it is inadequate. Except doubling of the line from Vijayawada to Madras or converting the Metre Gauge line to Broad Gauge from Guntur to Tadepalli and Guntur to Tenali and also from Gudivada to Bhimavaram and Masulipatnam to Vijayawada, there is nothing. When you look at the railway map of the State, you can see only one line running parallel to the side of the sea. That is on the east coast. The other line is running on the the west coast. In such a case, I think that it is essential that some new railway lines should be constructed. In this connection, I will also point out that the Nagarjunasagar dam is being constructed at a cost of Rs. 125 crores. It is essential that this important dam in the State should be connected by railway. Of course, the Metre Gauge line is there, going from Masulipatnam to Hubli. But this dam should be connected with the capital, Hyderabad, and also it should be connected with the main line either at Ongole or Nellore.

MR. DEPUTY CHAIRMAN: It is time. Please wind up your speech.

SHRI V. C. KESAVA RAO: In saying that the Nagarjunasagar dam is an important dam, I request the hon. Minister to consider to have a new line between Hyderabad and Nagarjunasagar and Nagarjunasagar and Ongole or Nellore.

As regards reservations, one Member, Dr Raghubir Sinh, yesterday spoke about the judgement recently given by the Madras High Court. As regards the selections, I doubt whether the percentage fixed by the Government has been adopted at all. If the percentage fixed is adopted, I think there will be no agitation by any side in regard to the selection of Scheduled Caste and Scheduled Tribe candidates. As regards the selection grade, one person has been appointed. Even then the hon. Minister has pointed ont, more than once, that he had kept up all the qualifications necessary even in regard to promotions. In a case like this, if a promotion is made, people have gone to the extent of criticising everyone. They have gone to the extent of collecting funds from every railwaymen, to fight this case. Is it justice? I say that, the Scheduled Castes are not up to the mark, it is the Father of the Nation, who first asked the Government to help these people and the Government has come forward to help these backward communities like the Scheduled Castes and Scheduled Tribes. When they are fixing some quotas, the other people, the so-called caste Hindus are grudging. In one way they do not want these people to come up to their level. Is this justice? A committee has selected the candidate and approved him. Now, every caste Hindu railwayman has joined hands to collect money to the tune of about Rs. 50,000 to fight out this case. This came to my notice recently. So, when things are happening like this, I request the Members at least to view this favourably and see that these communities are not neglected in future.

MR. DEPUTY CHAIRMAN: The hon. Minister will reply tomorrow. The House stands adjourned till 2.30.

The House then adjourned for lunch of five minutes past one of the clock.

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The House reassembled after lunch at half past two of the clock, THE VICE-CHAIRMAN (SHRI AKBAR ALI KHAN) in the Chair.

## MOTION RE REPORT OF HINDUSTAN ANTIBIOTICS LIMITED, PIMPRI

SHRI M. P. BHARGAVA (Uttar Pradesh): Sir, I beg to move the following motion:

"That the Fifth Annual Report of the Hindustan Antibiotics Limited, Pimpri, for the year 1958-59, together with the Auditor's Report thereon, laid on the Table of the Rajya Sabha on the 14th December, 1959, be taken into consideration."

[Shri M. P. Bhargava.]

Sir, to correctly understand the position, I would like to begin with quoting from the First Report of the Hindustan Antibiotics giving the historical background. It is said therein that "the World War II contributed great developments in human achievements, and one of these was the discovery of antibiotics PENICILLIN which constitutes a major revolution in our conception of treatment of diseases. The Government of India recognized its benefits and conducted during the years 1945 to 1948 exploratory investigations connected with the different aspects of putting up a penicillin plant in the country." I may mention here that two of our people, Major-General Sokhey and Dr. Ganapathi, submitted a report on the 27th October, 1948. The report goes on to say that various proposals were examined and ultimately in January, 1949, an agreement was entered into between the Government of India and a Swedish firm. The Government appointed a statutory Committee to take charge of the project, some of our technical personnel were sent abroad, and all that, and ultimately it is said that an agreement was signed on the 24th July, 1951, and the Swedish agreement was terminated. I may mention here that the scheme approved of in this agreement was an exact copy of the scheme submitted earlier in October, 1948. I have mentioned this only to show that these two people, Major-General Sokhey and Dr. Ganapathi, have had a pioneering hand in starting this project.

Now, on page 2 of the same report, in paragraph 2, the have mentioned the staff which have been trained and all that, and I will not take the time of the House in quoting that.

Then I will go on to the Third Report. On page 10 it is mentioned that there was a change over in the controlling Ministry. The Company which was hitherto under the Ministry of Production was placed under the Ministry of Commerce and Industry in April, 1957. Then it goes on to say:

> "Under section 24 of the Indian Companies Act of 1956, the name of the Company was changed to 'Hindustan Antibiotics Private Limited.' With the coming into effect of Indian Companies Act of 1956, our Memorandum and Articles of Association had to be revised and brought in line with the provisions of the Act. This has been taken in hand and after they are approved by the Department of Company Law Administration and the Ministry, it will be brought up before you for ratification."

Further it says:

> "Arrangements have been made by Government to entrust the responsibility of Managing Directorship to Shri S. T. Raja, whose services we have been fortunate to secure and who, as you are aware, is already working as Officer on Special Duty in the Company."

This is the background which I want the hon. Members to keep in view.

Coming to the present Report, about the finances it has been said that there is a surplus of Rs. 87 lakhs. That is mentioned in paragraph 4. It has been said that the Company is doing very well. Well, I have no hesitation in saying that the Company is doing very well and we have to see that the Company does well, because it is a public sector Company, and we have to see that public sector concerns do well.

Now, in the Report it is said that 12 million mega units of First Crystals were imported. The import price of these is 2:9 annas per mega unit. The conversion of this into penicillin costs about 3 annas per mega unit. That means the price at which we get the penicillin from the imported Crystals is 5·9 annas. The selling price in the market today is 11·5 annas, and that has been there for some time. Now,

if we calculate the profit, it works out to about Rs. 17 lakhs. This is from half of the Crystals received from abroad. The other half was sold to people who deal in this, and that was sold at the rate of 9·5 annas. That means, if we calculate the profit, it will work out to Rs. 22 lakhs.

Further we find that the Company was given the sole licence for importing streptomycin. There we find that the landed price is Rs. 160 per kilogram. From the figures given in the Report itself I find that the average selling price was Rs. 0·90 or even Re. 1 per mega unit, and I understand that a quantity amounting to about 10,000 million mega units was imported. Now, half of this was sold by the Company and half was given to other people. If we calculate the profit on that, we find that it comes to Rs. 35 lakhs. Adding together the three profits we arrive at the figure of Rs. 74 lakhs. Now, Sir, Rs. 74 lakhs is the profit of the Company from the imported penicillin and the imported streptomycin. The claim of the Company is that they have made a profit of Rs. 87 lakhs. Now, out of Rs. 87 lakhs if Rs. 74 lakhs on imported stuff is taken away, the net profit comes to only about Rs. 13 lakhs. So, this is the financial position, and the claim of Rs. 87 lakhs has only been made after taking into account the profit made out of the imported stuff.

Now, about the stocks I have nothing much to say. The figures have been given in paragraph 6, and it is gratifying to note that the stocks at the end of the year under discussion were very much less than those in the previous year.

Coming to the Report, let us examine what the Board of Directors of this Company is. We find that there are eleven Directors at present. They are all eminent people in their own lines. But I am sorry to mention that not one of them has qualifications about penicillin technology, the subject which is to be dealt with by the Company. I further understand—and if I am wrong, the hon. Minister will correct me—that no technology has been discussed in any of the meetings of the Board and the top research man at present is a mycologist and not a chemist.

Sir, in the first Report we find a mention about an Expert Committee. Now, I have here a letter dated the 7th May, 1954, from the Ministry about the constitution of the Expert Committee and its terms of reference. I may mention that the Committee consisted of Col. R. N. Chopra, Maj. Gen. Sokhey, Dr. Mukerji and Dr. Ganapathi, and the terms of reference were to examine the technical side of the Penicillin Project from the production as well as the research aspects and to advise the Government from time to time on the steps necessary to ensure the technical excellence of the project. I mentioned earlier about the control changing from the Ministry of Production to the Ministry of Commerce and Industry. And I have another letter where it has been said—

"Since its issue.....".

That means the last letter—

".....the control and management of the Penicillin Factory has been transferred to the Hindustan Antibiotics, Ltd., Pimpri. As, however, this Committee will give independent advice to the Government of India on the suitability of the methods adopted by and the degree of success achieved by the Board of Directors of the Company.....".

