

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

Ladies and gentlemen of the press,

INTRODUCTION

1. The Members of the Ghana National Chamber of Pharmacy (GNCoP) and the Pharmaceutical Importers and Wholesalers Association of Ghana (PIWA) jointly release this statement purposely to inform the good citizens of Ghana of some emerging developments in the country's pharmaceutical sector that may **pose serious health risks for Ghanaians, cripple the National Health Insurance Scheme (NHIS), destabilize the medicine security of the Nation in massive medicine shortages and huge price hikes across the country** .
2. We are by this statement respectfully calling on the office of the Minister of Health to **immediately suspend** the impending E.I. 2023 on the **Restriction of Medicines from Importation** to allow for further engagements especially on the **scope** and **timelines** envisaged under the instrument.
3. We wish however to indicate from the onset that, **we are fully aligned and in support of the Government's broad aspiration to deliberately deploy various interventions to boost local manufacture of medicines in Ghana**. Our concerns are however on the huge potential risks, costs and procedural improprieties associated with this draft E.I.

BACKGROUND

4. It will be recalled that historically, the first restriction on the importation of medicines for local-manufacture-only happened some years ago with **27** Products. Subsequently in 2016, pursuant to E.I. 181, the importation of **49** Products were again restricted for local manufacture. The New E.I. seeks to restrict, at a go, an additional **142** Products in three Schedules. Such a huge increase will undoubtedly have serious ramifications on the country's health sector.
5. Prior to the drafting of this E.I 2023, the Pharmaceutical Manufacturers Association of Ghana (PMAG) submitted a list of **116 pharmaceutical products** to the Ministry of Health for consideration. The Ministry thereafter forwarded the said list to the Food and Drugs Authority for their indispensable technical expert comments and recommendations.
6. Of the initial 116 products submitted to the FDA, the Authority recommended only **38 products** for restriction from imports and for local manufacture only. Their well set out advice was contained in a letter dated 23rd September 2020 to the Ministry of Health.

7. Yet, and rather curiously, the list has since been expanded twice between then and now to **142 products**, without any recourse to major stakeholders. This, in our opinion is highly dangerous to the scientific processes required in the drafting of such lists and raises huge questions about the integrity of the same list.
8. Aside a few meetings of a Technical Working Group (TWG) constituted by the ministry, it is instructive, to state that there has not been any formal broader stakeholder engagements to date. Our worry however, is that the following concerns have not been addressed:

CONCERNS

INTEGRITY OF THE LIST

9. We have serious concerns with the subsequent changes (additions) to the list since the process begun. All products added after the initial 116 were added arbitrarily without being subjected to the regulatory review and standards (by the FDA), something we had subjected every product item on the initial list and this raises questions about the integrity of the list.
10. Secondly, with the availability of countless molecules (including several off- patent products), we are wondering the data and analysis that was used in concluding on these 142 products. Were they just selected because the proponents of the list felt there was good market share for them?
11. An important and sensitive issue such as a medication import ban list, if allowed to be arbitrarily generated in such a manner as has been done, can undoubtedly **result in serious consequences, such as price hikes, medicine shortages and even loss of human lives, for the nation.**

CAPACITY OF LOCAL MANUFACTURERS (POTENTIAL MEDICINE SHORTAGES)

12. There is (a fact admitted expressly under Section 7 of the draft E.I) a clear absence of any data to support the capacity of local manufacturers to meet the pharmaceutical needs of the nation in the immediate and short term if this EI is passed immediately.

There is even no data to confirm this capacity for the products under the previous E.I 181. This fact is glaring from the Ministry of Health's own reports on the Framework Contract 1 and 2 statistics. Save, a maximum of two local pharmaceutical manufacturing facilities in Ghana, none of the remaining local manufacturers have demonstrated an ability to meet their contractual obligations to the full as far as awards to supply under MOH/GHS tenders are concerned. Most health facilities in the public sector are forced to rely on importers to keep serving their patients.

13. In fact nearly all the local manufacturers are well known importers of many finished products on the market. Even with their own customer needs/demands, they have to fall on imports to meet the needs of their customers as they are not able to produce enough for their own demands.

14. Should we, in the light of these facts, risk a significant increase in the list and hope that ONE or TWO COMPANIES can meet all the needs of our health facilities? Can these one or two companies cater for the over 70% medicine needs of the country, currently being served by over 300 importers? Certainly No, as this threat transcends public health to even national security!
15. Are we as a country ready for **massive drug shortages** and put the **lives of well-meaning Ghanaians at risk**? Medications for the treatment of hypertension, diabetes, malaria, emergency situations are all being sought to be banned immediately without a proper check on our sufficiency as a country to produce such essential medications. The looming danger such as **medicine non-availability for patients, price hikes and pressure on the NHIS and on private and government health institutions** can't be downplayed.

HEALTH RISK

16. Placing our medicine security in the hands of one manufacturer is a huge national security risk whose consequences could be dire. A classical instance is the attempt under the E.I to restrict the importation of **Isoflurane and Sevoflurane (important anaesthetic agents used in our theatres)**. Only **one local pharmaceutical manufacturer** manufactures these lifesaving, theatre-used, anaesthetic agents in Ghana. What happens if, for any conceivable reason, they are unable to manufacture at a given time? This can undoubtedly result in the **deaths of innocent citizens** in emergency situations. Bearing in mind the processes for obtaining dossiers, registering products with the FDA, and then importing from anywhere in the world to Ghana spans between a minimum of 6-18months. How does the national health system risk a sole source for such products by restricting it to only one Company in Ghana? The number of medicines used in **emergency situations** on this list that currently have only one or two manufacturers is alarming. Are we as a country ready to take such serious risks of **life losses** through shortages of such emergency and other essential medications across the length and breadth of the nation?

