention one or two points. I have a whole list of its functions. May be I will spell out some of the important functions. One of the functions of the NDPA would be to screen the therapeutic efficacy and rationality for introduction of new formulations based on bulk drugs for banning of formulations which are irrational and/or of proven harmful nature; to formulate guidelines for packaging instructions with a view to ensure proper dispensing and use of drugs.

As the hon. Member also mentioned a little later, the development of central information system to disseminate information will also be taken into account by this NDPA. So we are having an exercise with the Health Ministry. Various considerations have been made. Various dialogues and interactions have been made between this Ministry and the Health Ministry as to the functions of the NDPA. We are also going to study some of the models which are in existence in other parts of the world. We would like that this policy measure be implemented properly and we would like to see that NDPA is set up on the lines of other agencies which have been set up in some other parts of the world. We are also studying some of the provisions of the NDPA in other parts of the world.

On the quality control measures, in fact, one of the new measures for rationalisation is on the quality control. Since quality control is a very important aspect and since most of the State Governments barring a few do not have sufficient financial back up and also do not have sufficient infrastructure by way of laboratories, or the number of drug inspector is not sufficient we have thought that we would recognise some of the drug laboratories of the private institutions which are above par and we are going to have a certification system by which these companies which have got very good testing laboratories, would be recognised in different parts of

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the country. And those of the drug companies which cannot have in-house quality testing system we would ask those companies to go through these testing laboratories. We are working out on that. This is a very good measure if we are able to implement this. About the quality of drugs produced in our country there have been complaints in various quarters that some of the drugs are spurious and some are sub-standard. I think, this can be checked. We only hope that we are able to implement this in letter and spirit.

The last point which the hon. Member mentioned is about price vis-a-vis the Supreme Court's recent case some time in April. This will be taken care of when the DPCO is enunciated. Once the list of category I and category II is drawn up, then the new DPCO will come into being sometime in July or August. But we will try to bring it as early as possible. This aspect which the Supreme Court has mentioned will be taken care of when the new DPCO is enunciated.

DR. CHINTA MOHAN (Tirupati): The main thrust of the Government should be to give quality drugs and also essential drugs to all people at all times. But unfortunately in this country people are not able to get even one pill of aspirin. And in some of the north-eastern States so many tribal people are dying without Methargine even after delivery. This is the state of affairs which continues even after 39 years of independence.

The Government's policy is to give health to all by 2000 A.D. Recently the Government had come forward with a statement saying that all essential drugs will be available by 1986 but when we look at today, even the minimum important drugs are not available in the market, particularly in the North-Eastern States. Today, even Bangladesh has got a good drugs policy but unfortunately our Government do not have a policy. Recently the Government have come out with a document saying that this is the new drugs policy going to be adopted by the Government. But it appears to me that this is nothing but the old wine in a new bottle. It does not have any importance, it does not have any significance at all. When we see the pharmaceutical market today, there are about 60,000 formulations in the country, out of which, the scientists in the country say, 80 per cent are unscientific. Doctors say that most of these 80 per cent drugs are harmful to the people. In spite of knowing this fact, the Government is still keeping particularly the multinationals and big industrialists in the country. We all accept that this industry should grow in the country to improve the economy of the country but, at the same time, health of the people is important, not the industry or something else. With due respect to the Cabinet Minister and the Minister of State, I would like to seek clarifications from the Government on some of the points.....*(Interruptions)*.

SHRI J. VENGAL RAO: If there are any defects, we will certainly rectify all those defects.

SHRI BASUDEB ACHARIA (Bankura): We want a full-fledged debate on drugs policy.

MR. DEPUTY-SPEAKER: More or less, it is going on like a full-fledged debate.

SHRI BASUDEB ACHARIA: This will not serve the purpose.

MR. DEPUTY-SPEAKER: The whole session we can have for this, not only one day.

DR. CHINTA MOHAN: I would like to draw the attention of the Minister to this new document which he has released very recently wherein he has put the medicines into three categories instead of four categories, thus keeping 250 drugs aside. I do not know with what intention, with what logic in mind he has avoided these 250 drugs and allowed the price to go from 60 per cent to 300 per cent. What is the logic behind this, I want to know from the Minister.

