IN THE SUPREME COURT OF BANGLADESH
HIGH COURT DIVISION
(SPECIAL ORIGINAL JURISDICTION)

WRIT PETITION NO. 6969 OF 2016

IN THE MATTER OF :

An application under Article 102 of the Constitution of the People's Republic of Bangladesh.

A N D
IN THE MATTER OF :

Md. Human Rights and Peace for Bangladesh (HRPB), represented by it's Secretary Asaduzzaman Siddique, Hall No.2, Supreme court Bar Association Bhaban, Dhaka, Bangladesh and another.

.... Petitioners.

= Versus =

Bangladesh, represented by the Secretary Ministry of Health and Family Welfare, Bangladesh Secretariat, P.S. Shahbag Dhaka, Bangladesh and others.

.... Respondents.

Mr. Manzill Murshid, Advocate

…... for the petitioners.

Dr. Md. Bashir Ullah, D.A.G. with
Mrs.Yeadia Zaman, A.A.G. and
Mr. Md. Sarwardhi, A.A.G.
.. for the Respondent No.1-4.

Ms. Rimi Nahreen, Advocate

…. .... for the Added- Respondent No.8

Mr. A.K.M.Towhidur Rahman

….. ... for the Added-Respondent No.9.

Mr. Sakib Rezwan Kabir, Advocate

…..... for the Added- Respondent No.10

Mr. Tanjibul Alam with
Mr. M. Saquibuzzaman, Advocates
... for the Added- Respondent No.11

Mr. Habibul Islam Bhuiyan with
Mr. Md. Abdur Razzak, Advocates
….. .. for the Added-Respondent No. 12

Mr. Md. Aminul Islam, Advocate

….... for the Added-Respondent No.13

Mr. Abdullah Al Baki, Advocate

..for the Added-Respondent No.14

Mr. M.A. Hannan, Advocate

.. for the Added-Respondent No.15

Mr. A.K.M.Badrudduza,Advocate

…. for the Added-Respondent Nos. 16 and 17

Mr. M. Sayed Ahmed,Advocate

.. for the Added-Respondent No. 18

Mr. Maudud Ahmed with
Mr. Pankaj Kumar Kundu, Advocates
.. for the Added-Respondent No.19

Mr. A.K.M.Asiful Haque, Advocate

... for the Added-Respondent No.20

Mr.Abdulla Al Baki, Advocate
.. for the Added-Respondent No.21
Heard on
10.1.2017,11.1.2017,12.1.2017,15.1.2017
, 22.1.2017, 25.1.2017,
29.1.2017,30.1.2017 and

Judgment on 13.2.2017

Present :
Mr. Justice Syed Muhammad Dastagir Husain
and
Mr. Justice Md. Ataur Rahman Khan

Syed Muhammad Dastagir Husain, J:

Rule Nisi was issued calling upon the respondents to show cause as to why the inaction and failure of the respondents to cancel the license of 20 pharmaceuticals industries namely Aexim Pharmaceuticals Ltd., Avert Pharmaceuticals Ltd, Bikolpo Pharmaceuticals Ltd, Dolphin Pharmaceuticals Ltd. Drugland Pharmaceuticals Ltd. Globe Laboratories Ltd. Jalpha Pharmaceuticals Ltd., Kafma Pharmaceuticals Ltd., Medico Pharmaceuticals Ltd., National Drug Pharmaceuticals Ltd., North Bengal Pharmaceuticals Ltd., Remo Chemicals Pharmaceuticals Ltd., Rid Pharmaceuticals Ltd., Skylab Pharmaceuticals Ltd., Spark Pharmaceuticals Ltd., Star Pharmaceuticals Ltd., Sunipun Pharmaceuticals Ltd., Today Pharmaceuticals Ltd., Tropicdal Pharmaceuticals Ltd., and Universal Pharmaceuticals Ltd. which are producing life saving drugs & medicine such as antibiotic, steroid, hormone, and cancer drug etc. without maintaining quality control, should not be declared illegal and without lawful authority and as to why a direction should not be given upon the respondents to cancel the license of 20 pharmaceuticals industries namely Aexim Pharmaceuticals Ltd., Avert Pharmaceuticals Ltd, Bikolpo Pharmaceuticals Ltd, Dolphin Pharmaceuticals Ltd. Drugland Pharmaceuticals Ltd. Globe Laboratories Ltd. Jalpha Pharmaceuticals Ltd., Kafma Pharmaceuticals Ltd., Medico Pharmaceuticals Ltd., National Drug Pharmaceuticals Ltd., North Bengal Pharmaceuticals Ltd., Remo Chemicals Pharmaceuticals Ltd., Rid

Pharmaceuticals Ltd., Skylab Pharmaceuticals Ltd., Spark Pharmaceuticals Ltd., Star Pharmaceuticals Ltd., Sunipun Pharmaceuticals Ltd., Today Pharmaceuticals Ltd., Tropicdal Pharmaceuticals Ltd., and Universal Pharmaceuticals Ltd. due to their failure to produce life saving drugs & medicine such as antibiotic, steroid, hormone, anti cancer drug etc. without maintaining quality control.

The petitioner is an organization upholding Human Rights and Peace for Bangladesh (HRPB), a non profitable registered organization and the objects of the organization is to uphold the human rights of the citizen and to work for the poor people, to give legal support to the common people and to build up awareness amongst the people. Moreover the organization is also working to protect human health and takes legal steps against the activities subversive of public health as well as in case of violation of law. The respondent No.1 is Bangladesh represented by the Secretary, Ministry of Health and Family Welfare, Respondent No. 2 is the Director General (DG), Health Directorate, Mohakhaliu, Dhaka, Respondent No.3 is the Director General, the Department of National Consumer Rights Protection, Respondent No.4 is the Director, Directorate of Drug Administration, Respondent No. 5 The Secretary, Bangladesh Aushad Shilpa Samity/ Bangladesh Association of Pharmaceutical Industries (BAPI), Respondent No. 6 is the Inspector General of Police (IGP), Police Head Quarter, Ramna, Dhaka, Respondent No.7 is the Director General D.G. of RAB Forces, RAB Head Quarter, Kurmitola, Dhaka and their address are given in the cause title are correct. The instant writ petition is involved in respect of production of medicine who are violating the GMP principles which is vital need in day to day life of human beings. Due to the production of drugs which are not up to the mark affecting the life of the people. This being a matter of public issue and relating to public health because less quality medicine has a severe negative impact on all patients. Since the matter involves a great public importance, so this petition is treated as Public Interest Litigation. It is necessary to stop illegal production of antibiotic/drugs/medicine to save the health of the citizen otherwise the people will suffer a lot, which would have a severe bad impact on the life of the citizen and it violated the fundamental rights guaranteed by the Constitution of Bangladesh. It is stated here that due to production of less quality drug and medicine by some pharmaceuticals industries the issue