COST OF MEDICINES

17. Certainly, procurement and value-for-money will be compromised in a typical monopolistic situation. Already, some of these medicines whose ban is being anticipated by some local manufacturers have seen massive increase in prices. This certainly will have a heavy impact on the pockets of Ghanaians and negatively affect the country's economy through **inflation** .For the **National Health Insurance Scheme**, this coupled with the huge risk of medicine shortages will undoubtedly be the beginning of the end of the scheme as the NHIA will have difficulty in the reimbursement of service providers as well as **provision of medications for patients on the scheme nationwide**. The already **overburdened pockets of Ghanaians** will definitely be the bearer of such **price hikes**. Will we watch people **lose their lives** because they can't afford a particular medication?

QUALITY

18. We refer to the FDA's letter of 23rd September 2020 where the Authority clearly articulated, in the interest of product quality and availability the key conditions to be addressed before any restriction can be placed on the importation of certain classes of medicines.
19. As a nation, the haste of trying to ban this list will undoubtedly **compromise the quality** of some of these medications merely for the purpose of their import ban for local manufacture. As stated by the regulator (FDA), certain infrastructure and conditions need to be in place before ban on certain products can be implemented so as not to compromise the quality of same. The **lives of Ghanaians** are indeed at **serious risk** should we compromise the quality of the medications we want to consume in the country without first putting in place the requisite infrastructure, proper data collection and analysis and others before taking a step in this direction of medication ban. This will undoubtedly result in **price hikes** as well as have detrimental **effect on the lives of Ghanaians, the NHIS, as well as all health institutions across the country.**

RISK OF INCREASING UNEMPLOYMENT RATE IN THE PHARMA SPACE

20. Besides all the reasons above, the risk of collapsing over 300 importers and 1,200 wholesalers engaged in pharmaceutical businesses could create serious economic, financial and social challenges for the **over 150,000 employees** directly employed by these companies in various roles. This number is exclusive of all the Hospitals and clinics, retail pharmacies, OTCM(chemical) shops which employ over **500,000 people** whose jobs also, will definitely be affected.

SUPPORT SYSTEMS

21. One key reason for the above challenge/concern, is the absence of adequate support systems and structures for both local manufacturers and even importers who may venture into local manufacturing. We believe a real committed drive to boosting local manufacturing **MUST** begin with the establishment of state-led/controlled **CONTRACT MANUFACTURING PLANTS** either solely or in Public Private Partnership (PPP) to enable all companies to collaborate and manufacture products locally. Another is special bank facilities providing low interest rates and the establishment of a dedicated financial institution to work with pharmaceutical companies towards achieving the nation's aspiration to be a hub for pharmaceutical manufacturing in West Africa as is in the case of India. These must be in place as a precedent to any deliberate effort to restrict product importation so that there will be no infrastructural barriers to all players (importers and manufacturers) in their quest to meet the total medicine needs of the nation.

AFRICAN CONTINENTAL FREE TRADE AREA (AFCFTA)

22. We know one of the objectives for setting up AfCFTA is to liberalize intra-African trade

and for that matter its Secretariat was set up in Ghana .As the host country for AfCFTA, Ghana is positioned to lead the way in implementing the programs and activities required for a successful trade. How do we intend to achieve this, if we are keen on restricting imports from other neighbouring countries yet we expect them to accept our exports with open arms? If these neighbouring countries also decide to ban imports of pharmaceutical products from Ghana, won't the government's goal of making **Ghana a pharmaceutical manufacturing hub be hampered**? Restricting some of these essential medicines from trade, can pose major threats which will leave our country extremely susceptible in cases of healthcare emergencies.

PROPOSED ACTION

It is our submission that the **TWG** alone and the Ministry may not provide adequate and a comprehensive stakeholder engagement for such a monumental national activity with complex ramifications. In the light of the foregoing, and in the broader national interest, we are calling on the Minister that:

23. The finalization of the E.I in its current form be **suspended immediately** for a broader engagement with key stakeholders like parliamentarians, policy makers, service providers, manufacturers, regulators, importers, research centres, practitioners and Ghanaians for their perspectives and inputs.
24. Adjust the timelines for the restriction of the various classes of the products to make room for critical national interventions prior to their implementation. These include, firstly, the establishment and operation of the functional system for data collection and analysis on the capacity of local manufacturers to meet national needs of medicines restricted under E.I 181. Secondly, the establishment of effective support infrastructure like contract manufacturing plants in at least three locations in Ghana to significantly reduce the existing barriers to local manufacture.
25. The immediate restriction should only be on the **38 pharmaceutical products recommended by the FDA** as they are backed by the necessary regulatory support.

CONCLUSION

In conclusion, we commend the Government and affirm our support for the vision to create a local pharmaceutical manufacturing hub for Ghana. We however pray that the process must be systematic, realistic, transparent and strategic in such a manner to avoid any **potential public health crisis, a negative impact on the country's economy** and a **potential massive medicine shortage which can pose serious health risks for Ghanaians, deaths, cripple**

the National Health Insurance Scheme (NHIS), destabilize the medicine security of the Nation and cause huge price hikes across the country. This E.I if passed in haste will potentially put in jeopardy the healthcare of the good people of Ghana.

Long live the Ghana National Chamber Of Pharmacy (GNCOP),

Long live the Pharmaceutical Importers & Wholesalers Association of Ghana (PIWA)

Long live Mother Ghana

Thank you.

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