Coming to the banned drugs, the Government had announced four years back that 25 drugs are banned in this country. A murmur is going on outside the Parliament that some of the officials in charge of the Department of Chemicals have connived with the multinationals and the big pharmaceutical industrialists in the country and they are not announcing the banned drugs fully well. I know that they have announced it but in a very secretive fashion. Only about seven per cent of the practitioners know about these banned items today. Why is the Government failing to announce it through important media like T.V., radio, newspapers, etc.? I wish that the Government should come forward with these banned items at least by tomorrow, if not immediately.

Coming to the essential drugs, the big, important industrialists in the country are not producing even 50 per cent of the essential drugs in the country because they are not getting the remunerative price. There is no doubt about it. The Government is allowing the big pharmaceutical industrialists to manufacture tonics and other proteinous products, etc. I would like to know whether the Government is aware of the fact that these tonics, proteinous products, etc. are not useful to the human system at all. If so, then why is the Government not planning to ban these tonics and other formulations which are not useful to the human system at all?

As regards the committee for the monitoring of the drugs, just like the MRTP Commission, there should be a committee which should go into the quality of the drugs. Then only it can save the people from the present system of the drugs available in the country. Also I wish that there should be a Parliamentary Committee which should go into the policy. Just giving it to 3-4 persons who are not at all bothered to go into the details at all, will not serve the purpose. There should be an open debate on this. Then only we can put a thrust on this policy. There are some public sector undertakings like Hindustan Antibiotics Ltd., IDPL, etc. which are producing drugs. In spite of giving them incentives, in spite of giving them subsidy, these public sector undertakings are not able to produce even good antibiotics today. We are trying to import so much of anti-biotics from outside. Why is Government not planning to improve the public sector undertakings? Why is Government failing in this direction?

My friend Shri Naik said about the generic names. Parco Theraptic index does not permit 60,000 formulations as on to-day in the pharmaceutical market. Is there any plan with the Government that they are going to give only specific generic name to 400 pharmaceutical drugs as suggested by the pharmaceutical experts in the country as it is followed by Bangladesh?

I would like to know about these points from the hon. Minister.

SHRI CHINTAMANI JENA (Balasore): My other friends have already posed the problem. May I know from the hon. Minister-1. This new drug policy of the Government, can it counter the spurious and sub-standard drugs which are available in plenty in the market?

My hon. friend Shri Chinta Mohan has already told that about 60,000 formulations and medicines are available in the market now a days even if the physicians have prescribed about 400 varieties. Side by side there is no machinery either with the Union Government or with the State Government to compute about the reactions of 60,000 medicines which are used by the general public. Can this new drug policy counter and compute the reactions of these 60,000 or many thousands of medicines which are available in the country? If so, please give the details of it.

Is it a fact that a Committee was set up in the year 1979 to study and enquire into the allegations of the large scale profits done by multi-nationals foreign companies which are engaged in manufacturing the

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drugs? If so, what is the finding of this Committee and how can this new drugs policy counter such huge and undue profits by the drug manufacturers?

Hathi Committee in 1975 had suggested a list of 117 Life Saving and Essential Drugs, 34 of which were to be produced by the public sector industries. Since the big industrial houses were engaged in the production of drugs, they are not interested to produce it. So, may I know are the drugs like anti-malarial, anti-T.B., anti-falarial, anti-leprosy drugs available in the market are not available as per Demand: Essential, and life saving drugs are not available in plenty according to our indigenous requirements. How will this new drug policy help to produce such life saving essential drugs according to the indigenous requirement of our country?

I am grateful to the Government as well as the hon. Minister that in the new Drug Policy they have suggested delicencing of 94 bulk drugs. Will Government consider that this de-licencing benefit would be available to the small scale industries which are engaged in production of drugs and not to the big business houses?

According to the answers given to the question put by my hon. friend, Shri Shantaram Naik, that is, starred Question No. 8, the hon. Minister in his answer replied like this. I quote:

> "The prices have not yet been revised since the new drug price control order has not yet been announced."

May I know whether the new drug price control order has been announced? If not, when it is expected to be announced?