This was the idea which they had in mind at that time. Then there is a third letter dated the 6th June, 1957 where it has been stated that from thenceforward the Expert Committee need not meet regularly and the Board of Directors would consult them whenever any occasion arose.

Well, I fail to understand why the Expert Committee which was given a specific work in two letters was stopped from functioning. Probably, the hon. Minister will be able to throw some light upon that.

[Shri M. P. Bhargava.]

I have already mentioned that public undertakings should be a matter of pride to us. But there is a tendency of putting square pegs into round holes and to do away with the people who were responsible for bringing up the Factory at the first opportunity. Take the case of the Managing Director here. He is a B.A., B.L. I fail to understand what his qualifications are for being the Managing Director of a public concern dealing with penicillin.

DR. R. B. GOUR (Andhra Pradesh): He is a lawyer and can circumvent the laws.

SHRI M. P. BHARGAVA: There was Dr. Ganapathi who was the Research Superintendent. He was trained in penicilin technology abroad. He was in charge of research at Pimpri to begin with. Now, when this layman Managing Director comes, what does he do? He says, "Dr. Ganapathi, you go from the Research Department and become the Works Manager." He is given six months for being the Works Manager and after that period, a renewal is given to him for another six months. But before the second six-month period expires, he is told, "You better go away. We do not want you. You go to the parent organisation from where you came"—*i.e.*, the Haffkine institute.

Sir, mention has been made for the production figures in the Report here. I can only say that in the first Report it has been mentioned that the original plan was for 6—9 million mega units but the capacity was in fact for a production up to 20 million mega units, and it is only in the years 1957-58 and 1958-59 that they touched the figure of production of 24-25 million mega units.

I will not deal with the various other matters which have been dealt with in the Report, *i.e.*, matters about housing facilities, welfare activities, etc. provided for the workers at the Pimpri Factory, and I will come straight to research.

In the first Report I find nothing special except that they were building the Research Laboratory, this and that. But the real mention about research is made in the Second Report which I will bring to your notice. The Second Report mentions that "the Research Centre which has been put up at a cost of Rs. 15 lakhs has been doing valuable work. A number of important materials have been successfully substituted by indigenous ones" and all that. It also says that—

> "Research is also being carried out in antibiotics other than Penicillin. Indigenous manufacturers are being encouraged to produce corn steep liquor.
>
> The laboratories have been equipped with the latest scientific equipment and are manned by highly qualified and technically trained staff."

Then under 'Research' in the Fifth Report which is under discussion, I find one very outstanding claim and that claim is that the outstanding work done by them during the year was the production of oxytetracycline and chlortetracyclin from strains and processes evolved in their own laboratory without any foreign collaboration or assistance. Well, I am not an expert in this, but what I learn is that strains for these two medicines have not been found anywhere in India and nobody has been able to produce this, and they are doing work on the strains which were brought from Soviet Russia. I will read out a portion from a book.

> "In order to help Hindustan Antibiotics, the Soviet Union sent four bottles of cultures of the strains of mould from which penicillin is produced, and had them delivered through their Ambassador in New Delhi. Later on in 1957, they sent through somebody else six tubes of cultures of strain, with full instructions for their propagation, for the production of streptomycin, aureomycin, achomycin, terramycin, etc."

SHRIMATI YASHODA REDDY (Andhra Pradesh): Where are you quoting this from?

SHRI M. P. BHARGAVA: This is a book entitled "The Indian Drug Industry and its Future."

So, if I am wrong, I request the hon. Minister to correct me in his reply.

Now, the utility of medicine depends on its purity, efficacy and standard of quality. Now let us examine what is the condition of the quality control in the various reports. In the First Report what we find is:

> "Pimpri penicillin was tested abroad, and it is a matter of great satisfaction to note that the samples of penicillin produced at the Pimpri plant have been tested by the Food and Drug Administration, Washington, and the National Institute for Medical Research, London. They have found our samples up to the mark in respect of potency, purity and quality."

The Food and Drug Administration in their report states:

> "The samples you submitted compare favourably with the sodium penicillin, potassium penicillin and procaine penicillin manufactured in the United States."

Because of paucity of time, Sir, I shall not quote from the various other reports—I have got them with me—but I shall only say this that this tall claim of Pimpri penicillin being tested—as mentioned in the First Report—is far from truth. No samples were sent abroad, no reports were received, and yet a show was put up and advertisement was given that they had been tested. Well, Sir, that is about the First Report.

Then, Sir, I come to the Second Report. And what do we find in the Second Report about quality control?

> "The greatest care is being taken to ensure the highest quality of our products. As required under the Drugs Act an entirely independent Quality Control Section with all the modern equipment has been set up under the charge of Superintendent (Research) who is responsible directly to the Managing Director. The standards laid down for the passing of batches are rigorous and conform to those laid down by our Drugs Act or the British Pharmacopoeia or the U.S. Pharmacopoeia".

Now, Sir, I would like the House to keep in mind that Quality Control at that stage was under a fully qualified scientist, who was the Superintendent of the Research Section. No mention is made about Quality Control in the Third Report, and from the Fourth Report I shall read out what has been stated there.

> "There has been some misunderstanding in some quarters about the quality of our products. We would therefore like to outline the measures which are in existence in the Quality Control Department in order to maintain high standards of quality of the penicillin produced in the factory. The quality Control Department has been placed under a specially qualified Officer in charge and maintained as an independent department with adequate and qualified staff."

THE MINISTER OF INDUSTRY (SHRI MANUBHAI SHAH): I am afraid, Sir, that the wrong impression which the hon. Member seems to have formed may go round. To dispel that wrong impression, Sir, I suggest that he may read a copy of the letter from Washington, which we have placed on the Table of the House, which gives all the details, the number of vials sent by us, and so on. What is he drawing attention to, Sir? Is it his contention that we had not sent samples and yet the reports have come?

SHRI M. P. BHARGAVA: If the hon. Minister . . .

AN HON. MEMBER: Probably he is referring to . . .

SHRI M. P. BHARGAVA: I shall just explain the position, Sir. I said that in the First Report mention had been made . . .

SHRI MANUBHAI SHAH: Then he is bringing in the functioning of the Hindustan Antibiotics Limited during the last five years, but I thought we were taking up today—that is the motion of the hon. Member—consideration of the Fifth Annual Report of the Hindustan Antibiotics Limited, for the year 1958-59, together with the Auditor's Report thereon.

SHRI M. P. BHARGAVA: I am trying to show that what is happening about this Quality Control is not a thing of today; it has been there from the very inception.

THE VICE-CHAIRMAN (SHRI AKBAR ALI KHAN): Mr. Bhargava, what is under consideration is the Fifth Annual Report of the factory.

SHRI MANUBHAI SHAH: This is a very important factory, Sir, which comes into the picture not only here before the House for a discussion on its working but also touches the millions of consumers who use the antibiotics produced there. Therefore, I would request, Sir, that in the words that we use we may exercise a bit of caution because it is only recently that there had been an unhappy controversy over the functioning of Quality Control. Now, Sir, all the tests have been carried out and here are the original letters copies of which we have put in. At this juncture, Sir, I would submit that the First Report has no place, and while speaking on this Fifth Annual Report—which is the subject of the motion—while speaking on Quality Control or anything I would request that hon. Members be as circumspect as possible.

THE VICE-CHAIRMAN (SHRI AKBAR ALI KHAN): I am sure hon. Members will do so.

SHRI MANUBHAI SHAH: If yet there were doubts about the Quality Control processes or its functioning, I shall take it up personally or through correspondence, but I shall beseech the co-operation of the House in protecting the drug industry which the Hindustan Antibiotics Limited has taken in its fold.

SHRI M. P. BHARGAVA: I might make my position very clear to the Minister, that I am one of those who want the Hindustan Antibiotics to flourish from day to day. I am not criticising it for the sake of criticism. I am trying to place the facts before the House so that amends may be made and the management, if it is faulty, changed and in the drugs that are being produced and passed the highest standards of purity and efficacy restored.

Now, Sir, I shall read from the Fifth Annual Report, which is under discussion, on 'Quality Control'.

> "The high standard of Hindustan Antibiotics penicillin and its popularity have been well established in the country. Enquiries made not only by the company through its distributors and chemists, but also those by other independent agencies with the medical practitioners, have confirmed this position."

I am not reading the whole of it, Sir; it may be taken as read, the whole of it.

