For Immediate Press Release

RE: JOINT PRESS STATEMENT BY THE GHANA NATIONAL CHAMBER OF PHARMACY (GNCoP) AND THE PHARMACEUTICAL IMPORTERS & WHOLESALERS ASSOCIATION OF GHANA (PIWA) ON THE DRAFT EXECUTIVE INSTRUMENT (EI) FOR THE RESTRICTION OF SELECTED MEDICINES FROM IMPORTATION FOR LOCAL MANUFACTURE ONLY.

INTRODUCTION

1. The Members of the Pharmaceutical Manufacturers Association of Ghana (PMAG) immediately release this statement as a rebuttal to the misinformation released by the GNCoP and the PIWA on some developments in the pharmaceutical sector. This misinformation is dangerous as it seeks to suppress the growth and development of the pharmaceutical industry and the medicine security of Ghana. PMAG has been in existence for over 30 years, while GNCoP and PIWA have been around for less than 10 years. PMAG has 40 medium to large-scale manufacturers with up to 100 small-scale manufacturers. The number of companies and capacity to manufacture the various medicines has grown over the years from valuable government support and sustainable policies, which have been used by various countries including India and Nigeria to grow their pharmaceutical industry.

2. PMAG, by this statement, wishes to state that we support the Vision and Mission of the Office of the President and the Ministry of Health to make Ghana a manufacturing hub and to restrict some molecules for local manufacturing only. Ghana has the second-largest number of pharmaceutical manufacturers in West Africa and is the most trusted country in West Africa due to strong and a robust regulatory framework.

3. PMAG wishes to state that members of the pharmaceutical manufacturing industry have the capacity to manufacture all the medicines on the restricted medicines list to support Ghana for economic growth and job creation. It is heartwarming to know that most of the pharmaceutical importers have small-scale facilities with the roadmap to scale up in the near future.

BACKGROUND

4. As part of the agenda of Government to develop the local pharmaceutical industry, the list of medicines restricted for local manufacturing only has grown from 5 to 49 molecules over the years. Every time the list is to be updated, there is usually broad stakeholder engagement and then a selected group of organizations that form a committee to finalize the restricted medicines list. In the development of the new 142 list of molecules, this due diligence and process were followed to the latter.

5. Over the past 4 years, there have been broad stakeholder engagement and Committee deliberations with GNCoP and PIWA being represented. The engagements and the deliberations have been led by the Ministry of Health with systems and structures for feedback and complaints.

6. According to the Press release by the GNCoP and PIWA, the Food and Drug Authority recommended 38 products out of 116 products, which is false and very misleading. The Food and Drug Authority should be allowed to speak for itself as it is not represented by GNCoP or PIWA. Also, the FDA has reviewed and submitted a report to the Ministry of

Health on the various products and all the reports from FDA were deliberated on at the various Committee meetings. The first response from FDA was dated 23rd September 2020, and subsequent responses were reviewed in 2023 before the end of the year by the Committee.

7. The current list has been reviewed and discussed at the various Committee meetings, including the residential meeting held at Prampram, where GNCoP and PIWA (who are part of the major stakeholders) were effectively represented. This supports the robustness and integrity of the restricted medicines list.

8. GNCoP and PIWA have falsely stated that there have not been any broader stakeholder engagements, aside from the meetings of the Technical Working Group. There has been a broader stakeholder engagement at the Ministry of Health Auditorium where the GNCoP and PIWA jointly did a presentation on why the restriction should not be done in 2021.

CONCERNS

INTEGRITY OF THE LIST

9. PMAG fully supports the National Agenda and the Ten Point Agenda which includes the pharmaceutical industry. We believe in the robust and effective process for the development of the list. Any serious concerns from GNCoP and PIWA should be sent to the Technical Working Group and the Committee of the Ministry of Health.

10. Secondly, if GNCoP and PIWA are wondering about the data and analysis that was used in concluding on the 142 products, they should engage the Technical Working Group of the Ministry of Health (which they are part of) and not try to create a negative impression for the distinguished Ministry. It is imperative that the stakeholders engage using the right system and not create this tension at this time as the process for engagement has been going on over the past 4 years.