was discussed in the parliamentary standing committee and with the approval of the Hon'ble Speaker of the Bangladesh Parliament an expert committee was formed in September 2014 headed by Professor ABM Faruk alongwith four others professors of different universities. The committee was directed to visit the industries in order to ascertain the capacity and qualitative medicine produced by the Pharmaceuticals Industries in Bangladesh. It was also directed that the committee to submit a report. The expert committee visited 84 pharmaceuticals industries and submitted a detail report on 1.2.2016. Before submitting the report the members of the committee visited three times in the industries. The expert committee report firstly recommended to cancel the license of 20 pharmaceuticals industries namely Aexim Pharmaceuticals Ltd., Avert Pharmaceuticals Ltd , Bikolpo Pharmaceuticals Ltd , Dolphin Pharmaceuticals Ltd , Drugland Pharmaceuticals Ltd , Globe Laboratories Ltd. Jalpha Pharmaceuticals Ltd , Kafma Pharmaceuticals Ltd , Medico Pharmaceuticals Ltd , National Drug Pharmaceuticals Ltd , North bengal Pharmaceuticals Ltd , Remo Chemicals Pharmaceuticals Ltd , Rid Pharmaceuticals Ltd , Skylab Pharmaceuticals Ltd , Spark Pharmaceuticals Ltd., Star Pharmaceuticals Ltd ., Sunipun Pharmaceuticals Ltd., Today Pharmaceuticals Ltd., Tropical Pharmaceuticals Ltd ., and Universal Pharmaceuticals Ltd., . The expert committee also recommended to cancel the permission of production of Antibiotic (Non Penicillin, Penicillin and Cephalosporin group) by the Ad Din Pharmaceuticals Ltd , Alkad Pharmaceuticals Ltd ., Belsen Pharmaceuticals Ltd , Bengal Drugs Pharmaceuticals Ltd ., Bristol Pharma Pharmaceuticals Ltd ., Crystal Pharmaceuticals Ltd., Indobangla Pharmaceuticals Ltd., Millat Pharmaceuticals Ltd ., MST Pharmaceuticals Ltd ., Orbit Pharmaceuticals Ltd ., Pharmik Pharmaceuticals Ltd ., Phoenix Pharmaceuticals Ltd ., Rasa Pharmaceuticals Ltd ., and Save Pharmaceuticals Ltd ., due to their failure to control the quality of such medicine. On the similar cause the expert committee recommended to cancel the production license of another 22 Pharmaceuticals Industries. On 19.4.2016 a report was published in the Daily Jugantor with the heading " জীবন রক্ষাকারি ওষধ ভেজাল" In the report it was stated that despite of recommendation by the expert committee the government did not take any steps to stop less quality medicine production. The committee referred to "whether the concerned pharmaceuticals industries are capable of producing

drugs/medicines with their existing infrastructures as per GMP principles/guidelines, that has been considered in the instant report". The committee also expressed its concern in the words "if drugs /medicines are not produced in line with GMP guidelines, the produced drugs/medicines don't have any standard, diseases are not cured; severe injury may occur in human body that may also claim human life. And those drugs/medicines are to be abandoned in the context and all considerations of public health." Accordingly, as per the terms of reference, the Expert Committee prepared its report along with various observations and specific recommendations for each pharmaceutical industry addressing Good Manufacturing Practice (GMP)- principles which comprises some basic principles of drugs productions, i.e. its quality system, risk management, sanitation and hygiene, self- inspection personnel, premises, equipments, materials goods practice and above quality control of drugs. Thus the opinion is made in the report of the following pharmaceuticals which are in Annexure- A.

The Report in respect of Skylab runs as follows :-

> মতামতঃ কারখানার বিদ্যমান অবস্থায় জিএমপি নীতিমালা অনুযায়ী এখান মানসম্পন্ন ওষুধ উৎপাদন সম্ভব নয়। গত ৫ বছর কারখানার কোন সংস্কার করা হয়নি, এমনকি এর উৎপাদন লাইসন্সও নবায়ন করা হয়নি। তাই বর্তমান অবস্থায় এ কোম্পানি গোগন ওষুধ উৎপাদনকরল সে ওষুধ জনস্বাস্থ্যর জন্য ক্ষতিকর হব । এ প্রেক্ষিত কোম্পানির ওষুধ উৎপাদনর অনুমতি বাতিল করার জন্য সুপারিশ করা হলা ।

Respondent No.8: Skylab Pharmaceuticals Ltd.- Its factory premises is dirty and dusty. It did not renew license. It has not capability for production of drugs in line with GMP.

The Report in respect of Universal Pharmaceuticals Ltd runs as follows :-

> মতামতঃ কারখানার সার্বিক অবস্থা বিবচনা কর বিশষজ্ঞ পরিদর্শন দল মন কর যে, বিদ্যমান সুবিধাবলীত কারখানাটির পক্ষ কোন রকম ওষুধ উৎপাদন করা সম্ভব নয়। কারণ এভাব উৎপাদিত খাওয়ার ওষুধর প্রত্যাশিত কার্যকারিতা , উপযুক্ত মান ও যথাযথ স্থায়িত্ব অর্জন অসম্ভব। ফল এখানকার উৎপাদিত ওষুধ ব্যবহার প্রাণহানির মতা দূর্ঘটনা ঘটার আশংকা র-য়ছ বিধায় জনস্বাস্থ্য রক্ষার স্বার্থ এই কারখানায় সব ধরনর ওষুধ উৎপাদন অবিলম্ব বন্ধ কর অনুমতি বাতিল করার জন্য সুপারিশ করা হলা ।

Respondent No.9: Universal Pharmaceuticals Ltd.- It has no ETP, its personnel entry is not satisfactory, documents unavailable for collection of raw materials from legal source, scarcity of skilled manpower, no

sampling and dispensing booth, no cleaning SOP and cleaning records, and cleaning pay and its warehouse is severely dirty. After all it does not follow GMP guidelines for drugs manufacturing.

The Report in respect of Star Pharmaceuticals Ltd. runs as follows :-

> মতামতঃ কারখানার বিরাজমান ভয়ংকর অবস্থায় কোন রকম জিএমপি শর্ত না মেন এবং গোপন ও অনৈতিকভাব যাচ্ছ তাই উপায় যে ওষুধ উৎপাদন করা হচ্ছ তা একান্তই মানহীন, অগ্রহণযাগ্য ও জনস্বাস্থ্যর জন্য ক্ষতিকর বিধায় এর ওষুধ উৎপাদন লাইসন্স অবিলম্ব বাতিল করার জন্য সুপারিশ করা হলা ।

Respondent No. 10: Star Pharmaceuticals Ltd.- has no personal entry, its factory premises is dirty and dusty, sub- standard Machineries are used for manufacturing, which are not cleaned for years, it does not keep records for finished drugs, it has no water system, and many others.