Then I shall come to other things. I shall not touch on any of the points which had been raised in that half-an-hour discussion. I shall raise two or three points now, and one of them had been raised in my friend Diwan Chaman Lall's question yesterday, Question No. 431.

DR. R. B. GOUR: But that was withdrawn.

SHRI M. P. BHARGAVA: Yes, yes, but I can raise it. That question asked whether the Quality Control Department of the Hindustan Antibiotics

Ltd., Pimpri, had been placed back under the control of the Superintendent of Research. In this connection, Sir, I have information that it was put back under the Superintendent of Research on the 1st January, 1960, and I am very sorry to mention that the batches tested in January, many of them, had to be rejected. This may be checked up by the hon. Minister.

Now, there is a lot of violation of Drug Rules, double registers, etc., but I shall not go into all these but shall go direct to the Report which has been circulated today. As the House might know, it was announced during the last Session that the Board of Directors had appointed a sub-committee to go into the complaints that arose after the death of the hon. Mr. V. D. Tripathi. Fortunately for us it was found that the batch from which penicillin was given to Mr. Tripathi was in order. I am very very happy about it and we have been saved a very very serious situation which would have cropped up if it had been the case otherwise. Now, I may refer to the findings of the Sub-Committee:

> "The general standards, procedures and practices followed at Pimpri have from the beginning been in accordance with the required procedure adopted by the factory since its inception, *i.e.*, the procedures laid down in the U.S. Pharmacopoeia, and all the quality standards, test procedures and practices were satisfactory."

Now comes the relevant paragraph, the next paragraph.

> "The Committee has, however, found that during a short period from the 6th September, 1959, to 1st October, 1959 the Quality Control Department adopted the B. P. method of testing for sterility in the case of new batches, and in doing so failed to observe fully the instructions in regard to the carrying out of those tests. Although the change in procedure did not adversely affect the quality of the products produced and supplied during this period, as the samples on re-test according to U.S.P. method were found to be sterile, there was an infringement of the Rules during that period."

Now, there has been an infringement of the rules. This has been stated by a sub-committee of the Board of Directors; they have admitted it. Sir, in the last Session it was promised that if this report was not found satisfactory, another Committee would be appointed. On that the decision of the Government now is.

3 P.M.

> "As the issues are very clear and the findings of the sub-committee are positive, Government considers that there is no need to appoint another committee."

Then, they mentioned about the Drug Controller, Bombay, issuing orders. I would not go into that.

Then paragraph 7 of the Statement says:—

> ".....Considering all these factors, Government have decided that the Managing Director of Hindustan Antibiotic, should be strictly enjoined to keep a more vigilant watch over the work of the Quality Control Department of the Factory so as to ensure that such lapses from procedure do not occur in future and that the quality of the products of this factory is of the highest International standards. As regards the other officers concerned, the Board of Directors are being asked to take appropriate action."

The Board is authorised to take appropriate action against everybody else who is involved. But what about the main man under whom the Quality Control worked and who should be held responsible for lapses, if any? I mean the Managing Director. Where is the decision of the Government about that point? Here is a question of life and death for the people. They must use this wonder drug to get the benefit of modern medicines to

[Shri M. P. Bhargava.]

save themselves and their beloved children from infectious diseases that kill them. Can we afford to leave the management of this factory in the hands of a layman? The Expert Committee must meet, enquire and suggest ways and means which will allay the fears of the public about the quality of drugs produced by the Hindustan Antibiotics Limited whose fair name should not be allowed to be tarnished. I am sure the Ministry of Commerce and Industry will not stand on any prestige and will do everything to restore the confidence of the people by punishing the guilty, and place this great public sector industry in the hands of properly qualified people.

*The question was proposed.*

DR. R. B. GOUR: Sir, I move:

"That at the end of the motion the following be added, namely:—

'and having considered the same this House is of the opinion that the Experts Committee be asked to give independent advice to the Government of India on the suitability of the methods adopted by, and the degree of success achieved by, the Board of Directors of the Company'."

*The question was proposed.*

DR. R. B. GOUR: Sir, fortunately for me, and accidentally, my amendment is to the same effect as the conclusion reached by my friend Mr. Bhargava that the Expert Committee must be mobilised for the job.

Mr. Vice-Chairman, participating in this debate I would like to confine my remarks to certain aspects of the working of the Hindustan Antibiotics. Sir, I and we as a Party, are second to none in the defence of the public sector. But let us remind the hon. Minister that it is against the public sector that intrigues and conspiracies are being hatched there. Let me remind the hon. Minister that when the W.H.O. wanted the antibiotics factory in our country to be put in the public sector, the international cartels manufacturing antibiotics approached the Director and the Assistant Director of the W.H.O. in Geneva and protested against the measures that they were proposing to be taken. These things have, to my mind, been brought to the notice of the Prime Minister also.

Sir, when the whole matter was being discussed about agreement with the Mereks, this problem was raised during Question Hour in our House as well as in the other House. Therefore, the question of keeping the purity and the strength of the public sector has always been the concern of this House. But, I am sorry that the Ministry of Commerce and Industry has always in this matter surrendered to certain considerations of the private sector.

There is the question of maintaining standards in the public sector, in the interest of the standards of Hindustan Antibiotice, in the interest of such an important drug industry that we have in the shape of Hindustan Antibiotics Limited and in the interest of this great mission . . .

RAJKUMARI AMRIT KAUR (Punjab): On a point of order, Sir. May I just make one explanation because I happened to be the Minister of Health when this factory was started? May I say, Sir, that it was the Government itself, on my advice to the Cabinet, who accepted this factory in the public sector and did not allow it to go into the hands of the private sector, because I felt that we should be able to produce better drugs so important for the public? Therefore, it is not fair to say what has been said; I do not know who approached the W.H.O. All I know is that I had to have a fight with Maj. Gen. Sokhey and others that this factory should go into the public sector. I want it to be made perfectly clear that Government has never wanted it to go anywhere else except to the public sector. He should not, there-

fore, make this indictment against the Government.

DR. R. B. GOUR: I would agree with Rajkumari Amrit Kaur because the factory is in the public sector. That is not the point. The question is, let Mr. Manubhai Shah not get away with the fact that we are here doing a certain thing that will bring down this public sector industry in the estimates of the people. No. I want to request Mr. Manubhai Shah here kindly not to give shelter and protection to individuals and those who directly or indirectly bring this concern down in the estimates of the people. That is my complaint against the Ministry of Commerce and Industry.

Sir, about profits, it is said that the factory made a profit of about Rs. 87 lakhs You imported 12 million mega units of crystalline penicillin. Half of it you converted into pure penicillin. This point has been ignored.

SHRI MANUBHAI SHAH: If the hon. Member refers to the reply given by me to several questions that were put to me, he will find therein that we have given quarter-to-quarter cost of production of the product as it came out of the Hindustan Antibiotics. Therefore, there should not be a mixing up of the imported stuff in these figures which I have laid before the House. I may again indicate that from Rs. 1|8|4, the cost of production in the last few years has come down to 5½ annas during the last quarter. So, the hon. Member need not mix up the locally manufactured thing with the imported things.

DR. R. B. GOUR: I do not worry. You are worried. Take the cost of production of your own factory and judge its performance. I am taking the profit figures that you have in this report. You say you have earned Rs. 87 lakhs net profit. But I am telling you how much you have actually earned, and how much you could have earned if your own production was properly looked after. That is my complaint.

You have imported 12 million mega units of crystalline penicillin. Out of this 6 million mega units have been converted into pure penicillin. The rest you have sold as it is. The whole thing costs 17 nP. per unit, and its conversion into pure penicillin makes the whole thing cost 28 nP. per unit. Then, the sale price is 72 nP. per unit roughly. The net profit from this 6 million mega units of crystalline penicillin as it is and 6 million mega units of pure penicillin will fetch you Rs. 22 lakhs and Rs. 18 lakhs respectively.

Then I come to streptomycin. If streptomycin per gram costs 20 nP. and bottling costs 30 nP., the cost per gram comes to 50 nP. You are selling it at 100 nP. per gram. That brings you a profit of not less than Rs. 50 lakhs. The total comes to Rs. 72 lakhs here. Then there is another item of profit, Rs. 18 lakhs. This way you have earned about Rs. 90 lakhs of profits merely by selling imported penicillin, and also bottling streptomycin and selling it. How can you say that your entire production has increased so much? You are announcing that the net profit from Hindustan Antobiotics has been increased. I would like a straight answer to this question. You have imported 12 million mega units of crystalline penicillin. Out of this, 6 million mega units have been converted into pure penicillin, and the rest is sold as it is. You get out of it Rs. 41 lakhs. Then over bottling and selling, the total cost comes to 50 nP. per gram. You are selling it at 100 nP. per gram. How much do you get? You get another Rs. 50 lakhs. How much does it come to? Whom are you going to bluff? Is it a sound running of your industry? And then ultimately you say that you have earned Rs. 87 lakhs of profit on your own production. On these two counts you must have earned Rs. 90 lakhs. Give us an explanation on that score.