SHRIMATI JAYANTI PATNAIK (Cuttack): Sir, many of my questions have been put by the previous speakers. I would like to restrict myself about the broad-banding policy. Sir, broad-banding policy is to help production of right type of drugs and reduction in their prices. But I would like to draw the attention of the hon. Minister to the fact that the New Drug Policy may allow a licence to produce a mixture of say three types of analgestic or vitamins. It can change their proportion or slightly change the chemical structure of one or more of its ingredients and sell the new product under the new brand names. Sir, earlier the companies had at least to undergo the formality of applying and getting permission for manufacture of these drugs. Now, there may be uncontrolled growth of all sorts of irrational drug combinations sold under more and more number of newer and newer brand names. Under broad-banding policy, it is supposed to help the production of right type of products. But here there is no distinction between the ex-FERA Companies and the holding Indian companies. It is not the fact that equating the ex-FERA multinational companies with the holding Indian companies will jeopardise the interests of the Indian companies? There is no distinction between these two companies and because of this at the take-off stage the Indian companies may suffer a great deal. The Hathi Committee had recommended for channelisation of the foreign companies and also for encouragement of the growth of the national interests. I would like the hon. Minister kindly to throw some light on this.

Sir, for weeding out harmful drugs, the Government have already appointed an expert Committee. But sometimes what we see is that after using the medicines for so many years, we find one fine morning news item in the newspapers about the drugs that are in common use have become harmful. They give a wide publicity to this. For example, there was much hue and cry for quinoline group of medicines which was found toxic in foreign countries. These are treated as common medicines in our country for many years now. For instance, analgin is one such medicine which has been commonly used in the country. Generally people do not go

to the doctors for getting the prescription. They will use the slips which are already with them and they get the medicines and use them. But I would like the hon. Minister to come out clearly stating features of the drug policy and the Government should make it known to us that they either reject or accept these medicines. So, in this also we want to be enlightened.

Another thing, Sir, is about estrogen-progesterone. This is also a drug. It is said that one group of medical professionals advocate that there is a high dose of EP in it and it is dangerous for using it for pregnancy tests and that should be totally banned. One group of professionals say this. Another group defends the use of estrogen-progesterone. Sir, it is also reported that the drug is still being prescribed by many doctors for pregnancy testing and there seems to be no move on the part of the Health Ministry and medical bodies to send circulars to doctors all over the country warning them not to prescribe the drug like this for pregnancy testing and it is also seen that there is no move to develop and make available safer and cheap pregnancy testing kits. When two opposing medical viewpoints are stated and that too also equally and forcefully, what criteria will the Health Minister apply to decide which of the two opinions is more sound? And he should pronounce it in a much clearer way that the people should understand, specially the common people must understand.

About the pricing also, our previous speakers have already told about it and you know hundreds of price revision applications remain pending for months and years together and when the prices were revised after long delays, they had already been rendered obsolete by cost escalation that took place in the interim period. Of course, the present new drug policy the Minister had already announced. But now so many applications must have been pending and what is he going to do with them? And about the quality control also I would like to know whether all States have decided to have an independent body for the regulation. Of course, the Minister has already said about the Laboratory tests and all these things, but keeping in view the limited resources available, what is he going to say about it and what does the new drug policy speak on this?

[*Translation*]

SHRI VIRDHI CHANDER JAIN: Mr. Deputy Speaker, Sir, I want to ask only one question in this regard. A number of medicines which are banned in foreign countries, are being imported and supplied to the people in India. We are thus playing with the lives of the people. What steps are being taken in this regard? What is the policy of the Government in this regard?

Secondly, the prices of life saving drugs are very high which lower class and middle class people can ill-afford. I want to know the steps proposed to be taken by the Government to bring down the prices of such drugs.

So far as quality control is concerned, it is understood that the services of private companies or firms will be utilised. How far it will be justified to entrust laboratory job to them without confirming the suitability of the concerned private company or firm? Will the Government try to bring down the prices of these drugs by exempting them from the Sales Tax etc. imposed on them by the State Governments?

[*English*]

SHRI BASUDEB ACHARIA: Sir, I want to ask one question which has not been asked by any of the Members.

MR. DEPUTY-SPEAKER: I cannot allow. No.

SHRI BASUDEB ACHARIA: Allow me to put one question, ver important question.

MR. DEPUTY-SPEAKER: Let the hon. Minister finish his speech. If at all anything remains, we will see.