The Report in respect of Ad Din Pharmaceuticals Ltd. runs as follows :-

> মতামতঃ কারখানায় বিদ্যমান পরিবশ ও উৎপাদন সুবিধা, জিএমপি অপুর্ণতা এবং এর উৎপাদিত ওষধ জনস্বাস্থ্য ঝুঁকির কথা বিবচনা কর এই কারখানায় কোন নন- পেনিসিলিন, পেনিসিলিন এবং সেফালাস্পারিন গ্রুপর এন্টিবায়াটিক কিংবা স্টেরয়ড/হরমানজাতীয় ওষুধ উৎপাদনর অনুমতি প্রদান না করার জন্য সুপারিশ করা হলা । তব কারখানাটিক অন্যান্য ওষুধ উৎপাদনর অনুমতি দেওয়া যেত পার ।

Respondent No.11: Ad Din Pharmaceuticals Ltd.- It has no ETP, Warehouse no GMP-, No certified vendor list, Raw & Packaging materials stores not satisfactory, expired raw material used for drugs, etc. no label of date of retest found on items at warehouse, ventilation is vulnerable, all kinds of antibiotics (non penicillin, penicillin, cephalosporin etc.) are produced in a single building, AC non- workable at production area, no conformity test available etc. machines are dirty and no documents are available for them.

The Report in respect of Avert Pharma Ltd runs as follows :-

> মতামতঃ ওষুধ উৎপাদনর জিএমপি নীতিমালা অনুসরণ অক্ষমতা দূরীকরণর জন্য কারখানা কর্তৃপক্ষ প্রায় ৬ বছর সময় পেলও তারা কারখানাটির প্রত্যাশিত সংস্কার করনি, কেবল বিপুল পরিমাণ ওষুধ উৎপাদন অব্যাহত রেখছি। উৎপাদন বন্ধ ঘোষণা সত্ত্বও কারখানায় গোপন ওষুধ উৎপাদনর আলামত পাওয়াত প্রতীয়মান হয় যে, কারখানাটি অনৈতিক কর্মকান্ড লিপ্ত এবং এর উৎপাদিত ওষুধ জনস্বা্স্থ্যর জন্য অত্যন্ত ঝুকিপূর্ণ । এই প্রেক্ষিত জনস্বাস্থ্য

রক্ষার স্বার্থ জরুরি ভিত্তিত কারখানাটির সব ধরনর ওষুধ উৎপাদনর অনুমতি বাতিল করার জন্য সুপারিশ করা হলা ।

Respondent No.12: Avert Pharma Ltd.- it includes incapability of drugs manufacturing in line with GMP, No ETP, No material receiving and clearing bay, temperature at warehouse area not satisfactory, fictitious labeling at warehouse, no status labeling on machines and they are dirty, no documentations for illegal drugs manufactured after closure down of factory.

The Report in respect of Spark Pharmaceuticals Ltd. runs as follows :-

মতামতঃ কারখানাটি জিএমপি নীতিমালা মেন চলত একান্তই ব্যর্থ। পাঁচ বছরর বেশি সময় পেলও তারা জিএমপি নীতিমালা অনুযায়ী কারখানাটির সংস্কার করনি । বর্তমান অবস্থায় যেভাব ওষুধ উৎপাদন হচ্ছ তাত কোন কার্যকর ও নিরাপদ ওষুধ তৈরি করা সম্ভব নয়। তাই এখানকার উৎপাদিত ওষুধ জনস্বাস্থ্যর জন্য অত্যন্ত ঝুঁকিপুর্ণ বিধায় এর ওষুধ উৎপাদন লাই-সন্স বাতিল করার জন্য সুপরিশ করা হলা ।

Respondent No.13: Spark Pharmaceuticals Ltd.- Factory is at residential area, personal entry incomplete4 and unacceptable, Label without expiry date, Warehouse not GMP standard, antibiotic premises is not separate from production area, rain falls down at tablet room, uncontrolled tablet coating room posing threat to health of employees.

The Report in respect of Sunipun Pharmaceuticals Ltd.runs as follows :-

মতামতঃ দীর্ঘসময় অতিবাহিত হওয়ার পরও কোম্পানিটি চালু না হওয়ায় ও জিএমপি নীতিমালা মেন চলত ব্যর্থ হওয়ায় এর উৎপাদিত ওষুধ ক্ষতিকর এবং জনস্বাস্থ্যর জন্য ঝুঁকিপুর্ণ হব বিধায় এর উৎপাদন লাইসন্স বাতিল করার সুপারিশ করছি ।

Respondent No.14: Sunipun Pharmaceuticals Ltd. has been illegally manufacturing antibiotic and other drugs, it has no ETP, its factory is at densely populated area, it has no cleaning bay, material receiving facility, it has been failed in observance of GMP guidelines.

The Report in respect of MST Pharma & Healthcare Ltd.runs as follows :-

মতামতঃ কারখানা ভবনটি নতুন ঠিকানায় এবং নবনির্মিত হলও জিএমপি নীতিমালা অনুসরণ কর ওষুধ উৎপাদন সক্ষম নয় । কারখানাটিক তাই নন- পেনিসিলিন, পেনিসিলিন ও সেফা-লাম্পারিন গ্রুপর এন্টিবায়াটিক এবং স্টেরয়ড/ হরমান বাদ অন্যান্য ওষুধ উৎপাদনর জন্য অনুমতি দেওয়ার সুপারিশ করা হলা ।

Respondent No.15 : MST Pharma & Healthcare Ltd.- have no Certification for raw materials bought from local market, Store temperature not acceptable, No AC for capsule cell and foil roll etc. Its labeling on drum is suspicious, raw materials at sensitive material stores are at risk of damaged due to heat, machines are dirty, there is no material dispensing records, and BSTI certified weight, calibration SOP etc.

The Report in respect of Bristol Pharma Ltd. runs as follows :-

> মতামতঃ- কারখানার সার্বিক অবস্থা বিবচনা কর বিশষজ্ঞ পরিদর্শন দল মন কর, বিদ্যমান সুবিধাবলীত উৎপাদিত ওষুধর প্রত্যাশিত কার্যকারিতা, উপযুক্ত মান ও যথাযথ স্থায়িত্ব অর্জন সম্ভব নয়। বরং এগুলার ব্যবহার রোগী ক্ষতিগ্রস্থ হত পার ও দুর্ঘটনা ঘটার আশংকা রয়ছ । তাই বর্তমান অবস্থায় উপরিল্লিখিত সমস্যাসমূহ দূরীকরণ সাপক্ষ এ কারখানায় নন্-পেনিসিলিন, পেনিসিলিন ও সেফালাস্পারিন গ্রুপর এন্টিবায়াটিক এবং স্টেরয়ড/ হর-মানজাতীয় ওষুধ ব্যতীত অন্যান্য ওষুধ উৎপাদনর অনুমতি প্রদানর জন্য সুপারিশ করা হলা ।

Respondent No. 16: Bristol Pharma Ltd.- It's Lay- out and infrastructures are not GMP standard, dispensing booth is not up to the mark and it is too small, raw materials are allowed to be entered directly; there is no warehouse container for that, raw materials and packaging are stored altogether, there is cleaning bay inside the factory premises, records are not available for manufacturing drugs of six months etc.