[Dr. R. B. Gour.]

Then I go straight to the question of targets. You say something about target. I do not know who fixed these targets. This is what you have written under production:

"The target of production for the year under report was 24 m.m.u...."

Who told you that the target is 24 m.m.u.? How many fermenters are working? Even when the original consideration was of 10 fermenters, the target was put down at 30 m.m.u. That was in 1956. Since then the technology of antibiotic production has advanced. Obviously, you have at least 12 fermenters. Have you not got more than 12? Have you not got 16? Have not at least 12 been working during the year under review? Then the target must be roughly at least 40 m.m.u. Even if the 1956 technology is used, your target should have been 40 m.m.u. How is it that you have said that it is only 24 m.m.u.? There must be something wrong somewhere. You have to give an explanation to that.

Then you talk of research. In that section you have said:

"The outstanding work done by them during the year was the production of Oxytetracycline and Chlortetracycline from strains and processes evolved in your own laboratory without any foreign collaboration or assistance."

I think my mind is clear that Major-General Sokhey visited the Soviet Union and brought certain strains. Where did you get the strain from? Where was the earth? Where was the fungus? Could you produce all these things in your laboratory at Pimpri? Tell us the truth. Did not Dr. Tirumalachar go to the Soviet Union and did he not learn certain things and bring some strains? Why do you say that everything has been done in the laboratory and tell us that the laboratory has been functioning well? Why do you say that research has grown so much that you can create strains, fungus etc? Do you want to deceive us?

Then I would like to go to Quality Control. Here I must very categorically disabuse the mind of the hon. Minister and if I have that capacity, I must say that I must disabuse the mind of the people in the country on the controversy that has arisen around the sad demise of Mr. Tripathi. It is evident that that death was due to allergy and one death in a million is due to allergy to antibiotics. We never thought that one in that million would be Mr. Tripathi. Serum allergy is much more but just because of allergy we cannot give up drugs. Therefore, let us not confuse such a death due to allergy of our friend, Mr. Tripathi, with the question of violation of the rules and the proper procedure at Pimpri. These are two different things.

The Quality Control Section was earlier under Research, Research was under the Superintendent of Research and he was under the Managing Director. Afterwards, this re-organisation has been done so that the Quality Control Section comes straight under the Managing Director. How did this reorganisation come about? This was proposed earlier to the Expert Committee consisting of General Sokhey and Col. Chopra. They rejected that, saying that Quality Control was something which could not be gambled with. The Expert Committee of General Sokhey and Col. Chopra rejected that question at first when it was suggested by others and by the Board. But later on without reference to the Expert Committee the Board of Directors appointed a Committee and in that Committee, the Managing Director himself, Mr. Raja, is there as well as Dr. Venkataraman and others. They decided that Quality Control must be brought under the Managing Director himself. The

Managing Director suggested that Quality Control must be brought under the Managing Director and then the Board, on the basis of the recommendation of the Committee, of which the Managing Director was a member, took the decision ignoring what the Expert Committee had said about this suggestion that was made earlier and Quality Control was brought under the Managing Director. Again the Board of Directors appointed a Committee of which the Convener was the Managing Director himself—Mr. Raja —to go into the irregularities . . .

SHRI MANUBHAI SHAH: Just to clarify a point. The consideration to put Quality Control under the Managing Director was neither entirely of the present Managing Director nor entirely of the present Board. It was decided about 2½ years back to consider this question and that decision has been enforced with respect to the present Managing Director. Therefore, it is not his hand that suggested it. Of course, the present Board and the Managing Director finally decided this issue. Many considerations went on in the Commerce Ministry and it was decided that in the interests of Quality Control being properly protected, it should not be left to any particular officer but should be under the overall charge of the Managing Director.

DIWAN CHAMAN LALL (Punjab): May I also interrupt? Has it now been taken away from the Managing Director?

SHRI MANUBHAI SHAH: No, it still continues with him.

DR. R. B. GOUR: That means the folly continues. Let Mr. Bhargava make amends as to what he thinks about the information he has. I am saying this that there was a Technical Sub-committee on Staff Reorganisation which was appointed by the Board of Directors. This Committee recommended this and this Committee included Mr. Raja. On his recommendation the Board took the decision with reference to that recommendation. I have extracts of those minutes. Let him examine it. Mr. Raja the Managing Director, is in this Sub-Committee. He recommended that this be brought under the Managing Director straight and that very Managing Director is again in another Board and that Board takes the decision that the recommendation of the Committee is accepted and the Quality Control comes straight under the Managing Director. Therefore, for all the irregularities in Quality Control during that period he must take the supreme responsibility. When it was to be enquired into, again a Committee was appointed with Mr. Raja. He is there. The gentleman who went into it is the same person. He recommends that the standard of Quality Control is to be examined. He takes over control himself. He appoints himself as the person to enquire into it and again comes back and says that some irregularity is there. So, this is the position. Can you inspire confidence even in the most gullible people through such action of yours? That means that this gentleman must be hauled up for the lapses in Quality Control. So, he must take full responsibility. There should have been an independent enquiry into it. Mind you, the shifting of Quality Control was rejected by the Expert Committee earlier. Was it taken into consideration? Why was it rejected? Quality Control is the one thing that is necessary in any drug factory.

The hon. Minister has laid certain statements on the Table. Here is the label of the bottle of penicillin. Here are the papers laid on the Table of our House some time back in this Session wherein it is said that this vial was sent abroad and the reports are there. Here you say that the penicillin vial contains a total of 400,000 units out of which 300,000 units are penicillin buffered with Crystalline Penicillin G Sodium 1,00,000 units. That means there is

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a total of 400,000 units. Here is the American report, which says:

> Total Penicillin—369,200 units comprising
>
> Sodium Penicillin—88.300 units and
>
> Procaine Penicillin—280,900 units.

That means that the potency has been reduced. It is not 4 lakh units. It is not 3,00,000 and 1,00,000. This happens within three months of the vial passing out of the factory. That means you stamp the utility of the vial for a particular period and within three months the potency is reduced from 4,00,000 units to 3,69,200 units. There must be something wrong somewhere. In fact the international standards indicate that you have to add a little more of units so that when a loss of potency is there, the minimum requirement is always there. This is what your own report says.

Then, Sir, you see, in this Report it is said that the Haffkine Institute analysed it and they found the procaine content to be 30 per cent. Here it is written as 25·3 per cent. I understand that the Haffkine Institute wrote to the Ministry that it was 30 per cent. and that it should be read as 30 per cent. and not 25·3 per cent. I am open to correction, because after all that is the information I got. And then I think the Washington report does not indicate the content. Then there is the Calcutta report perhaps which says that the procaine content was 30 per cent. Sir, if you examine this thing, this label, you will find that the procaine content is put down as 25·3 per cent. Here on this label you write that the procaine content is 25·3 per cent. and here the analysis indicates that the procaine content is 30 per cent. Either you have misprinted the label which again is a violation of the Drugs Laws, or you have sent a wrong sample for consultation. There cannot be any other interpretation.

Sir, this morning he was kind enough to refer to the Committee and say:

> "The Committee, however, has found certain rules have been violated."

Sir, I went through the debate of the 22nd December—unfortunately I was not present then—the hon. Minister, Shri Manubhai Shah, said that he was quoting something from the U.S. Pharmacopoeia, but when I compared the notes, I found that he was quoting exactly sub-rule (2) of Rule 119 of our Drug Rules. Exactly they are quoted verbatim. You can compare them. That says that there should be re-sterilization, that without re-sterilization nothing can be done. The fourth test must be after the re-sterilization. Where is this done? He has been using the American method, he says, but I am sorry to say, the American method does not mean no re-sterilization.

Of course, the Bombay Drug Controller is not under the Government of India and therefore, Mr. Karmarkar need not worry. In every State the Drug Controller is responsible for it and the drug laws are such that the State Government or the State Drug Controller has to do it. Therefore, he is absolved of that responsibility. I want to assure him that. But the Bombay Drug Controller, how can he say that you can use the U.S. method?

SHRI BHUPESH GUPTA (West Bengal): He is a friend in need.