SHRI R.K. JAICHANDRA SINGH: Hon. Member, Dr. Chinta Mohan has raised the point that some important drugs are not available in some parts of the country, particularly in the Northeastern region. It is with this view in mind, we have come out with these measures. One of the measures is to promote the growth of the pharmaceutical industry, the investors would be encouraged to invest more money, particularly in the production of category 1 and 2 i.e. essential area of drugs or drugs of essential type. That is why, we have come out with series of measures to induce the investors to invest more money and encourage companies to produce more of these drugs. I have answered on the floor of this House on many occasions that the trend over the last 5 years is that the companies have been shying away from production of drugs belonging to the erstwhile categories 1 and 2. We will have to admit that. In the production of essential drugs, the companies have been shying away. The investment has gone down in this sphere. Unless there is production in the country, unless there is availability of drugs, the question about prices would be meaningless. If we have to go absolutely from the consumers angle, we need not support the indigenous production in this country. May-be, we can import everything else because imports are cheaper. The indigenous production is costlier because your inputs are costly; the power is costly; infrastructure is costly. The Government has to take a very balanced path that we have to see that imports do come into rationalise the price because the common people are affected. But in the same breath, I will have to add that we will have to take care about the indigenous production because we do not know what will happen to the international market. They can jack up the prices, if the indigenous production is not there. The international companies who are producing mostly important drugs, once they see that indigenous production in our country is halted or is hampered, would surely jack up the prices and as a result, our people will suffer. It is from this point of view, we will have to take an overall view that indigenous production is also started and also see that some import does take place. But one of the important measures that we have included in this document is the minimum economic size. For the first time, we are coming out that the drug manufacturing unit must have at least minimum level, economic size so that if there is more production from a particular company, the price of thsoe drugs which are manufactured by that company would stabilise and the market forces would operate. We are confident that the prices would come down if the production goes up in a particular company. We have been having a case where there are too many producers but the amount of production is so limited that their prices are much higher than the international prices. So, we have come out with series of incentives, specially for the bulk drug manufacturers to invest more money into the production of bulk drugs. Of course, the formulations are based on the bulk production of various drugs. Once we have bulk drug production from the basic stage, then we would be able to have self-sufficiency in this.

On quality, I have mentioned about it. In fact, many of the Members did mention on quality control, because our State Governments, and I did mention this in my reply to the earlier Member, that because our State Governments, barring Maharashtra and Gujarat and may be one or two other States, most of the other States, do not have good laboratories. The Organisation of Drug Controller which is of course not in my Department which is under the Ministry of Industry—It is with the Health Ministry—needs strengthening. It needs strengthening both by having more Drug Inspectors and by Improving laboratory testing facilities. A lot of money will have to be put in because today, a particular drug can be introduced, may be in a small State like Mizoram or Manipur where the infrastructure or the level of testing is low because drugs are not produced there. But this then can be introduced in other parts of the country if the State Drug Controller certifies that the particular drug can be

introduced. If the State Government or the Drug Controller in the State says 'Yes', it can be introduced in all parts of the State. Therefore, the standard of drugs is going down. There have been cases of the so called 'harmful and irrational drugs being introduced in other parts of the country and being marketed in different parts. That is why, we have suggested on quality control that we should have a certification system, that we should recognise some of the institutions which the Central Government and the State Governments have.

DR. CHINTA MOHAN: Point of order.

MR. DEPUTY-SPEAKER: You have to quote the rule. If you just simply say point of order, I would not allow. Is any rule violated?

DR. CHINTA MOHAN: Here the hon. Minister said *(Interruptions)*.

MR. DEPUTY-SPEAKER: No, no. That is not. Let the hon. Minister finish. It is not a point of order. There is no point of order.

SHRI. R.K. JAICHANDRA SINGH: Therefore, over and above the facilities which are available for quality control, with the State Governments and also the Central Government we would be recognising some testing laboratories which are of proven good nature owned by the private institutions and they will be certified by a team of experts appointed by the Department and, may be every year, their testing facilities will be checked and if found necessary, more often, so that we could have all the drugs which are produced in the country to go through the channel either owned by the private institutions or owned by some of the State Governments or owned by the Central Government. On quality control. With this new measure, I do not think there should be any apprehension. Our main concern should be on implementation and, as I said the NDPA will be a very important Body which would look into all these aspects. However, interaction on quality control between Health Ministry and this Ministry is still on as to whether we should include this in the NDPA. But I have every hope that we would be able to include this as one of the functions of the NDPA.