The Report in respect of Bengal Drugs & Chemicals (Pharma) Ltd. runs as follows :-

> মতামতঃ ১ম ও ২য় পরিদর্শনর রিপার্ট উল্লখিত সমস্যাবলীর সমাধানকল্প কারখানার প্র-য়াজনীয় সংস্কার কোম্পানি এখনা করনি । যে কারণ কারখানাটি এখনা জিএমপি নীতিমালা পুরাপুরি মেন চলত সক্ষম হচ্ছ না । এই প্রেক্ষিত নন্-পেনিসিলিন, পেনিসিলিন ও সেফালা-স্পারিন গ্রুপর সব এন্টিবায়াটিক এবং সব ধরনর স্টেরয়ড/ হরমানজাতীয় ওষুধ বাদ অন্যান্য ওষুধ উৎপাদনর জন্য কারখানাটিক অনুমতি প্রদানর সুপারিশ করা হলা ।

Respondent No.17: Bengal Drugs & Chemicals (Pharma) Ltd.- It includes the following: it has no environment certification, no washing facility at the entrance of antibiotic production building, no balance at dispensing booth, no standard measurement for temperature at warehouse of non- penicillin area, no sufficient ventilation, records and standard for measurement of temperature at tablet organic coating room etc.

The Report in respect of Pharmik Laboratories Ltd. runs as follows :-

মতামতঃ এই কারখানায় জিএমপি নীতিমালা অনুযায়ী ওষুধ উৎপাদনর সুবিধাদি পর্যাপ্ত নয় । এর ওষুধ মানসম্পন্ন না হওয়ায় এবং নিয়ম- বিরুদ্ধভাব এখান ওষুধ উৎপাদনর অভিযাগ আদালত প্রদত্ত আদশ কারখানাটি বিশষজ্ঞ দলর ৩য় পরিদর্শনর সময় বন্ধ পাওয়া যায় । এরপর কারখানাটি আদালতর আদশ পুনরায় খুল দেওয়ার পর পরির্শন গিয় গত ৪ বছর এর সুবিধাদির তেমন উন্নতি পরিলক্ষিত হয়নি । এই প্রেক্ষিত কারখানার সীমিত সুবিধার কারণ সব ধরনর এন্টিবায়াটিক, নারকাটিক ড্রাগ এবং স্টেরয়ড/ হরমান উৎপাদনর অনুমতি প্রত্যাহার কর উপরিউক্ত সমস্যাবলী দুরীকরণর পর অন্যান্য ওষুধ উৎপাদনর অনুমতি প্রদা-নর জন্য সুপারিশ করা হলা ।

Respondent No.18: Pharmik Laboratories Ltd.- its Factory is at densely populated area, building structure and design have no GMP, scarcity of skilled manpower, no qualified vendor list, warehouse not clean, sanitation and personal hygiene not satisfactory, records system are very poor etc.

The Report in respect of Bikolpa Pharmaceuticals Ltd. runs as follows :-

মতামতঃ কারখানা বন্ধ থাকলও বাজার এই কোম্পানির কিছু কিছু নিম্নমানর ওষুধ পাওয়া যাওয়ার প্রেক্ষিত কারখানার অভ্যন্তরভাগ পরিদর্শন করা প্রয়াজন ছিল । কিন্ত কারখানা কর্তৃপ-ক্ষর অসহযাগিতার কারণ তা সম্ভব হয়নি । এই প্রেক্ষিত গোপন নিম্নমানর ও জনস্বাস্থ্যর জন্য ঝুঁকিপূর্ণ ওষুধ উৎপাদন এবং করাখানা কর্তৃপক্ষর অসহযাগিতার কারণ এর সব ধরনর ওষুধ উৎপাদনর অনুমতি বাতিল করার জন্য সুপারিশ করা হলা ।

Respondent No.19: Bikolpa Pharmaceuticals Ltd.- had not developed its facilities for the last six years, the committee members were not allowed to enter into the premises, however, earlier it was seen that there were no ETP, material receiving and cleaning bay, separate storing system etc. However, there were piles of rejected packaging materials and unacceptable environment.

The Report in respect of Aexim Pharmaceuticals Ltd. runs as follows :-

মতামতঃ কারখানাটি আগর মতাই জিএমপি নীতিমালা অনুসরণ কর ওষুধ উৎপাদন করত ব্যর্থ । গত ৫ বছর ধর কারখানাটি সংস্কার ও উন্নয়ন কাজর সুযাগ পেলও তারা তা করনি । বরং তারা কারখানা সাসপন্ডড ঘোষণা কর অনৈতিক ও নিয়মবহির্ভূতভাব গোপন ওষুধ উৎপাদন নিয়াজিত রয়ছ । বন্ধ থাকার পরও গোপন জিএমপি ও কোনা মান নিয়ম্এণ পরীক্ষা ছাড়াই উৎপাদন চালিয় যাওয়া গুরুতর অপরাধ । তাছাড়া এভাব তারা ভ্যাটও ফাঁকি দিয় চ-লছ । এ প্রেক্ষিত মানহীন ওষুধ ব্যবহার জনস্বাস্থ্য ঝুঁকির মধ্য পড়ছ । তাছাড়া যারা অনৈতিক কাজ কর তাদর ওষুধ ব্যবসার সাথ জড়িত থাকা উচিত নয় । তাই জনস্বাস্থ্য রক্ষার স্বার্থ কোম্পানির ওষুধ উৎপাদন লাইসন্স বাতিল করার জন্য সুপারিশ করা হলা ।

Respondent No.20: Aexim Pharmaceuticals Ltd.- Mainly: drugs are produced illegally even of close down of factories , production symptoms are found at tablet machineries, Huge granules are found at production areas. Factory floors and tiles are dirty and dusty. Required facilities are not available but separate portion for production of antibiotic has been made.