DR. R. B. GOUR: The U.S. method means what? The U.S. method does not mean that you can over-rule your own laws. Rule 119, in sub-rule (2), mentions re-sterilization. No method can over-rule your own rules and I do not think even the Drug Controller can give permission to over-ride the rules under your own law. He can suggest or use different methods of test, different media of tests, or processes of test. But in one test, if

you find contamination, you cannot have another test without re-sterilization.

SHRI MANUBHAI SHAH: Again though I would not like to interrupt, I might point out that these matters are spoken of without going through the full information. There is no pharmacopoeia in the world where sterility is not one of the tests. It was never intended to be said at that time that sterility was to be avoided. The only point is how you had tested, whether ten vials were taken, whether they were tested once, twice, thrice or four times and so on. It is only in the question of procedure that the pharmacopoeia really comes in. Sterility has to be tested . . .

DR. R. B. GOUR: It is again unfortunate, Sir, that in this matter I have to speak about this matter to a layman. Shri Manubhai Shah is not a scientist or a research worker. No, I am sorry, Sir, he was in the research laboratory and he should know these things better. I need not tell him.

THE VICE-CHAIRMAN (SHRI AKBAR ALI KHAN): That is why he is interrupting you again and again.

DR. R. B. GOUR: He is interrupting me again and again in . . .

SHRI MANUBHAI SHAH: This is only unnecessarily causing misunderstanding, Sir, over a thing which is, really speaking, of a highly technical nature. I can only submit this, that the pharmacopoeia of India is supreme as far as Indian drugs are concerned. But there are powers under the Indian Drugs Act and to vary a particular test and to have a test which is supposed to be superior in order to safeguard the health of the nation is permitted under the Drugs Rules.

DR. R. B. GOUR: I entirely agree with the hon. Minister, Sir, and Shri Manubhai Shah need not tell me that. I know that the Drugs Control Act provides for different methods. Under Rule 114, the Drugs Controller can ask you or allow you to carry out tests in any other manner. He can also withdraw it. But Rule 114 does not mean that Rule 119 is to be ignored. Rule 114 deals with the method of testing. You can use different methods, use different media or different processes. There are so many processes and tests and you can use whichever you think is superior or available to you. But Rule 119 says:

> "Provided that if the same organism is visible in more than one test, the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch unless and until it has been sterilized and has passed the tests."

So re-sterilization cannot be ignored under any revised scheme of things under Rule 114. That is my contention. You may examine that contention. It cannot be. Rule 114 does not over-rule Rule 119. That is my contention.

DIWAN CHAMAN LALL: What does Rule 119 says?

DR. R. B. GOUR: What I read out just now. But under Rule 114 the Drugs Controller can permit the use of other methods of testing. But that method of testing does not mean that re-sterilization can be ignored. It only says that the method of test may be different or the process may be different. But violation of Rule 119 cannot be allowed by any different method allowed under Rule 114. That is my contention.

Then, Sir, on page 5 of the Report that was given to us this morning, he says that everything is according to the U.S.P. Now those 10 vials also, was that according to the U.S.P.? Therefore, I say, let this thing be properly gone into. It has been gone into and they have accepted the thing. But my only point is that it is not

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proper. Why? Because the same person here recommends that the Quality Control is to be brought under him. And he himself appoints himself to enquire into the vagaries of the Quality Control and he exonerates himself. Therefore, what has happened? Ultimately, the result is that all violations have been proved. They could not be concealed and yet the decision of the Government is that the Managing Director of the Hindustan Antibiotics Ltd. should be strictly enjoined. He has not even been warned. This is wrong. This is sheltering people who have been careless, people who have been gambling, people who have no right to remain in the posts where they had remained because of your shelter.

DIWAN CHAMAN LALL: There is in this Report which I have seen, a statement that some people are going to be warned. Who are the people to be warned?

DR. R. B. GOUR: Who? You know who will be warned. If the Railway Board commits a crime, it is the clerk who is punished. So, some younger member of the staff, somebody lower, some lower people—against them some action will be taken, not against the Managing Director under whose instruction it happened. He is simply asked to be careful. "It is enjoined on him to be a little more careful". What does it mean? I understand that the Ministry has no intention to go against him. I say, the Managing Director must be removed, in the interest of the Hindustan Antibiotics, in the interest of the goodwill it has got and in the interest of the confidence that the people will have in the Hindustan Antibiotics and the increasing confidence that the people should have in the Hindustan Antibiotics. The Managing Director must be changed. Bring the Quality Control under the supervision of the Research Section, and put at the head of the Research Section a person of the calibre of Dr. Ganapathi who is a scientist. A mycologist doing research? I am sorry, he is not a chemist and he has been doing it. The mycologist can find fungus if any exists. But the whole job later on has to be done by the chemist. In fact, the preliminary work is that of the mycologist and afterwards everything has to be done by the chemist and he has to go into it.

Therefore, Sir, my amendment which is a simple amendment, only says this. Bring back the old method. The order of the Ministry of Production dated the 15th November, 1954 says they have appointed a committee with certain terms of reference and I have here included only those very terms of reference. Your subsequent revision was wrong. The experts ought to be there and they should be allowed to function. Under those terms of reference you had said that the Expert Committee should be asked to go into the question and:

> "asked to give independent advice to the Government of India on the suitability of the methods adopted by and the degree of success achieved by the Board of Directors of the Company."

These were the terms of reference for the Expert Committee envisaged in the Ministry of Production's Order dated the 15th November, 1954. My submission is that with the same terms of reference this Expert Committee must be allowed to function.

Finally, Sir, my last word would be that there should be the removal of the Managing Director, there should be the revival of the Expert Committee in the interest of the Hindustan Antibiotics, in the interest of the goodwill that it has got and the goodwill that it should continue to enjoy, and in the interest of the confidence that the people repose in the Hindustan Antibiotics and the confidence that they must, in the future, have in an increasing measure in our drug industry. With these words, Sir, I conclude my remarks.

SHRI JASPAT ROY KAPOOR (Uttar Pradesh): Mr. Vice-Chairman, I have very carefully and attentively listened to the two speeches, those of Mr. Bhargava and Dr. Gour, but I must confess that I have felt considerably unhappy at the attitude that they have adopted in discussing this Report. The motion given notice of by Mr. Bhargava is to take the Fifth Report into consideration but neither he nor Dr. Gour has really considered this Report. They have subjected this Report only to condemnation. While considering a report of this kind, we must adopt a fair attitude, a fair and an impartial attitude. We must have an absolutely open mind and only then can we come to right conclusions. Where praise is due, it must be given and where condemnation is merited, it must be expressed and even strongly, but then only to look at any thing in a one-sided way is doing hardly any justice to the subject. My hon. friend, Mr. Bhargava, had not a word of praise or appreciation for this useful institution and he seemed to think that the sooner this institution is done away with the better would it be; of course, he did not say so but that is what it practically amounted to.

SHRI M. P. BHARGAVA: Mr. Vice-Chairman, on a point of personal explanation, I may say that the remarks of Mr. Kapoor are not correct. I have categorically said that I want this institution to flourish and prosper day by day.

SHRI JASPAT ROY KAPOOR: I am sure that on reconsideration my hon. friend, Mr. Bhargava, will regret having said what he had said here, and I find that after a few minutes of making his speech he is beginning to have second thoughts on the subject.

SHRI BHUPESH GUPTA: No, he said it before.

SHRI JASPAT ROY KAPOOR: He said that the Board of Directors consisted of inefficient persons, that the Managing Director was not worthy of being placed in the post which he was holding and that he would like either a scientist or an expert to be put there. That is an astounding proposition, if I may say so with all respect to my hon. friend, Mr. Bhargava. Anybody who has any knowledge of management of business institutions would readily say that a managing director should be a person who has the qualities of management, one who knows how to manage an institution and one who knows how to run an institution successfully. You will hardly ever find a scientist or a technical expert being in charge of such institutions. If ever you find a scientist or a technical man in such a position, then almost invariably you will find him to be a failure. Technical experts, the scientists, must be in charge of technical work. Of course, a scientist must be in charge of quality control and must be in charge of production but if you ever think of placing a scientist in the post of a managing director, you may rest assured that you will always see the institution going to dogs, generally speaking.

RAJKUMARI AMRIT KAUR: No, no.