Many speakers have mentioned about banned drugs in different parts of the world. Why is it that some of them are being used in our country? I do not think it will be proper for me to answer this question since it does not in any way relate to my Ministry. It is the absolute concern of the Health Ministry. But recently I read in the newspapers, many Members must have read that also that the Health Ministry came out with a List of Drugs which they banned and I saw that List in the newspapers. I can pass on the concern of the Members to the Health Ministry. I am told that they are already having a Committee which is looking into this but this is something which concerns to them. *(Interruptions)*. It does not concern the Industry Ministry.

Dr. Chinta Mohan also mentioned about banning of tonics. This is a very serious proposition. May be in some countries, they put a stop to everything. Bangladesh is the one country which is being referred to.

There is a gulf of difference between the drug industry in Bangladesh and the drug industry in our country. In Bangladesh, they don't produce anything—I mean, it may be that they produce very little. We will have to admit that atleast because of the policies of the previous Government, today the drug industry in India has grown vertically and it can stand on its own legs. Whatever be the shortcomings of the earlier policy, atleast the drug industry in India must be congratulated because we are able to produce a wide variety of drugs in our country. It is not the horizontal growth. It is the vertical growth during the last 20 years. So, the drug industry will have to be complimented on this.

About the banning of particular drugs,

[Shri R.K. Jaichandra Singh]

you know Sir, that ours is a democratic country. On what basis can we ban a tonic unless it is proved harmful. That will have to be looked into, as I said, by the Health Ministry. This will have a number of litigations and counter-litigations. That is why we are coming-out with a new system and we have mentioned in the measures that we have taken that is the Central Information System. We will have to educate our people. No two doctors will prescribe the same medicine for the same illness and in fact I am told that in the MBBS Course for the Doctors, there is no paper on how to prescribe the medicine. Doctors themselves differ. Their opinions differ. As you know, whenever we have a particular disease, we go to a particular doctor. One doctor says that you have this kind of medicine. Another doctor says that you have that kind of medicine....*(Interruptions)* Therefore, it is very difficult.....*(Interruptions)*.

[*Translation*]

SHRIMATI PRABHAWATI GUPTA *(Motihari)*: What is your opinion on whether pain killers should be taken or not?

[*English*]

SHRI R.K. JAICHANDRA SINGH: Therefore, the idea of banning tonics, will have a serious repercussions in the country because ours is built on a different system. Ours is a democratic system. We have the rule of law. The Courts are there. You know, how the Courts are liberal in our country to grant stay orders also.

Then, I think, the another point that was mentioned was about the antibiotics not being produced enough by the Public Sector companies. Now, we have the case of Penicillin being produced by the two major public Sector companies in our country. I have said, in my answers to many questions that production of Penicillin and its demand that the country needs, this gap is so big that in 1984-85 or rather in 1985-86 i.e. last year, the import figure went up to more than Rs. 24 crores. Now, we have enough information that this figure would even go up this year much more than what it was in the earlier period. So, with this view in mind that we had de-reserved Penicillin from the Public Sector. It is true that the Public Sector is important. The Government pays very important consideration. The Prime Minister has said on many occasions that the amount of money which is being poured in our Public Sector is much more in this particular Plan than the previous Plans. But we will have to have the national perspective in question. Rs. 24 crores last year were incurred on import of Pencillin, which is such a drain in foreign exchange. This has been there for quite some time. We feel that this will continue and in fact it will even cross this particular figure this year. It is with this view in mind that we have de-reserved. We did not want this money to go out in terms of foreign exchange. We are supporting any company which can come in and invest because, as you know, drug is a very closely-held technology. We would like that more drug companies whether they are FERA, Ex-FERA or other multinational companies to come in because to obtain technology on drug is not like getting a technology in other areas. It is a very closely-held technology. To introduce a particular new drug takes years and years. You already know that. Therefore, we are encouraging people to come in, in areas where we do not have indigenous technology and even if you have indigenous technology, it may not be sufficient enough to bring the cost down. So, these are the areas where we have taken measures. Then, Mr. Jain referred to medicines banned in other countries. I think, I have mentioned about that.

19.00 hrs.