The Report in respect of Dolphin Pharmaceuticals Ltd. runs as follows :-

> মতামতঃ এতা নিম্নমানর এবং জিএমপি সুবিধাহীন একটি কারখানা কীভাব ওষুধ প্রশাসন থেক নন- পেনিসিলিন ও পেনিসিলিন গ্রুপর এন্টিবায়াটিকসহ গুরুত্বপুর্ণ ওষুধগলা উৎপাদনর অনুমতি পেল তা বোধগম্য নয় ।
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> ৫ বছরর বেশি সময় অতিবাহিত হওয়ার পরও কোম্পানিটি জিএমপি সক্ষমতা অর্জন ব্যর্থ হওয়ায় এর প্রকাশ্য এবং গোপন উৎপাদিত ওষুধ ক্ষতিকর এবং জনস্বাস্থ্যর জন্য ঝুঁকিপুর্ণ হব বিধায় এর উৎপাদন লাইসন্স বাতিল করার জন্য বিশষজ্ঞ পরিদর্শন দল সুপারিশ করছ ।

Respondent No. 21: Dolphin Pharmaceuticals Ltd.- No GMP facility is available at factory, no improvement of facilities are seen for the last five years, illegal production of antibiotic are detected along with records. Blister roll are piled at production area. Unlabeled Drums of raw materials are found. Documentations are poor, warehouse, lab are also poor.

Though the expert committee recommended for some action against some pharmaceutical Industries but they were not complying GMP policy. The Government did not take any steps to stop less quality medicine production though there was report in the paper. The petitioner has to file the instant writ petition, challenging the inaction and failure of the respondents to close down the pharmaceuticals industries which are producing life saving drugs & medicine such as antibiotic, steroids, hormone, anti cancer drug etc. without maintaining quality control, consequently affecting the right to life of the citizen of Bangladesh recommended by the expert committee. The respondents being the responsible persons and the responsible bodies, they are to duty bound to abide by laws and regulations. But the respondents have failed to perform their duties and their responsibilities lawfully and so the inactions of the respondents have gone beyond the scope of law. The petitioner finding no other alternative efficacious remedy came before this court and obtained the present Rule.

The learned advocate Mr. Manzill Murshid appearing on behalf of the petitioners submits that the medical treatment is one of the fundamental human rights of citizens. Therefore, no authority can show any negligence in any way to this right. Rather it is the duty of the Government to give full support for arranging effective and quality medicine for the safety of the citizen. But without keeping in mind about the Constitutional obligations the respondents failed to take any steps to stop production of less quality or adulterated medicine and ultimately the people are deprived off from proper medicine. Due to less quality or adulterated medicine, the lives of the people fall in a dangerous situation, which is violation of Article 18(1) of the Constitution of Bangladesh. According to the provision of Article 18(1) of the Constitution, the State shall regard the raising of the level of nutrition and the improvement of public health and it is the primary duty, therefore the respondents may be directed to take immediate steps to stop production of antibiotic and cancer medicines. The license of the Pharmaceuticals Industries which were recommended by the expert committee may be stopped. Further he submits that the respondents being the responsible persons and the responsible bodies, they are duty bound to abide by laws and regulations and since they have failed to perform their duties and responsibilities lawfully and the inactions of the respondents have gone beyond the scope of law, therefore the license as given to the Pharmaceuticals Industries should be cancelled as per the report of the expert committee. Further he submits that in every moment the life of the citizen are depending on medicine available in the market but due to some inconsiderate manufactures of drugs/medicine the people are suffering from adulterated medicine. It is necessary to stop illegal production of antibiotic/ drugs/ medicine to save the health of the citizen otherwise the people will suffer a lot, which would have a severe bad impact on the life of the citizen and violation of fundamental rights guaranteed by the Constitution of Bangladesh.

However, the learned lawyer of the petitioner further submitted that the reason behinds the formation of expert committee is to examine non compliance of the GMP policy by the drug manufacturer. It is the duty of the Drug Administration to monitor the function of the Pharmaceuticals Industries as to ascertain whether the industries are following the GMP policy during their function. But it was reported in media that many Pharmaceuticals Industries are not complying the license condition to

follow the GMP policies, hence the issue was discussed in the parliamentary standing committee who is also responsible to oversee the function of the concern Ministry. Considering the urgency and need to production of medicine complying with GMP policy in order to safety of the life of the citizen the expert committee was formed in September 2014 headed by Professor ABM Faruk along with four others professors of different universities on the approval of the Speaker of the Bangladesh Parliament. The steps were taken in order to ensure better production of medicine through compliance by GMP policy not only that the members of the committee are expert in concern issues. The expert committee was formed for the sake of public purpose with the approval of competent authority as per the Rules of Procedure of Parliament of the People's Republic of Bangladesh. That the committee prepared its report within its legal periphery and terms of references after visiting the said 84 pharmaceuticals industries-in-questions for the third times. The committee observed the condition of WHO-approved-Good Manufacturing Practice (GMP)-principles in the industries and made various observations and specific recommendations for each pharmaceutical industry. In its report, the committee referred to "whether the concerned pharmaceuticals industries are capable of producing drugs/medicines with their existing infrastructures as per GMP principles/guidelines, that has been considered in the instant report...". That the committee also expressed its concern in the words: " if drugs/medicines are not produced in line with GMP guidelines, the produced drugs/medicines don't have any standard; diseases are not cured; severe injury may occur in human body that may also claim human life. And those drugs/medicines are abandoned in context of all considerations of public health." Accordingly, as per the terms of reference, the Expert Committee prepared its report along with various observations and specific recommendations for each pharmaceutical industry for addressing a public purpose as per Good Manufacturing Practice (GMP)-principles which comprises some basic principles of drugs productions, i.e. its quality system, risk management, sanitation and hygiene, self-inspection, personnel, premises, equipments, materials good practice and above quality control of drugs.

Mr. Murshid also submits that the matter is involved a public importance. As per Article 32 of the Constitution of the People Republic of Bangladesh right to life of the citizens is guaranteed as a fundamental

right. But by way of less quality medicine/drug/antibiotic, the right to life of the citizens is violated. Moreover, as per Constitution of the People Republic of Bangladesh the fundamental human rights of the citizens in the republic shall be guaranteed. Medical treatment is one of the fundamental human rights of citizens. So, no authority can show any negligence in any way to this right. Rather it is the duty of the government to give full support for arranging effective and quality medicine for the safety of the citizen. But without keeping in mind about the Constitutional obligations the respondents failed to take any steps to stop production of less quality medicine and ultimately the people are deprived from proper medicine. The matter involved in the instant petition in respect of production of medicine violating the GMP principles which is vital need in day to day life of human beings. Due to the production of drugs which are not up to the mark affecting the life of the people. This being a matter of public issue and relating to public health because less quality medicine has a severe negative impact on all patients. Though the matter involves a great public importance, as such this petition be treated as Pubic Interest litigation. It is necessary to stop illegal production of antibiotic/drugs/medicine to save the health of the citizen otherwise the people will suffer a lot, which would have a severe bad impact on the life of the citizen and it violated the fundamental rights guaranteed by the Constitution of Bangladesh. This writ petition also covered by the judgment reported in 18 BLC(AD) 116in which criteria has been set up to maintain the writ petition as public interest case, hence the instant writ petition is maintainable. The Court can entertain an application under Article 102 of the Constitution filed by any interested person or organization who works for public cause. Issues of public importance, right to life and functions of the State can be treated as a Public Interest Litigation. The court has been quite conscious that the forum of this court should not be abused by any one for personal benefit. On perusal of the report and considering the submission of the petitioner, we are of the view that the instant application filed as a Public Interest Litigation (PIL) is maintainable. Though the expert committee recommended some action against some Pharmaceuticals Industries which are not complying GMP policy but the government did not take any steps to stop less quality medicine production. A report was published on 19.04.16 in the Daily Jugantor with the heading: "জীবন রক্ষাকারি ওষুধ ভেজাল" in which it was stated that despite of report submitted