11. If the GNCoP and PIWA are very concerned about the restricted medicines list, resulting in serious consequences such as price hikes, medicine shortages, and even loss of human lives, for the nation, why have they not started manufacturing in consortiums or group manufacturing over the past 4 years? Where were they when PMAG members made preventive and supportive medicines for COVID 19 available and reduced prices significantly? When the United Kingdom and India ban the export of medicines to Ghana and the rest of the world during COVID 19, what did GNCoP and PIWA do about it?

CAPACITY OF LOCAL MANUFACTURERS (POTENTIAL PHARMACEUTICAL GROWTH AND DEVELOPMENT)

12. There is no fact from GNCoP and PIWA to support their claim of the inadequate capacity to manufacture medicines locally. The data is readily available on ICUMS and it is false and misleading for their very young organization to present a claim where they do not have any counter data to support their false allegations. There is also no data to support that after there was shortages or any lack of capacity after the last Restricted Medicines list. It is misleading to cite the Framework Contract Arrangement 1& 2 as a basis to support the Restricted Medicines list as the policy has been modified and is ongoing. When an agency owes a supplier, after the agreed period, the supplier can decide to supply or not supply and this does not have anything to do with capacity.

13. The fact that all the local manufacturers are well-known importers of many finished products on the market shows that all the importers can transition to manufacturers and now is the time. We would appreciate data to support that manufacturers are falling on importers as speculations are dangerous.

14. There are 40 medium to larger scale manufacturers, over 100 small-scale manufacturers, and over 5,000 pharmacists with the capability to manufacture these 142 medicines and this is a good opportunity to create jobs and grow the economy. This is not nosiness for one or two companies and this is an opportunity for the 300 importers to become manufacturers so that local manufacturers can manufacture 70% of the needs of Ghana. Currently most manufacturers are operating an 8 hour shift instead of a 16-24 hour shift and some machines are not being used continuously. Currently Ghana requires less than 30 million bags of infusions and local manufacturers have a capacity to make 60 million bags with plans to scale above 100 million bags for export under Africa Continental Free Trade Area. Some manufacturers have the capacity to make 1 million bottles of syrups or suspensions in 8 hours. There are 6 GMP facilities with road map to attain WHO pre-qualification with 30 more companies in various stages of construction. The government through EXIM Bank has supported local manufacturers to get to this success should be sustained.

15. The statement that supporting local manufacturers would create massive drug shortages and put the lives of well-meaning Ghanaians at risk is false and should not be entertained. The current list has 4 schedules with some medicines already restricted, some with 3 years before restriction and others needing bioequivalence before restriction is granted.

HEALTH PROMOTION

16. Creating a roadmap to support local manufacturing is the way to go as is being done by many countries to ensure we meet medicine security. The Halothanes which include the Isoflurane and Sevoflurane are currently not being used by some countries as there are novel and more efficient anesthetic agents used in our theatres. There are many innovative and cost-efficient anesthetic agents that can still be imported.

COST EFFICIENCY OF MEDICINES

17. The statement that certainly procurement and value for money models would be compromised in atypical monopolistic situations is false and very misleading. There are 40 medium to large-scale manufacturers with over 100 small-scale manufacturers, there would be no monopoly. There is no data to support that some of the medicine to be restricted have seen an increase in prices, this is false and a very dangerous lie. The macroeconomic indicators which include inflation, depreciation of the cedi, amongst others are having an effect on the pharmaceutical sector and not just the manufacturers. The National Health Insurance Scheme would not be at any risk of medicine shortage and will not have any difficulty in reimbursing. These lies and false statements purported by GNCoP and PIWA should not be listened to.

QUALITY

18. With reference to the FDA letter dated 23rd September 2020, the Authority never stated product quality and availability as the key conditions to be considered before any

restriction for local manufacturing. The Authority, over 3 years ago, stated that there are medicines in different classes and some of them would require a bioequivalence study before restriction is considered and currently Ghana has a Bioequivalence center. Also, the Authority stated that the capacity of local manufacturers would be assessed and that has been done over the years. The GNCoP and PIWA should not be allowed to misconstrue or falsely represent the Authority in any way.