SHRI JASPAT ROY KAPOOR: The Minister, Mr. Shah, interrupted more than once during the course of the earlier speeches and rightly so. He said that this is an institution of public importance. It is serving the public, the ailing public, and if a sort of feeling is created in the minds of the consuming public that the products manufactured by this institution are not of high quality, that they should not be trusted, then you are not only doing harm to the institution—that is a very small matter—but you are doing a great harm to the ailing public. If the drugs manufactured are declared so bad as they have been reported then what is going to be the effect on the consuming public and the medical practitioners? They will not use these products; and then who will suffer as a result of this, apart from the institution? The

[Shri Jaspat Roy Kapoor.]

ailing public will suffer. Are you, therefore, serving the public by condemning the products of this institution without reasonable grounds? Sir, in a matter like this I would like to be guided by the views of the experts rather than by the views of laymen, if I may say so with all respect to my hon. friend, Mr. Bhargava. The view of the experts on this subject is, so far as I have been able to find out from the material placed before us, that the quality of the products is certainly not bad, not only not bad but that it is good. My hon. friend, Mr. Bhargava, during the course of his remarks, chanced to read paragraph 14 of this Report which deals with the question of quality control. He read only one sentence, namely:

> "The high standards of Hindustan Antibiotics penicillin and its popularity have been well established in the country."

Immediately after this he said that the rest of the paragraph may be taken as read. Obviously, he found it to be a little bit inconvenient for him to read the rest of the paragraph for therein are contained facts which go to show that the products of this institution are of a high quality. Well he had so much to say against this institution but when he came across this portion of the quality control paragraph, he immediately gave up reading after reading the first sentence. May I, Sir, read one or two sentences more?

It is said:

> "Enquiries made not only by the company through its distributors and chemists but also those by other independent agencies with the medical practitioners have confirmed this position. Complaints about deterioration of quality during storage or presence of foreign particles have been extremely few. Increased bulk sales of penicillin made to bottlers like Sarabhai (Squibbs), Glaxos, Dumex and Alembics have not resulted in any rejection . . ."

Not even once was there any rejection.

> "....of supplies on grounds of inferior quality."

There is one more sentence.

> "The standards accepted by this department for tests are higher than the minimum prescribed in international standards".

With all these things before us, may I ask as to whether we would be justified in saying that the quality of the products of this institution is not up to the mark? No doubt we find from the statement circulated to us this morning that during a short period of twenty-one days there was a slight fall in the care that should have been exercised in the manufacture of these articles but even there it is said that the change of procedure did not adversely affect the quality of the products produced and supplied during this period. So, so far as the question of quality is concerned, even this Report has no adverse comments to make. It is only said that there was an irregularity. This is what they say:

> "There was an infringement of the rules during that period."

There was only an irregularity resulting not in any deterioration of the quality but only of a technical nature and for that small reason, which of course has not been ignored by the Board of Directors, nor could we ignore it, it is said that the Board of Directors should be sacked, the Managing Director should be sacked and that the whole of the products of this institution must be condemned outright. Now, Sir, that is an attitude with which I for one cannot find myself in agreement.

Sir, while the Report says that during this period there was a huge surplus of about Rs. 84 lakhs or more, it is contended that this surplus is not merely because of the profits made out

of the products manufactured here but a part of it is made up by profits accruing from imported articles. I submit, Sir, is there anything wrong about it? If they have made some profit even out of the imported articles, what is wrong about it? And how have they made the profits? In this connection I would like to draw the attention of the House to paragraph 10 in which we find that the articles imported were sold to the trade at a price about 50 per cent less than at which it used to be sold prior to the articles being imported by this institution and even thereafter there has been a surplus of Rs. 6·14 lakhs. So, there have been two-fold advantages; one that the articles imported have been sold to the trade at about 50 per cent. of the original price and secondly even thereafter a substantial amount of Rs. 6·14 lakhs accrued to the institution. Now, what is wrong about this? Even taking at their face value, the figures that have been quoted by Mr. Bhargava, the net result according to him is that the net profit accruing out of the manufactures of this concern is to the tune of Rs. 13 lakhs.

[MR. DEPUTY CHAIRMAN in the Chair]

Even if it be so, is this amount or Rs. 13 lakhs something over which we should weep and wail? Or should we say that this institution has done well even if the facts and figures which have been presented to us in a manipulated way by Mr. Bhargava are accepted? My friend, Dr. Gour, says that they had no business to say that the targets that had been fixed by them had been exceeded. He wants to know who fixed the targets. Who would fix the targets? Not Dr. Gour of course; the targets can be fixed only by the institution itself and the target that they had fixed has been exceeded by 1·20 million mega units. That is surely something for which the institution can rightly take credit.

Then, again, we find that the prices have been coming down substantially, very substantially. Sir, in October 1958 the price of streptomycin 1 gram was Rs. 1·25 and on 1st August 1959 it was reduced to a small figure of Re. 0·75. Such is the trend with regard to other products also. Even after reduction of the prices by such a substantial extent, the institution has been making very good profits. That is something to its credit. Surely, it is not something for which it should be condemned. In this connection I am glad to find that the institution proposes to reduce the prices of its manufactures substantially even hereafter.

MR. DEPUTY CHAIRMAN: The time is limited; the number of speakers is more.

SHRI JASPAT ROY KAPOOR: I shall finish in a minute or two,

In that connection I would suggest that the discount which is being given to Government hospitals and other charitable institutions—it now stands at 10 per cent.—may be increased to 20 per cent. The trade at the moment is being given a discount of 10 per cent. and the Government hospitals are also being given the same discount. I would suggest that while reducing the price—they may reduce it to such extent as is possible—they may increase the discount for Government hospitals and other charitable institutions.

Now, Sir, with regard to the Board of Directors, I have one suggestion to make and that is, in this concern, as also in every other concern, my view is that Parliament might be represented by one or two Members. That will, I would say, have a very good effect and you may always have either one Member of Parliament or two, one from that House and one from this House on the Board of Directors.

In the end I have two small things to comment upon.

MR. DEPUTY CHAIRMAN: There is no time, Mr. Kapoor. There are six more speakers.

SHRI JASPAT ROY KAPOOR: Last sentence, Sir. It is proposed by the Board of Directors that in course of time even the raw materials shall be analysed by the Quality Control Department and it is said that it will take some time. I would suggest that this step may be taken as soon as possible. And in the end I want to associate myself with the appreciation which the Directors have extended to the Managing Director and members of the staff, and in addition I would like to express my appreciation on behalf of Parliament to the whole Board of Directors. I wish this institution greater and yet greater success.

MR. DEPUTY CHAIRMAN: Rajkumari Amrit Kaur. Not more than ten minutes.

RAJKUMARI AMRIT KAUR: Sir, I will only take just two or three minutes.

Sir, I am interested in the Pimpri Factory because I am proud that I have had a hand in bringing it into being in the public sector. I have watched its progress with immense interest and now I am proud of what it is doing today. There was unfortunately the question of the death of a Member of Parliament but I am glad that Dr. Gour has said that that question should be kept completely apart from the Pimpri Factory itself and how it is managed, because allergy to penicillin is a common thing. It happens everywhere. And since that particular batch has been completely analysed both at home and abroad, I do not think that we have any reason whatsoever to doubt that Shri Tripathi's death was due to allergy and nothing else.

Now comes the question of the Pimpri Factory itself and its management and its production. The Report that we have in our hands speaks amply for what the Factory is doing and I think we may congratulate ourselves that it has brought a great deal of relief to human suffering in this country. It was brought into being—I would have the House to remember—with the intention of running it on a no profit no loss basis and even if there was any loss, the human factor had to be reckoned first and one of the conditions to the help that we got from abroad was that so much penicillin had to be given free for the children of this country and that has been done. But at the same time suggestions have been made that the present Managing Director should go. I am not acquainted with the present Managing Director and I do not know that we are justified in making sweeping statements of that nature. The Factory is not only a producing factory of drugs but every thing has to be done as economically as possible so that in the public sector our factories do not fail. Even if they do not make any profit, at any rate they should have a good business head. I have no objection to a lay head but the assurance that I would like to have from the Minister is this that every one of the recommendations given in the last Report of the Sub-Committee appointed by him shall be adhered to and adhered to not only in the letter but in the spirit also and that quality control should not be allowed to suffer at any cost. I therefore, hope that the quality control side of it will be completely independent and that there will be no interference in quality control by the Managing Director who is a layman today. I want that assurance from him because after all if we cannot have proper quality control—and that quality control can only come if we had good technicians at the head of the Department of Quality Control—we shall not be able to help production in this Factory and we shall not be able to hold our heads high and compete internationally. I want the assurance from the Minister that our quality control shall be the best and that at the head of it shall be some one who knows everything, whether he is a bacteriologist or a chemist—I do not

mind—or a mycologist. But he must know the job; he must be an efficient technician. That is all that I have to say.