by the expert committee the government is not taking proper steps and non compliance of the Pharmaceuticals Industries is continuing, which cause threat to the life of the people. The petitioner filed the instant writ petition challenging the inaction /failure of the respondents to take steps as per the recommendation made by the expert committee. It may me mentioned here that the duty vested upon the drug administration as per law to take steps against the Pharmaceuticals Industries who are not following the GMP guideline but while they failed to take necessary action against the medicine company at that time this court can give any appropriate direction in order to save the life of the citizen. The petitioners are seeking direction upon the respondents as such filed the instant writ petition and before filling the instant writ petition the petitioners did not serve notice to the respondents. That the manufacturers of antibiotic/ drugs/medicine are very much aware of the relevant rules and regulations of quality medicine as prescribed by the government and the government authority is also responsible to ensure quality medicine production complying the license condition. The respondents are responsible authority and they have knowledge about less quality medicine production violating the GMP policy as published in the dailies. The life of human being is dependent on drugs and medicine as they save life from being decayed and death. It is so pertinent and necessary to life a basic need of people around the globe. It is the common responsibility of all to keep the people's health safe and sound within everybody's means. But as per the reports of the dailies, some drugs manufacturers have made the life of common people uneasy and have brought sufferings to the life of the common people gaining inconsiderate profit personal from them only by producing less quality drugs/medicine ignoring the GPM policies. Hence, the common people suffer a lot, which has severe impact on public health and thus it cannot be allowed to be continued by this court. In every moment the life of the citizen are depending on medicine available in the market but due to some inconsiderate manufacturers of drugs/medicine without following the GMP guideline caused the suffering for people. It is necessary to stop production of antibiotic/drugs/medicine which are producing violating the GMP guideline and in order to save the health of the citizen, that the people will suffer a lot, and it would have a severe bad impact on the life of the citizen and violates the fundamental rights guaranteed by the Constitution of Bangladesh. Due to less quality or adulterated medicine, the lives of the people fall in a dangerous situation,

which is violation of Article 18(1) of the Constitution of Bangladesh. That according to the provision of Article 18(1) of the Constitution, the State shall regard the raising of the level of nutrition and the improvement of public health as among its primary duties. Hence this court is competent to stop production of medicine and antibiotic by way of canceling the license of the Pharmaceuticals Industries as per the recommendation of the expert committee. Some of the respondents made submission that they have some report in favor of them prepared by the Drug administration. Such kinds of report they obtained by way of managing the system and its related persons, while the expert committee several times visited the premises of the respondents industry and found violation of GMP guideline in case of their medicine production, in that case there is no reason to disbelief the report. It is not uncommon in our country to manage the officials by the monied or influential man. So considering the safety of the life of the citizen this court is competent to consider the repot of the expert committee for betterment of the citizen. GMP guideline is such a thing which covered many things such as Personnel's, warehouse facilities, production machineries, quality control instrument, process quality control , packaging , water system facilities, sanitation and hygiene facilities, documentation facilities. All of those facilities have to be maintained by the industry. In reference to Section 15 of the Drug Control Ordinance 1982, a provision has been laid down about GMP and it is mandatory to follow. If there is any violation of GMP in that case license would be cancelled. Though there is specific provision to cancel the license and report was submitted about specific non compliance of the GMP by respondent no. 8-21, so they are not entitled to hold the license or continue the production. Under these circumstances there is no ground for interference with the cancellation of license about 20 pharmaceuticals industries and production of antibiotic… by 14 pharmaceuticals industries, which has already been cancelled and stopped by the order of the Drug Administration.

On the other hand the learned Deputy Attorney General Dr. Md. Bashirullah, appearing on behalf of the Respondent Nos. 1-7 submits that as per order of this court the respondent No.1-7 has complied with the order and the respondents Nos. 1-4 who were directed to take immediate steps to stop production of Antibiotic (Non Penicillin, Penicillin and Cephalosporin group) by the Pharmaceuticals Industries and as per paragraph 7 of the writ petition has complied with and have submitted a

compliance report through affidavit within 2 weeks and the respondents Nos. 6 and 7 who were directed to ensure stop production of all life saving drugs & medicine such as antibiotic, steroid hormone, anti cancer drug etc. by the 20 pharmaceuticals industries within 7 days and to file affidavit of compliance within 2 weeks and the respondent Nos. 6 and 7 who were directed to provide all kinds of support in that effort have been complied with. The learned Deputy Attorney General in compliance of the order has filed affidavit in compliance as that has been done by respondent Nos. 1-4 and as per direction of this court respondent No.1-4 have taken action and also taken action by publishing in the daily news paper immediately for stopping of production of drugs and cancellation of the production of drugs license without any delay and submitted that 14 Pharmaceuticals Industries have stopped the production of all kinds of Antibiotic and all the 20 Pharmaceuticals Industries have stopped of production and manufacturing of all kinds of life saving drugs. The license of drug production of 11 Pharmaceuticals Industries have been cancelled as mentioned in Annexure 15-25 and the license of rest 9 Pharmaceuticals are under active process to be cancelled. Further he submits that the Government has already recommended to raise its manpower for proper administration in the drug Administration and it is under consideration of the Government.

By filing affidavit in opposition respondent No.8 Skylab Pharmaceuticals Limited represented by its advocate Ms. Rimi Nahreen that the respondent company is not producing any drugs and pharmaceuticals product since 2012 but all along renewed its drug license and also paying other taxes to the Government and other concern departments and they are trying to upgrade its company with modern equipments and machineries. The expert committee did not find any irregularities and latches while they visited the factory of the respondent No.8 and the committee observed that the factory is presently closed and they undertake that in future they will abide by all Rules and Regulations. They have also applied for loan for upgrading the industry. At present they are not producing any medicine any drugs. However, this court observed that if they are following the GMP and there is ETP and they are recommended by a committee headed by Ministry of Health, Expert committee, Drug Administration, Members of the World Health Organisation only on such recommendation their license would be renewed and they can go on production.