It was also said that the prices of life-saving drugs were too high. That is not true because we have not even come out with the list and it will be too premature to say

that the prices of life-saving drugs have gone up. In fact, since the new measure was announced some time in December, 1986, there were a lot of apprehensions expressed by various Members that the prices would go up. The prices of drugs belonging to Categories I and II have not gone up because the new DPCO has still not come in, finalisation of the two Categories has still not taken place. About quality control....

DR. CHINTA MOHAN: The prices of drugs have been raised from 60 per cent to 300 per cent.

SHRI R.K. JAICHANDRA SINGH: That must be in the de-controlled items. We have an area like tonic, for example, or vicks. These are items which are not needed. Therefore, we will have to educate our people. That is why we are coming out with an information system that we will have to teach our people through various media that these drugs are not necessary for them. Many of succumb to the pressure to use Vicks. I am told that it is not at all essential—Dr. Chinta Mohan is nodding his head; he probably, knows it—for curing cold. Therefore, some education will have to be given through our media, and each one of us will have to share this responsibility. We will have to educate our people that these drugs are not at all useful, are not at all essential, for any sort of ailment.

On sales-tax, I think, I have already mentioned that it is a State subject. We will be very happy if the State Governments take it up. From my side, we can write to all the State Governments to follow the Goa example.

Mrs. Jayanti Patnaik had mentioned about price revision, pending applications, in the Department. It is true that many applications are pending because the span of control of prices, under the present policy, that is, the policy which is undergoing changes, is so big that it has become difficult for the Department really to act on time. As a result, many of the drug industries have suffered and that is why we have come out in this new measure to reduce the span of price control so that we can have a more effective control rather than having a very big basket of control and not having any effective control on them. That is what the Hathi Committee has said: if at all you have to have control, you must have an effective control, and in order to have an effective control, the basket has to be brought down so that we can have an effective control; and that basket will include essential drugs. I have also been assured by various Associations of the drug industry and the drug companies that, to the extent that the Health Ministry using drugs for eradication of diseases under Health programmes, they are prepared to give a subsidy to the extent of 30 to 33 per cent. This is again another welcome step. So, to reduce these pending cases, we have taken these various steps.

Hon. Member Shri Chintamani Jena has mentioned about drugs to be available—anti-malarial, anti-filarial, anti-T.B. drugs. These would belong to Category I, coming under the National Health Policy. Since we are increasing the mark-up we also expect because of the new measures, that the drug companies will invest more in these areas, we expect that the availability of these drugs will not be hampered.

On de-licensing, I have answered.

Another hon. Member had raised one particular point whether in 1979 a Committee was set up. There was no such Committee set up.

I also agree that there are too many formulations in our country. In fact, there are about 40,000 or even 60,000. We should reduce them. But how it can be done is going to be very difficult. Again it is with the Health Ministry...

SHRI SHANTARAM NAIK (Panaji): Consider the WHO List.

SHRI R.K. JAICHANDRA SINGH: We have answered on many occasions that the WHO List is going to be one of the basis. The Kelkar Committee, that is, the Committee which is going to draw up the Category II List, is going to examine this WHO List. I am sure they will examine it, and this is going to be one of the bases.

I think, this is all.

Mr. DEPUTY SPEAKER: Only Mr. Basudeb Acharia. Only a question.

SHRI BASUDEB ACHARIA: Why was the Ministry of Health not involved while formulating this Policy?

SHRI R.K. JAICHANDRA SINGH: How do you know that they have not been involved?

SHRI BASUDEB ACHARIA: Why is the Drug Equalisation Fund proposed to be abolished?

SHRI R.K. JAICHANDRA SINGH: I do not know whether Hon. Member knows more than me. When formulating this, I can assure you that the Health Ministry was consulted. In fact, the delay in formulating this policy, to some extent, has been because we had to interact with the Health Ministry. With these new measures, we have come out with another clause wherein we have said that there will be Coordination Committee, a Committee set up at the Secretary's level between the Health Ministry and this Ministry so that all these problems, over-lapping positions could be interacted and discussed between the two Ministries.

MR. DEPUTY-SPEAKER: The House stands adjourned to re-assemble tomorrow at 11 a.m.

19.06 hrs.

The Lok Sabha then adjourned till Eleven of the Clock on Tuesday, May 5, 1987/ Vaisakha 15, 1909 (Saka)

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