19. As a nation, there has been no haste to try and restrict the molecules to compromise the quality of some of these medicines. Rather the Ministry of health has painfully engaged all relevant stakeholders over the last 4 years. The infrastructure and conditions needed to be in place before the restriction of medicine can be implemented included the Bioequivalence center, which is now available in Ghana. The lives of Ghanaians are not in any serious risk and no institution is compromising the quality of the medicines. The FDA with WHO Maturity Level 3 and Maturity level 4 for Pharmacovigilance with the Pharmacy Council are the institutions safeguarding the quality of medicines for the public and should be allowed to do their work with no negative image or prejudice.

NO RISK OF INCREASING UNEMPLOYMENT IN THE PHARMA SPACE.

20. The reality is that for every 10 jobs created by the pharmaceutical importer, the pharmaceutical manufacturer creates 100 direct jobs and 1,000 indirect jobs. From raw material analysis, warehousing, production, packaging to finished product analysis, amongst others, pharmaceutical manufacturers create more jobs than importers. The 300 importers can progress to become local manufacturers, as is happening in Nigeria, and 1,200 wholesalers would be maintained to distribute the various medicines manufactured in Ghana through West Africa and under the Africa Continental Free Trade Area. This would create over 1,500,000 jobs directly and 15,000,000 jobs indirectly.

SUPPORT SYSTEMS

21. Before the last restricted medicines list in 2016, there were 10 small-scale manufacturers. There are over 80 importers who have small-scale manufacturing facilities who would like to scale up. Over the last 4 years, more companies have joined PMAG and some have started local pharmaceutical manufacturing due to the favorable policies of the government. There are continuous engagements on Contract manufacturing which have led to Trading Terms, Guidelines, Prototype Contracts, amongst others. **PMAG members have contract manufactured medicines for importers over the last few years**. There is no need for state-led/controlled CONTRACT MANUFACTURING PLANT as the private sector can lead this with a favorable environment. The importers can create a Consortium to contract manufacture for their members if they do not want the current local manufacturers to do the contract manufacturing for them. The restricted medicines list is part of the roadmap and the precedent to making Ghana, a manufacturing hub and these are deliberate efforts that support local manufacturing.

AFRICA CONTINENTAL FREE TRADE AREA

22. The objective of the AfCFTA is to liberalize intra-African trade and the Secretariat is set up in Ghana. The agreement under the AfCFTA states that there would be a 90% of the items liberalized, 7% liberalized after an agreed period and 3% restricted for certain items to help grow and develop those items. There is a rationale for this agreement and no

pressure group should mar the hard work and good work of the Secretariat. The country has an objective to make Ghana, a manufacturing hub and this should be supported. Restriction is part of trading and would not pose a major threat which would leave the country extremely susceptible in cases of healthcare emergencies.

PROPOSED ACTIONS

PMAG would like to congratulate the President, the Honourable Minister of Health and the Technical working group for the agenda to support local manufacturing and for the patience of engaging all relevant stakeholders. The Ministry has had a comprehensive stakeholder engagement for such a monumental national activity with a focused objective to support local manufacturing, in the light of the unnecessary tension by the pressure group, we are calling on the Honourable Minister to:

23. The finalization of the E.I in its current form should continue and be done to support the national Agenda to support local manufacturing. The process for the formulation of an Executive Instrument has been duly followed and should continue. We know the Ministry through the Technical working group is willing to engage any stakeholders as a broader stakeholder engagement has already been done.

24. After 4 years of engagements and deliberations, the timelines for the restricted list for the various Schedules should continue and be finalized. The Policy, Monitoring, and Evaluation models have been set in place as part of the recommendation of the Technical working group and should be considered.

25. No pressure group should be allowed to dictate to the Ministry of Health after over 4 years of broad stakeholder engagement and discussions. The recommendation of the Technical Working group should be considered.

CONCLUSION

In conclusion, PMAG would like to appreciate the Government of Ghana for the policies and instruments being used to grow and develop the local pharmaceutical manufacturing industry. PMAG would also like to appreciate the Ministry of Health for the strategies and engagements, which are systemic, realistic, transparent, and robust, that are supporting the vision to create a local pharmaceutical hub for Ghana. PMAG would like to state with these favorable policies, there would be growth of the economy and creation of millions of direct and indirect jobs. This EI if passed, after these several years of engagements, would lead to the self-sufficiency and development of the medicine security of Ghana.

Long live Pharmaceutical Manufacturers Association of Ghana!

Long live the Ministry of Health!

Long live the Government of Ghana!

Long live Mother Ghana!

Thank you!