The Respondent No.9 Universal Pharmaceuticals Ltd. represented by his Lawyer Mr.A.K.M.Towhidur Rahman by his affidavit in opposition submits that the Respondent No.9 has taken all initiatives like cleanness healthy atmosphere and hygienic work in places, electricity and water, dump free floor and other place, log book, production files, separate dispatches, GMP training for its employees, fire protection, ventilation, controlled temperature and humidity, sampling system according to SOP, separate QC lab, analytical, instrumental and microbiological lab etc. since its commencement and has been updating its practices day to day and moreover the recommendation as to cancellation of license and the action is totally unreasonable, unacceptable and improper and they did not also test any specimen/samples of any drug/medicine of the Respondent No.9 and moreover the quality of their production like as ORS and Vitamin-C had not been questioned as such their permission to cancel the production is therefore without any jurisdiction and the Rule is to be discharged. The sealing of the Universal Pharmaceuticals Ltd. without given any opportunity of being heard and reports so far as it relates to the respondent No.9 has no basis and as such they are to be allowed for production. They also are going to set up modern machineries for manufacturing drug medicine through bank loan as sanctioned by the bank authority, therefore their license and their sealing may be waived. However, they may be given permission while there would be recommendation by the committee as set out as said above for production of the medicine.

Affidavit in opposition of Respondent No.10 Star Pharmaceuticals Ltd. represented by his Advocate Mr. Sakib Rezwan Kabir submits that the Respondent company obtained license from the respondent No.2 for production of some medicines and after obtaining the permission, it started its production following the guidelines and directions as provided by the law as well as by the Respondent No.2, but subsequently in the year 2013 the Respondent No.10 company due to shortage of investment and other reasons stopped all kinds of production temporarily and by the letter dated 23.9.2013, the deponent communicated the decision to the Respondent No.2. The respondent No.10 already by this time has given an undertaking on 15.6.2016 stating that he will stop all kinds of medicine production activities, and in the said undertaking, it was also mentioned that the production of the company has been stopped since September, 2013. They have published a report submitted by the

company mentioning that they will abide by the decision of the inquiry committee. Under such facts and circumstances he submits that though the production was stopped since 2013 but now they are trying to improve their quality of production. Since there is undertaking and there is promise that they will follow the terms and conditions of GMP and ETP as such if there is any recommendation made by the Expert committee as set out then only they can go on production. Therefore the cancellation of their license is a valid one. We do not find anything wrong in cancellation of license of their Pharmaceutical Industries.

Affidavit in opposition by the Respondent No.11 Ad-Din Pharmaceuticals Ltd. represented by the learned advocate Mr. Tanjibul Alam along with Mr. M. Saquibuzzaman, submits that on inspection it was found that there is incompentency of GMP and production of medicine is in danger and they were prevented in producing, The Non Penicillin, Penicillin Chephalosporin and Antibiotic.

On this context the learned advocate submits that they are in complete compliance of all the requirements as per GMP, Drugs Act, 1940, the Drugs (Control) Ordinance, 1982, the Drugs (Control) (Amendment) Act, Ordinance, 2006 and the Rules and regulations and circulars made thereunder from time to time. The Respondent No. 11 has incurred significant expenses in upgrading its facilities to meet the regulatory requirements and was conducting its affairs as per law. Therefore he prays that the name of the Respondent No.11 be struck out. Under such situation the committee as has been opined by this court to see actually whether they are following the Rules and only on their inspection report the production of their medicine may be allowed to continue.

The learned advocate Mr. Habibul Islam Bhuiyan along with Mr. Md. Abdur Razzak appearing on behalf of the Respondent No.12 Avert Pharma Ltd. by filing affidavit in opposition submits that for last 6 years they could not follow the GMP and it was declared to be closed but there is a report that in disguise they were producing medicine. Therefore the committee has recommended for cancellation of their permission.

On this context by filing the instant affidavit in opposition the Learned Advocate submits that the company took loan from different sources at the high interest for establishing its infrastructure as well as for the production of medicine and they are under obligation to pay the loan

money and its interest. The contents of the medicine for manufacturing by the deponent's company were being imported from foreign countries and after physical test of the Raw materials and its quality, those were being released. They are manufacturing but there is no report of substandard medicine. However, he submits that the Department of environment, the fire service authority regularly made inspection and there is no complain against the factory nor by the authority. Under such facts and circumstances if it is manufactured by following GMP and there is ETP and further on the recommendation of the committee as we have opined, they can be allowed to continue their production.

The learned advocate Mr. Md. Aminul Islam appearing on behalf of the Respondent No.13 Spark Pharmaceuticals Ltd. by filing affidavit in opposition submits that the Parliamentary committee in their opinion has stated that though they got 5 years or more but now they have developed or improved for production as per GMP but recommended for cancellation of license.

On this context we also refrain from passing any order and at least we can only opined that if the committee recommends only then they can go on production.

Respondent No.14 Sunipun Pharmaceuticals Ltd. had the allegation and the recommendation that if they follow the GMP then only cancellation of license be waived. However in any view of the matter they are to take clearance from the committee and can go on production.

On this context by filing affidavit in opposition the learned advocate Mr. Abdullah Al Baki, submits that there is existing of clearing bay, material receiving facility, materials entry and personal entry in the company. There is good condition to manufacture medicine by following Rules. They do not produce any medicine which are harmful for public health and they do not have permission by the drugs authority to produce antibiotic, steroid, hormone, anti cancer drugs and the observation made by the committee is in correct. However, that they are going to develop the production according to guide line and as such their license cannot be cancelled. However, if the committee as we have opined and if they approved only then they can go on production only on their recommendation. However, since the license has been cancelled and there is appeal pending and unless and until that has been allowed of

getting their license we therefore refrained from passing any order since there is no license, but there will be no production unless and until the license of Pharmaceutical company has been approved and approved by the committee.

The learned advocate Mr. M.A. Hannan appearing on behalf of the Respondent No.15 MST Pharma & Healthcare Ltd. by filing affidavit in opposition submits that there is recommendation by the inspector and they have got GMP license and there is also recommendation for upgrading and that has been complied with like establishment of ETP and GMP. Moreover the company has applied for renewal of their license on 29.11.2015 and after conducting appropriate inspection the Drug Administration Department vide Memo dated 17.12.2015 renewed their license for production of medicine for a period of further 2 years starting from 27.1.2016 which will expire on 27.1.2018. The inspection for third time was made by the expert committee on 19.9.2015 but did not visit the factory building wherein the antibiotic products are produced. The Drug Administration Department on the basis of the report of the expert inspection committee and the Standing Committee and after being satisfied with the performance of the respondent No.15 the company has renewed its license for a period of 2 years which will expire on 27.1.2018 and thus the company has a valid license for production of medicine and is producing medicine complying all relevant regulations and law. The Ministry of Health & Family Welfare certifies that the company complied with good manufacturing practices recommended by the World Health Organization (WHO) and further approved the company to sell and distribute the manufactured pharmaceuticals products within the country as well as to export the same to foreign countries. Under such circumstances we also recommend that they may be allowed to go for production as ETP and GMP as maintained properly. Since in their opinion the production of antibiotic and hormone are not permitted for production, therefore the committee is the authority can recommend whether they can go on production of antibiotic.

