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March 24, 2021

TL2021/03/24/1B

Mr. Aamir Ashraf Khawaja,
Secretary NHSR&C
Ministry of National Health Services, Regulations & Coordination
Islamabad

Sub: Procurement of COVID-19 Vaccines by the Private Sector for commercial sale in Pakistan

Dear Sir,

Transparency International Pakistan refers to your response vide letter No. 1-1/2021/Secy/NHSR&C dated 24th March 2021 to TI Pakistan letter No. TL 2021/03/22/1A **(Annex –A).** Your clarification that the "Drug Pricing Policy for import of drugs under hardship category was applied to Covid vaccine to keep a check on prices instead of leaving it solely to free market dynamics", is a misstatement.

It may be pointed out that the Drug Pricing Policy 2018 clearly defines the mechanism for hardship cases, as quoted below:

For imported drugs in finished form and local labeling & cartooning

- Trade Price = (Landed cost + packaging cost) + markup @ 45% provided that in case of anti-cancer, biological, immunosuppressant and anti-retroviral drugs, that markup shall be **40%.**

- In case of imported drugs in finished form and finished import & local packaging, MRP shall be calculated by grossing up trade price to provide for retail discount @ 15% (for biological, immunosuppressant drugs). **(Annex – B)**

Internationally, single dose of Sputnik V cost $10. If we apply DRAP pricing formula Sputnik V **two doses** price in Pakistan should be RS. 1600 + 40% =2240*2 = 4480. **However, the DRAP approved price for two doses is Rs. 8, 449 which is 89pc higher. The above shows that the DRAP has violated Drug Pricing Policy 2018.**

Similarly, clause 6 (iii) of Drug Pricing Policy 2018 is quoted for your reference: "…….**If average price of the Originator Brand in India & Bangladesh is lower by between 0% and 30% then MRP will be reduced by that differe**nce and simultaneously will be netted off over the applicable annual increase under this Policy. In case the Originator Brand is available in one of these countries, retail price in that country will be taken as reference for this purpose". **(Annex – B)**

The retail price for a single dose Sputnik V vaccine in India in less than INR 734. With this rate, taking into consideration the currency value difference, a single dose of Sputnik V vaccine should cost approx. Rs. 1500 in Pakistan.

Secondly, your letter mentions that "The courts have given further strength to the government by endorsing its diverse efforts to fight the pandemic". It may be pointed out that there is no Court

order on commercial import of COVID-19 vaccine, which was the main objection of TI Pakistan in its letter dated 22nd March 2021, and Supreme Court of Pakistan has already taken up Suo Motu on COVID-19 related procurement by the government.

Third, the letter mentions that the government "as a deliberate policy tool, allowed private sector to import vaccine to cater to those segments of the society, which were not on the immediate priority list of the government". It may be pointed that such a policy is a tool to exacerbate the already existing inequality in Pakistan. People who want to bypass the priority list, and get vaccinated first, they are already travelling to other countries to get vaccinated on priority basis. The government should not encourage such a policy of favoring a certain section of the society at the cost of transparency. **It is also not clarified as to why Pakistan is the only country in the world to allow private import of COVID-19 vaccine for commercial sale.**

The biggest apprehension of TI Pakistan is that with the permission of commercial sale of the COVID-19 vaccine, there are possibilities that some of the government's vaccine may end up illegally in the private hospitals for commercial sale. There are also news reports that the decision to allow private sector to import COVID vaccine has been done under pressure.

Therefore, to avoid such controversies, it is important that the Ministry of National Health Sciences, Regulation & Coordination put a complete ban on private import of vaccine for commercial sale in Pakistan.

TI Pakistan is striving for across the board application of **Rule of Law**, which is the only way to stop corruption and achieve zero tolerance against Corruption,

With Regards,

Nasira Iqbal

Justice (R) Nasira Iqbal,
Vice-Chairperson
Transparency International Pakistan

Copies forwarded for the information with request to take action under their mandate to:

1. Chief, National Command Operation Centre, Isalambad

TI Pakistan requests Mr. Asad Umar, Chief NCOC to take notice of these anomalies in the approved price of COVID-19 vaccine by DRAP so as to ensure that the pricing mechanism for Covid vaccine is in compliance with the Drug Pricing Policy 2018 and review NCOC decision to put complete ban on the private import of Covid vaccine in Pakistan for commercial sale.

