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Local HPV Vaccine Production in Iran: A Strategy to Improve Access and Strengthen Supply Chain Security

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Dear Editor,

Persistent infection with high-risk human papillomavirus (HPV) is a necessary cause of most cervical cancers and remains a preventable public health burden. The World Health Organization has placed HPV vaccination, cervical screening, and treatment of precancerous and invasive disease at the center of its global strategy for cervical cancer elimination (1). In Iran, however, the key policy challenge is not only whether HPV vaccination is effective but also whether effective vaccines can be obtained, afforded, trusted, and delivered at sufficient scale.

In this context, locally manufactured HPV vaccines warrant evidence-based policy attention. The primary policy recommendation of this letter is that Iran should consider locally manufactured HPV vaccination as an access-oriented backbone within a transparent national prevention strategy while continuing to evaluate broader-valency options as cost, supply, and evidence permit. In this letter, "locally manufactured HPV vaccine" refers to domestic HPV vaccine production as a policy category, whereas "Papilloguard" refers specifically to the Iranian bivalent HPV vaccine evaluated in the available phase III trial. Papilloguard was evaluated in a randomized, controlled, double-blind, phase III noninferiority trial conducted in Tehran, Iran, among healthy female volunteers aged 15 - 25 years. The trial compared Papilloguard with the reference bivalent vaccine, Cervarix, and reported comparable immunogenicity and safety against HPV-16 and HPV-18 (2). This clinical evidence supports Papilloguard against its target HPV types. By contrast, arguments regarding improved affordability, supply chain security, and reduced reliance on unverified vaccine channels should be interpreted as policy-based benefits that depend on implementation, regulation, and monitoring.

The argument for locally manufactured HPV vaccination should therefore be framed carefully. Local manufacturing alone does not guarantee broader genotype matching because HPV vaccines are based on recombinant virus-like particles targeting specific genotypes rather than the routine inclusion of regionally isolated viruses. Iranian studies have shown heterogeneity in HPV genotype distribution, with HPV-16 consistently important and other high-risk genotypes also reported across different populations (3). This variability strengthens the case for genotype surveillance and postvaccination monitoring rather than unsupported assumptions of superiority.

Affordability is central to implementation. Imported HPV vaccines may be expensive, intermittently available, and vulnerable to supply chain disruption. Recent cost-effectiveness modeling in Iran suggests that HPV vaccination policy is highly sensitive to vaccine price and program assumptions (4). However, lower prices alone will not ensure equitable access. Previous discussions in Health Scope have similarly emphasized that underserved areas face economic, geographic, infrastructural, workforce, managerial, and sociocultural barriers to health service delivery, reinforcing the need to evaluate HPV vaccine access beyond price alone (5). If local production lowers procurement costs and stabilizes supply, it may provide public health value, provided that uptake is monitored across regions and population groups.

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Access is also a matter of trust and regulation. When vaccines are costly or scarce through official channels, patients may turn to informal markets, online sellers, or unverified cold-chain pathways. Alerts about falsified and illegally marketed Gardasil 9 in other settings should not be interpreted as evidence of established counterfeit HPV vaccine circulation in Iran; rather, they provide risk context for high-value vaccines (6). Previous Iranian and regional experience with counterfeit medicines also underscores that falsified medical products can threaten patient safety and require active professional vigilance (7). In the absence of local evidence specific to HPV vaccines, the counterfeit discussion should therefore be understood as a precautionary risk-management rationale. Local production alone cannot prevent falsification, but a regulated supply with visible authentication systems, tamper-evident packaging, batch-level tracking, enforcement against informal sellers, and public awareness of trusted vaccination sites may reduce reliance on unverified supply channels.

Vaccine valency remains a central policy issue. Papilloguard is a bivalent vaccine targeting HPV-16 and HPV-18; quadrivalent vaccines also include HPV-6 and HPV-11, whereas nonavalent vaccines add other oncogenic types such as HPV-31, HPV-33, HPV-45, HPV-52, and HPV-58. This distinction matters for Iran because HPV-16/18 are estimated to be present in approximately 58.6% of invasive cervical cancer cases, leaving a clinically relevant residual burden attributable to other high-risk genotypes (8). Iranian studies have also reported other high-risk genotypes, including HPV-52, HPV-31, HPV-39, and HPV-45 (3). Consistent with this surveillance-oriented approach, a recent Health Scope population-based study of high-risk HPV infection showed that spatial analysis of screening data can help identify regional clusters and guide localized cervical cancer prevention strategies (9). In addition, although Papilloguard has national clinical evidence, it is not currently listed among WHO-prequalified HPV vaccines in publicly available WHO prequalification records; pursuing or documenting progress toward WHO prequalification would strengthen international credibility and future policy confidence (10). Thus, a bivalent vaccine may be highly relevant for cervical cancer prevention, but it should not be presented as equivalent to broader-valency products.

A practical policy should not rely exclusively on a locally manufactured product. Rather, locally manufactured bivalent vaccination may serve as an access-oriented backbone, while mixed procurement or phased integration of broader-valency vaccines is considered as cost, supply reliability, and regulatory evidence permit. Procurement decisions should weigh genotype coverage, vaccine price, supply reliability, regulatory status, and program feasibility together.

If this approach is adopted, monitoring and quality assurance should be built into the program from the outset. The highest priorities are national HPV genotype surveillance, pharmacovigilance, procurement transparency, and vaccine traceability. These priorities require reliable cold-chain maintenance, batch-release oversight, standardized documentation of vaccine name and batch number, trained vaccinators and pharmacists, and periodic regulatory audits. Part of any savings achieved through lower procurement costs should be earmarked for postmarketing monitoring, registry linkage, pharmacovigilance, and quality audits. Program performance should be evaluated using predefined indicators, including vaccine uptake, schedule completion, cold-chain deviations, adverse events following immunization, reports of suspected falsified products, breakthrough HPV infections, cervical intraepithelial neoplasia, and invasive cervical cancer trends.

Professional societies in obstetrics and gynecology, pediatrics, infectious diseases, oncology, and pharmacy can support implementation by developing evidence-based guidance on locally manufactured and imported HPV vaccines. Such guidance should clarify vaccine valency, target groups, schedule completion, documentation, and reporting pathways. At the clinical level, clinicians and pharmacists should counsel families that HPV vaccination is most effective before exposure, discourage purchases from informal channels, document the exact vaccine name, batch number, schedule, and source, and report suspected falsified products or adverse events through official systems.

This letter has limitations. It is a policy-oriented argument and does not present new clinical, epidemiological, regulatory, or market-surveillance data. The clinical evidence discussed for Papilloguard is limited to its reported immunogenicity and safety against HPV-16 and HPV-18 in the available phase III trial. In addition, the discussion of falsified HPV vaccines relies on international regulatory alerts as risk-context evidence and should not be interpreted as direct evidence of established counterfeit HPV vaccine circulation in Iran.

In conclusion, local HPV vaccine production in Iran should be viewed neither as automatic evidence of superiority nor as a substitute for broader-valency vaccines when these are affordable and reliably

available. Its main value lies in its potential to improve timely access, reduce cost barriers, strengthen supply chain security, and limit reliance on unverified vaccine sources. A pragmatic national strategy should therefore use locally manufactured HPV vaccination as an access-oriented backbone while maintaining genotype surveillance, pharmacovigilance, transparent procurement, batch-level traceability, and clear public communication. Under these conditions, local production can become a disciplined public health strategy rather than a promotional claim.

Footnotes

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