DR. M. D. D. GILDER (Bombay): Mr. Deputy Chairman, I shall confine myself entirely to the medical aspect of the case and not to the business aspect. The unfortunate death that had occurred, I am perfectly sure, had not occurred because of want of quality control. These deaths have occurred in other parts of the world. As the hon. Minister said the other day, they have occurred and they have been investigated. The cause of the deaths has been found to be either allergy or inadvertent injection of the suspension into a vein. Against both these inadvertent accidents, the doctor is warned in the paper which is issued with every bottle of penicillin, and he is told how to prevent them and what measures to take if such accidents unfortunately occur. I am perfectly sure that the death in this case was due to one of those causes. But it has raised a question on a very broad basis. I speak with a certain amount of knowledge because the scheme of the manufacture of penicillin was sent to the Government of India by the Government of Bombay when I was the Minister of Health. The scheme at that time included not only the production of penicillin, but also anti-malarial drugs and sulpha drugs as well. The Government of India brought it down to antibiotic drugs only. Dr. Sokhey and Dr. Ganapathi were connected with the plans for this institution. From the very beginning, we had, through Maj. Gen. Sokhey's advice, united ourselves to a Swedish company. In the meantime, the Swedish company went to Mercks in America and they advised us to join with Mercks. We sent Mr. Neville Wadia and Mr. Choksi of the Tatas, with Colonel Sokhey to America to investigate the scheme further. That was the scheme submitted to the Government of India and we made a condition, which the Government of India immediately accepted, that excepting for a certain sum of money to be set apart for research, there should be no profit and no loss. That factory, when built, would be on a national scale for the provision of the necessary drug over the whole of India. There was also a possibility of having another factory in Bengal in those days.

When the factory was established, for certain reasons the Government of Bombay went out of the concern and the Government of India undertook the whole concern themselves. It was between the two of us, Rajkumariji as Minister of Health of the Government of India and I, as Minister of Health of the Government of Bombay, that the scheme was first discussed. The Government of India took up the foundation of the factory and Bombay gave them all the conveniences, land, water, etc. We built a dam in a river to supply them with water.

Now, there are certain statements that have been made which seem to me to be very surprising. For instance, Rajkumariji herself stated in the House in the first year of the factory that the penicillin made by them had been sent out and had been examined by various factories in the United States and in Europe and that it had been pronounced to be of good quality in every respect. My hon. friend, the mover, here today states that no batches were sent out. Rajkumariji must have had her authority for saying that. If the mover is correct, then it is a very reprehensible thing which ought to be corrected, because it had led the hon. Minister at that time to make a statement which was not true. Therefore, I would request the hon. Minister to go into that question also.

A charge that is brought is that the Managing Director is a B.A., B.L. and not a technical man. Well Sir, the Haffkine Institute had as its head—in my days, and from the

[Dr. M. D. D. Gilder.]

days when it was founded as the Bombay Bacteriological Laboratory in the days of the early plague epidemic—an I.M.S. officer, a medical officer, a scientific officer. When it turned its work from pure research to making of products and selling them—I can give you my experience with regard to some of those products—it made vitamins. And we found that because we had no sales organisation, the vitamins were lying rotting in the godowns of the Haffkine Institute. The scientific man at the head was not a salesman. It was difficult for a scientific man to be also a salesman. Similarly, when the fisheries department made shark liver oil and so on, there was no sales department. There was no sales director and so the thing failed there too. And, Sir, if you look at all the private companies that make these drugs, or even the nationalised organisations that make drugs, you will find that they have on the directors' board, and often as the managing director, a layman who understands the sales department and the organisation of the various departments. So, I do not see any reason why the Managing Director should not be a layman, provided he gives the technical department full sway and does not interfere in their work. That is one of the essential conditions.

Then, Sir, it has been said that cultures for streptomycin, aureomycin and terramycin were brought from abroad. But the method of production of the drugs was ours. What the Report says is that they were made from indigenous materials, by indigenous methods. There are drugs which are not chemicals. These antibiotics are drugs which are made by cultures of various organisms. They may be bacteria, but they are generally moulds. We call them moulds. For instance, penicillin itself is made from a mould which grows on stale bread. The original discovery of penicillin was made when a plate with a culture of various bacteria was lying exposed in a laboratory together with the white stuff that grows on moist bread. They were lying exposed. That mould had got into the culture plate and the bacteria were killed. From the accidental discovery came the preparation of penicillin. Penicillin is made by the penicillin mould. To take it out is a different process. During World War II the penicillin discovery was made in England, but the process of separating it was practically worked out in America. So, the process of separating aureomycin from the mould was ours. That does not mean that the culture was ours. And my hon. friend said that the culture was brought from Russia. Well it may be; one knows of a former Member of this House, whom we have heard talking about the Russians and their excellence in this House on many occasions. But bringing a culture does not mean that the method of separation was not ours.

Then, the question comes about the Research Department. As I said, we had from the very beginning made arrangements that whatever profit we got, a part of the profit was to be reserved for research. The Research Department is a department with accent on new methods of preparation, new types of cultures, and so on. What has that got to do with quality control? If you mix up the sale of drugs with research, you will neither do the one nor the other. The Research Department is an entirely separate department. Then, the question is, where should the quality control go? I would say that the quality control should be an independent department under the general head, whoever he may be. And the general head, whether he be a technician or whether he be a layman, should accept the decisions of the quality control department without interference. That would be my suggestion for the management of the institution.

4 P.M.

Sir, as far as my information goes the original rules adopted were—let me put it this way— there are various

countries and they have got various drugs that they use, and they call the list of these drugs the Pharmacopoeia. Of course all drugs must be pure. Even for an ordinary chemical drug they always give the test to ascertain the standard of its purity. The British Pharmacopoeia for the drugs processed in Great Britain is there. Similarly the United States Pharmacopoeia is there. The French Pharmacopoeia is there. The Swedish Pharmacopoeia is there, and so on. Now, we have got an Indian Pharmacopoeia also. Each Pharmacopoeia prescribes certain tests for the purity of its drugs. The United States pharmacopoeia has its regulations for the purity of its drugs. The British Pharmacopoeia has its regulations for the purity of its drugs. They are generally the same but may differ in one or two points of detail. According to our rules the British Pharmacopoeia tests should be used. The United States tests are a little more rigid, a little more strict. They require a greater number of samples to be examined than the British Pharmacopoeia. It seems to me that the United States Pharmacopoeia tests were being used by the Quality Control Department, though according to our rules they should be the British Pharmacopoeia ones. I do not know whether the Drug Controller in Bombay had noticed that or not. But whatever it may be they were following a very reputed Pharmacopoeia, a Pharmacopoeia whose tests were to a certain extent more rigid than the Pharmacopoeia of the British.

Now, Sir, in August or September—this is my information and I would like the hon. Minister to correct me if I am wrong—the person in charge of the Department made a departure from the United States Pharmacopoeia in as much as he took three bottles instead of ten bottles for testing. The British Pharmacopoeia is satisfied with three, but the United States Pharmacopoeia which is, as I said, more rigid requires ten. He mixed up the two, and though he applied the test of the United States Pharmacopoeia, he took the number from the British Pharmacopoeia. When that was found out by the Drug Controller in Bombay, the Drug Controller gave a severe notice—and of course the notice goes to the Director under whom this thing is being done. The Director got that notice and it was acknowledged that that was deserved. That is my information, and steps were immediately taken to rectify it. Whether you accept the British Pharmacopoeia or the United States Pharmacopoeia does not matter, because both are reputable Pharmacopoeias. Both are big countries doing the tests according to the one or the other of the Pharmacopoeias. The main thing was, if we followed the United States Pharmacopoeia, we did not follow its rules rigourously. That I think was wrong, and I hope that the hon. Minister will see that such a thing does not occur again. Apart from that I do not see that there was any mismanagement or any thing for which blame should be laid on the factory.

As far as the death of the hon. Member was concerned, that was an unavoidable accident. Sir, I may tell you that my wife nearly collapsed after an injection of penicillin given by my daughter who is an M.D. herself. And luckily for all of us in our family she recovered. But no doctor can assure recovery, can guarantee recovery of any patient, unless the illness is a very minor one. These things do occur and, although I am very sorry that the hon. Member's life was sacrificed, this discussion and this clarification should help in restoring the confidence of the public in such an important undertaking as far as the economy and the health of this country are concerned.

SHRI AKBAR ALI KHAN (Andhra Pradesh): May I seek one clarification from the hon. Member? Is the hon. Member fully satisfied that the technical and Expert Committee had its independent say in this arrangement particularly with regard to the quality of the tests?