The learned advocate Mr. A.K.M.Badrudduza appearing on behalf of the Respondent No.16 Bristol Pharma Ltd. by filing affidavit in opposition submits that the expert committee opined to cancel the permission of production of Antibiotic (Non penicillin, penicillin and cephalosporin

group) and as such the committee as we have suggested and only on recommendation they can go on production.

The learned advocate Mr. A.K.M.Badrudduza appearing on behalf of the Respondent No.17 Bengal Drugs & Chemicals (Pharma) Ltd. by filing affidavit in opposition submits that there is GMP but their license is cancelled for production of antibiotic. Therefore if they could improve as there is GMP and on recommendation by committee as suggested only then they can go on production.

The learned advocate Mr. M. Sayed Ahmed appearing on behalf of the Respondent No.18 Pharmik Laboratories Ltd. by filing affidavit in opposition submits here also the expert committee opined to cancel permission of production of Antibiotic (Non penicillin, penicillin and cephalosporin group) and as such the committee as we have suggested, to be formed and if they permit and only on their recommendation they can go on production.

The learned advocate Mr. Maudud Ahmed along with Mr. Pankaj Kumar Kundu appearing on behalf of the Respondent No.19 Bikolpa Pharmaceuticals Ltd. by filing affidavit in opposition submits that the expert committee closed down the manufacturing of product. But some medicines are available in the market, despite there direction for stopping manufacture of such medicine.

On this context the learned advocate submits that they have requested the Director General for taking necessary action as per letter dated 23.10.2014 since it has been shut down. Therefore unless and until it is reopened by the Expert Committee as opined by us they cannot go on production of such medicine.

The learned advocate Mr. A.K.M.Asiful Haque appearing on behalf of the Respondent No.20 Aexim Pharmaceuticals Ltd. by filing affidavit in opposition submits that the expert committee closed down his production. Despite there is direction for stopping manufacture but some medicines of their production are available in the market.

On this context the learned advocate submits that they have requested the Director General for taking necessary action as per letter dated 1.3.2015

as it has been shut down. Therefore unless and until it is reopened by the Expert Committee as opined by us they cannot go on production.

The learned advocate Mr.Abdulla Al Baki appearing on behalf of the Respondent No.21 Dolphin Pharmaceuticals Ltd. by filing affidavit in opposition submits that the expert committee closed down their manufacture of production. Despite there is direction for stopping manufacture but some medicines were available in a market.

On this context the learned advocate submits that they have requested the Director General for taking necessary appropriate action. Therefore unless and until it is reopened by the Expert Committee as opined by us they cannot go on production.

Further the Learned Advocate by supplementary affidavit submits that the Expert Committee also recommended to cancel the permission of production of all kinds of Antibiotics (Non Penicillin, Penicillin Cephalosporin Group) by 14 pharmaceuticals Industries and they are Ad Din Pharmaceuticals Ltd., Alkad Pharmaceuticals Ltd., Belsen Pharmaceuticals Ltd., Bengal Drugs Pharmaceuticals Ltd., Bristol Pharma Pharmaceuticals Ltd., Crystal Pharmaceuticals Ltd., Indo-Bangla Pharmaceuticals Ltd., Millat Pharmaceuticals Ltd., MST Pharmaceuticals Ltd., Orbit Pharmaceuticals Ltd., , Pharmik Pharmaceuticals Ltd., Phoenix Pharmaceuticals Ltd., Rasa Pharmaceuticals Ltd., and Save Pharmaceuticals Ltd., due to their non-capability of manufacturing standard antibiotics as per GMP Policy. Having visited the said 14 Pharmaceuticals Industries, the Expert Committee outlined their recommendations to follow GMP Policy. The said 14 Pharmaceutical Industries did not meet up the GMP policy guidelines in manufacturing their medicines and drugs. The life of human being is dependent on drugs and medicine as they save life from being decayed and death. It is so pertinent and necessary to life that it has become a basic need of people around the globe. It is the common responsibility of all to keep the people's health safe and sound within everybody's means. But as per the reports of the dailies, some drugs manufacturers have made the life of common people uneasy and have brought sufferings to the life of the common people due to gain in inconsiderate profit, only by producing less quality drugs/medicine ignoring the GMP policies. Hence, the common people suffer a lot, which has severe impact on public health, which can not be allowed by this court. In every moment the life of the citizen are depending on medicine

available in the market but due to some inconsiderate manufacturers of drugs/medicine without following the GMP guideline caused the suffering for people. It is necessary to stop production of antibiotic /drugs /medicine which are producing violating the GMP guideline in order to save the health of the citizen, otherwise the people will suffer a lot, which would have a severe bad impact on the life of the citizen and it violates the fundamental rights guaranteed by the Constitution of Bangladesh. In the report there is specific allegation against the respondent Nos. 12,20 and 21 along with Globe Laboratories, Jalpha Laboratories, Medico Pharmaceuticals, Rid Pharmaceuticals, Kafma and Star Pharmaceuticals Ltd. for production of medicine illegally and those industries have to be closed down. Under these circumstances they should be dealt with in accordance with law. The respondent Nos. 6 and 7 are to take legal steps against them for their criminal offence under the provision of law. The respondent Nos. 20 and 15 made submission that they have GMP certificate but it is controversail because in the report it was not revealed that they are following GMP rules. So the respondent No.1 is directed to form a committee consisting of 5 members, one member from the expert committee. If any application is filed by respondent No. 15 and 20 or any Pharmaceuticals Industries for GMP license, the respondent No.4 will send it to the committee and after submitting the report if it is positive the respondent No.1 is at liberty to issue GMP license otherwise they should not issue license.

Therefore for the safety and security of the public interest it should be looked into that the production of the medicine /drugs are to be produced as per law and as per GMP. The committee as we have suggested to be formed and only on their recommendation necessary action for production to be taken. Yet they are to be monitored in all those aspects whether those are going on production properly and to report to the authority concerned in every 6 months. The Drug Administration from time to time at least thrice in a month should see whether they are producing their medicines as per GMP and for that matter a committee consisting of 5 members should be constituted. One member from the expert committee, one expert selecting from WHO Dhaka office, one representative from Drug Administration, one expert selected by the respondent No.1 and a professor of Pharmacy from Dhaka University, on whose recommendation only the parties can go on production and it is for

the benefit of the people. We therefore, with this direction made the Rule absolute in part.