2. Dr. Faisal Sultan, Special Assistant to Prime Minister on Health, Ministry of National Health Services Regulations and Coordination, Islamabad
3. Managing Director, Public Procurement Regulatory Authority (PPRA), Islamabad
4. Chairman, National Accountability Bureau (NAB), Islamabad
5. Registrar, Supreme Court of Pakistan

Annex-A

No.1-1/2021/Secy/NHSR&C

GOVERNMENT OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES,
REGULATIONS & COORDINATION

SECRETARY

Islamabad, the 24th March, 2021

Subject: **PROCUREMENT OF COVID-19 VACCINES BY THE PRIVATE SECTOR FOR COMMERCIAL SALE IN PAKISTAN**

My dear Justice (Retd) Nasira Iqbal Sahiba! السلام علیکم ورحمۃ اللہ وبرکاتہ

Reference letter No.TL2021/03/22/IA, dated 22nd March, 2021 addressed to Secretary to Prime Minister on subject above. Pakistan remains committed to fighting Covid with everything available at its disposal. Over the last one year, Pakistan made a huge effort to put together a 'whole of the government approach' to make sure that the pandemic is contained, testing is ramped up, healthcare facilities are equipped and ramped up to deal with the rush of Covid patients, and finally that the general population is vaccinated expeditiously starting with the most vulnerable. The courts have given further strength to the government by endorsing its diverse efforts to fight the pandemic. Pakistan's efforts in this regard have been acknowledged by the world from time to time. Though the fight is far from over, we remain committed to employ all policy tools at our command to save as many lives, as we can.

2. Covid vaccination partly through the private sector is one such tool. It was a well considered decision of the Federal government to allow private sector to import vaccine as the national vaccination priorities favoured the healthcare workers and the elderly, involving some lag in reaching other segments of the society. This is expected in a large country like Pakistan, with population over 220 million. The government therefore, as a deliberate policy tool, allowed private sector to import vaccine to cater to those segments of the society, which were not on the immediate priority list of the government.

3. Initially the government approved such import without fixing the price, as no reference price under the law was available. Later on, a provision of Drug Pricing Policy for import of drugs under hardship category was applied to Covid vaccine to keep a check on prices instead of leaving it solely to free market dynamics.

4. It may be added that the government is fixing the maximum retail price, leaving room for competition and free market dynamics. It may also be added that Covid vaccine market dynamics entail sale in large quantities, typically in millions, and it is not easy for small players to access small number of doses. The economies of scale available to big players like governments and GAVI are not available to small players. Whatever number of doses they can bring in however, means potentially saving lives.

With kind regards,

21/08/2021

(AAMIR ASHRAF KHAWAJA)

JUSTICE (R) NASIRA IQBAL,
Vice Chairperson,
Transparency International Pakistan

Copy for information to:

- Dr. Faisal Sultan, SAPM on Health, M/o NHS,R&C, Islamabad.
- Mr. Azam Khan, Secretary to PM, PM's Office, Islamabad.

Annex-B

For imported drugs in finished form and local labelling & cartooning

Trade Price = (Landed cost + packaging cost) + mark-up @ 45% provided that in case of anti-cancer, biologicals, immunosupressants and anti-retroviral drugs, the mark up shall be 40%.

(ii) In case of imported drugs in finished form and finished import & local packaging, MRP shall be calculated by grossing up trade price to provide for retail discount @ 15%.

(3) Cost of raw and packaging materials and imported finished drugs will be as per actual of applicant. In case of locally produced raw materials, evidence of actual price as per commercial invoice and in case of packaging material, actual price as per sale tax invoice will be submitted along with application. In case of imported raw and packaging materials and finished drug, evidence of value as determined on bill of entry under the Customs Act, 1969 along with commercial invoice and import documents will be submitted.

(4) MRP of an Originator Brand shall not be increased over and above its average retail price (exclusive of VAT, GST, Excise Duty or any other levy on sale of drug) in India and Bangladesh or retail price in any of these countries if available only in one country or if Originator Brand is not available in any of these countries, MRP of Originator Brand shall not be increased over & above its retail price in other reference countries as per mechanism provided in paragraph 4 of this Policy.