MR. DEPUTY CHAIRMAN: The hon. Minister will reply to it.

DIWAN CHAMAN LALL: Sir, I did not intend to speak in this debate, but as I came into the House and heard the speeches that had been made, I requested you to give me a few minutes of your time. The reason is this. I would like to pay my tribute to the mover of this motion for having raised a debate on this issue which is of very great importance to us, and I entirely agree with Dr. Gilder, whose beautiful voice unfortunately we shall not be privileged to hear very often in this House, in the last statement that he made that a debate of this nature is important in order to reimpose upon the public mind complete confidence in this great institution of ours. It is necessary because certain things have happened, and because those things happened the hon. Minister in charge appointed a committee to go into this matter. The Committee has presented a report, and I regret to say that, although the report is dated the 17th January, it was presented to us only today just before the debate was to take place.

SHRI MANUBHAI SHAH: The Board had to consider the report, the minutes had to come, and all that.

DR. R. B. GOUR: This Committee was appointed by the Board.

DIWAN CHAMAN LALL: Whatever it may be, it functioned probably under the advice of the Ministry.

DR. R. B. GOUR: He says no.

DIWAN CHAMAN LALL: They all listen to their advice whether it is officially given or unofficially given. I agree with the hon. Minister that the Board has taken some time, but thereby it is made rather difficult for hon. Members, who have had this report placed before them just before the debate, to give their minds to the subject which is contained in this report.

Reading cursorily this report, Sir, certain issues arise which I would like my hon. friend to refer to. The former Minister of Health, Rajkumari Amrit Kaur, made one very important point when she suggested that no matter what happens, it was very necessary that the Drugs Control Department should be divorced completely from the management side. That was so in the past, and unfortunately it did not continue to function accordingly, and now the time has come when this thing has got to happen.

The second issue that arises is a very very serious one indeed. Why did this debate take place? Why did this issue arise? You will recall, Sir, that my hon. friend, the Minister of Health, made a categorical statement on the floor of the House in regard to a particular batch which was under criticism at the time. He made a categorical statement and we in this House were completely misled by that statement. He himself was misled. Who misled him? We have had no answer to this particular question. Whoever was responsible for misleading the hon. Minister who in his turn misled this House in regard to that particular batch has got to answer to this Parliament. It becomes a matter of privilege for this Parliament. This Parliament cannot be misled by any Minister, and if the Minister, as in this case, is not himself responsible but spoke on the authority of some information given to him, that matter has got to be gone into. Therefore, Sir, I do hope that my hon. friend, the Minister in charge, will look into this matter whether it is correct or it is not correct that four tests were made. If it is correct that four tests were made, then the statement is completely untrue when it says that four tests have not been made. Who gave the information? Whoever gave the information is not fit to hold the job that he holds today, and I want my hon. friend to remember that this is one of the serious matters that have got to be taken into consideration by

the Ministry and dealt with properly on that basis.

That is one of the issues. The second issue is in regard to this Report itself. Now, Sir, I do want to pay my tribute to this organisation which during the period of Rajkumariji's tenure of office was created in India. It is an institution which is not concerned with profits. In fact, one of the conditions is that it shall make no profits. It was a gift given to us. It is a great institution and I want that every assistance should be given to this institution and its products to be popularised, because the products are good products. Mistakes have been made, there is no doubt about it. Mistakes have been made as even admitted in this Report by the Board of Directors on which the Managing Director himself was a member. They admit that mistakes were made. What we want is that mistakes should never be made in this institution. It is a fine institution; its products are wonderful products and if mistakes have been made, they have to be rectified, not only rectified but every step taken to see that those mistakes are not committed again.

Reference was made by my hon. friend who is not sitting behind me now to the fact that they were technical breaches of the law. What are the technical breaches of the law? There is Rule 119 of the Drug Act Rules. I asked my friend to read it out but apparently he did not. This is what it says—

> "(1) If at this examination no growth of micro-organisms is found in any tube, the sample may be treated as having passed the test.
>
> (2) If at the examination a growth of micro-organisms is visible, further samples may be taken and the tests may be repeated on the further samples taken; but no container the contents of which form part of the batch shall be issued until such further samples have passed the test. The process of taking samples from the batch for a test may be repeated twice:"

Here it was repeated four times.

SHRI MANUBHAI SHAH: There times. Again, what Dr. Gour meant was quite different from what my hon. friend says. This is the test under the Indian Pharmacopoeia. Under the United States Pharmacopoeia four tests are allowed. What the breach is that instead of taking the sample from ten vials for those 26 days for sterility purpose, it was drawn from three vials. That is the only thing.

DIWAN CHAMAN LALL: I am coming to that. I do not know why my learned friend is being a little impatient about this. I am perfectly aware of this. When I asked Dr. Gour to read out Rules 119 and 114, he did not. Now, I read out the Rule. Why was the U.S. Standard used? Why was not the Standard laid down in the Rules? That was the mistake. That was made, and it is admitted . . .

SHRI MANUBHAI SHAH: The Drug Rules were there right from the inception.

DIWAN CHAMAN LALL: If the Drug Rules were there from the beginning my hon. friend will realise that those four tests were not necessary. Then they should have been discarded; the material should have been discarded straightway according to the United States Standards. However, I am not taking umbrage at the fact that four tests were made under the United States Pharmacopoeia. What does this Report itself say? For God's sake, do not go on using different types of Pharmacopoeia for the purpose of testing the products of this factory. It says, "Don't use the U.S. Standards once; the B. P. Standard the next time and the I.P. Standard another time". It is there in this Report which my learned friend has placed on the Table of the House. Don't use different tests. Make up your mind to use one type of test and stick to it. This is your own Report, not my Report. There-

[Diwan Chaman Lall.]

fore, I suppose in view of what has happened, that my learned friend would be well advised to take action, take this House into his confidence whether a person who makes a mistake like that is a fit person to continue in charge of a great institution like this. Let us make that perfectly clear. If we have been misled, if this House has been misled, somebody is responsible for misleading this House, and it is a matter of privilege of this House. Therefore, let necessary action be taken. This is No. 1.

Secondly, Sir, the question arises with regard to Drug Rule No. 114. My learned friend behind me said that that was really a technical matter. A technical matter? Any contravention of the Rules results in what? Section 27 of the Drug Act itself provides for imprisonment which may extend to three years. It says:

> "Whoever himself or by any other person manufactures for sale, sells, stocks or exhibits for sale, or distributes any drug in contravention of any of the provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment which may extend to three years, or with fine, or with both."

The reason is very simple. Here is a factory of which we are very proud. We want that nothing that is produced in this factory should be under any challenge by anybody, and hence the Rules have got to be strictly adhered to. Any infringement of these Rules is not a technical matter. It is a serious matter and therefore I submit, Sir, that my learned friend will, having taken this action, take further action firstly suggested by Dr. Gour and secondly by me and thirdly see that in future no statement will be made by any hon. Minister on the floor of this House unless it is checked properly and if found that it is not correct, then it is up to the Government to take necessary action against those persons who have misled them.

Sir, I want to end by merely stating that there is nobody in this House who does not welcome an institution of this nature and who is not prepared to support an institution of this nature. All that we are concerned with is that the products of this institution should be properly tested according to the Drug Rules that have been laid down and the methods of manufacture that are appropriate to the safety of the public.

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## ANNOUNCEMENT *RE* MOTION ON DR. JOSEPH'S SUICIDE

MR. DEPUTY CHAIRMAN: Before I call the next speaker, I have to inform Members that the motion regarding Dr. Joseph's suicide put down in the List of Business for Thursday, March 10, 1960, will not come up on that day. Instead, the House will take up consideration of the amendments to the Dowry Prohibition Bill, 1960, on 10-3-1960.

SHRI BHUPESH GUPTA: (West Bengal): But I understand that it is an accommodation that has been made to suit Mr. S. K. Patil. I have been demanding it. Now, he is going to Amritsar, and he will not be here. Therefore, it will come during the next session. It stands pending. That is there.

MR. DEPUTY CHAIRMAN: It will stand over.

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## MOTION *RE* REPORT OF HINDUSTAN ANTIBIOTICS LIMITED PIMPRI—*continued.*

SHRI BHUPESH GUPTA: Mr. Deputy Chairman, Sir, first of all, I would like to ask one question of the hon. Minister in this connection. Mr. Dhage on the 22nd December, 1959, produced certain photostat copies of the Hindustan Antibiotics Limited's register wherein entries were not made. Where entries should have