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The GAVI AVMA CMO Proposal

Overview

GAVI has made available an amount of USD750m to 1bn for the AVMA over a 10 year period. The purpose of the AVMA is to achieve sustainable African manufacturing that contributes to the strengthening of a global vaccine market and improved vaccine equity. It also aims to improve Africa's pandemic outbreak capability and pandemic preparedness. The nexus to achieving these objectives is for African manufacturers to achieve **sustainable and predictable demand** on the one hand and on the other, **economies of scale in order to compete with their contemporaries in other geographies**.

Securing predictable volumes and sustained economies of scale remains the basis of this CMO proposal.

The African vaccine market which consumes around 1,2bn doses annually, historically providing significant demand supplied by manufacturers in other geographies. The health security and economic benefits to Africa from redressing this total imbalance between supply and demand have been well documented. A first step to correcting this inequity has been the regional development of FF capability, with sufficient capacity now available on the continent through current and future capabilities by regional manufacturers. This redress must be supported and CMO activity constitutes a bona fide manufacturing activity ensuring volume to African manufacturers, thereby lending itself to increased certainty and predictability in volumes and increased economies of scale with a knock on impact on local attractiveness and competitiveness. In a nutshell, what Africa needs is to attract the right investment and technology transfer for manufacturing activity in order to strengthen its manufacturing network and a combination of CMO and license product manufacturing is the way of encouraging this.

Does CMO activity weaken the continent's ability to achieve licensing arrangements?

Whilst this is often stated, a reasonable counterview is that licensing arrangements are potentially more lucrative to the licensor than if they are participating in contract manufacturing activities, the former being more profitable through the sale of either drug substance or transfer pricing to the licensee. There is also a strong case to be made that some MNC's will not license their products immediately, if at all and consequently CMO could be the most obvious entry point into achieving accretive and incremental volumes. In other cases, a CMO might very well lead to a longer term licensing arrangement being secured . In the broader context, very little downside would be realized through inclusion of CMO in terms of the overall objective and mandate of sustainable volumes on the continent. In order to provide further comfort around this issue, it is proposed that the incentives for CMO are set at 50% of those for the present FF AVMA arrangement i.e., USD 0,15 per dose up to a maximum of USD 0,6c. This arrangement would apply to the existing antigens as set out in the AVMA term sheet and could apply to more than one CMO arrangement for the same antigen.

Eligibility

Any manufacturer who is invested on the African continent and who performs authentic drug substance and drug product manufacturing, and/or formulation, fill & finish using African manufacturing assets, utilities and personnel and who pay their taxes in that particular African country.

Some practical considerations

It has been mooted that the holder of the WHO PQ license should be the entity receiving the incentive. The way to overcome this would be for the payment to be furnished to the contractor and the contractee would then bill an additional USD 0,15c per dose to the contractor in order to recover the incentive.