(5) All new hardship applications filed after issuance of this Policy shall be decided within 180 days of submission of the hardship case on the specified form and complete in all respect with the DRAP (Division of Costing and Pricing) in manner as specified in this Policy. In case, no response is sent to the applicant of hardship case under provisions of this para within 180 days, the applicant may increase its MRP upto maximum of 10% on the existing approved MRP and inform the DRAP (Division of Costing and Pricing) with evidence that a complete case was submitted with the DRAP (Division of Costing and Pricing) provided that the applicant must have sent a reminder to DRAP 30 days before the expiry of the 180 days period. Further provided that if the matter has been referred by DRAP to the Federal Government within the aforesaid 180 days and the notification is not issued within a further period of 90 days (i.e. within a period of 270 days from the date of the submission of the hardship application) then the applicant may increase its MRP upto the level recommended by the DPC of DRAP to the Federal Government. For this purpose, DRAP will share the minutes of the relevant meeting with the applicant upon the expiry of 180

(i) Calculation of MRP of lower strength (new strength is of half of the existing strength)

MRP = MRP of higher strength - 40%; and

(ii) Calculation of MRP of higher strength (new strength is double of the existing strength)

MRP = (MRP of lower strength x100) /60.

(2) MRPs of other strengths shall be calculated proportionately to formula in sub-para (1) above.

(3) MRPs of changed or additional pack sizes of existing drugs shall be calculated on pro-rata basis of already fixed MRP of the existing pack size of an oral dosage form or topical preparation or pack size with different number of injections of the respective drug / brand. In case the new pack size is 2 times of the existing pack size, MRP of new pack size, after calculation of pro-rata MRP, shall be reduced by 2% and 4% reduction shall be applied if new pack size is triple or larger of the existing pack size.

(4) Pharmaceutical concern may apply for additional / changed pack size of their existing registered drugs as specified in sub-para (3) above to the DRAP (Division of Costing and Pricing) and a confirmation of filing of application & calculation of MRP in accordance with the Policy will be issued within 60 days of submission of the application. In case of any correction or deficiency, the pharmaceutical concern shall make the correction within 30 days and resubmit the calculations and document. If no intimation or advice is sent to the applicant within 60 days, the applicant may market the additional or changed pack size at MRP calculated in accordance with this Policy.

(5) MRPs of drugs containing combination of already registered drugs will be sum of MRPs of individual drugs and sum total reduced by 5%.

6. **Reduction in MRP of Originator Brand.**—(1) MRPs of Originator Brands of drugs & biologicals listed in National Essential Medicne List shall be reduced by 10% per annum for 3 consecutive years (cumulative reduction of 30%) of MRPs as fixed by the Federal Government except the following.—

(i) Where less than 3 generics are available in the market;

(ii) Lower priced Originator Brands as defined in para 10.

(iii) Originator Brand where average retail price (exclusive of VAT, sales tax, excise duty or any other levy on sale of the drug) of the same brand in India and Bangladesh is higher at the time of reduction. In case, the Originator Brand is available in one of these countries, retail price (exclusive of VAT, sales tax, excise duty or any other levy on sale of the drug) in that country shall be taken as reference for this purpose. If average price of the Originator Brand in India & Bangladesh is lower by between 0% and 30% then MRP will be reduced by that difference and simultaneously will be netted off over the applicable annual increase under this Policy. In case the Originator Brand is available in one of these countries, retail price in that country will be taken as reference for this purpose.

(iv) Where Originator Brand has not been marketed in India or Bangladesh its MRP is not higher than the lowest of the following, namely.—

(a) Retail price (exclusive of VAT, Sales Tax, Excise Duty or any other levy on sale of the drug) in basket of countries as listed in para 4(2)(i);

(b) Whole sale price in UK Monthly Index of Medical Supplies or British National Formulary or Australian Pharmaceutical Benefits Scheme or New Zealand Pharmaceutical Management Agency (exclusive of VAT, Sales Tax, Excise Duty or any other levy on sale of the drug); and

(c) Originator Brands for which bona fide hardship application are under review.

(2) If MRP of any Originator Brand has already been reduced or frozen for 15 or more years by the Federal Government or the manufacturer or importer itself, any such earlier reduction or freeze by the Federal Government or the manufacturer or importer itself shall be adjusted while calculating reduction under sub-para (1). However, annual increase linked with CPI shall not be granted to such Originator Brands from years 2015 to 2019. Thereafter, from July, 2019 these Originator Brands will be entitled to such annual increase.

(3) MRP of any generic shall be at least 15% less than the MRP of Originator Brand so reduced under sub-para (1) and generics where lower MRPs have been fixed shall not be allowed to increase their MRPs except any increase as expressly allowed under this Policy.