




## COARSUCAM/ « ASAQ » Registration strategy

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### What is COARSUCAM « ASAQ »...

- **A fixed-dose combination, presented as a bi-layer tablet**
- Innovative pharmaceutical presentation requiring a dedicated industrial facility, intended to meet short-term (compliance) and long-term (resistance) objectives
- Same active ingredients as Arsucam
- Same indications as Arsucam
- Simplified dosing regimen
  - 1 tablet a day up to 13 years (instead of 2 to 4 tablets)
  - 2 tablets once a day up for 14 years and above (instead of 8 tablets)

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## Regulatory strategy with 2 objectives....


- Bring to endemic countries populations, as fast as possible, a fixed dose combination of artesunate+amodiaquine accessible to all (private market, public market).
- High quality scientific documentation through a development plan consistent with current European recommendations.



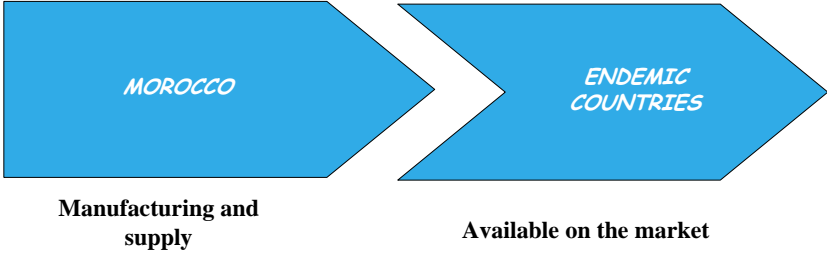
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## The search for the most optimal registration strategy





*MOROCCO*

*ENDEMIC COUNTRIES*

Manufacturing and supply

Available on the market

... for the largest possible number of patients




préqualification

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## What is a stringent authority....


- ICH members: Europe, Japan, US
- ICH observers: Canada, Switzerland, WHO ?
- ICH associated countries: Australia, Norway, Iceland, Liechtenstein
- PIC-S member ?(Pharmaceutical Inspection Cooperation Schema): Argentina, Malaysia, Singapore, South Africa(no more valid)



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## 3 registration steps necessary to meet the objective....


Manufacturing authorization	Marketing authorization	Prequalification
↓	↓	↓
Morocco	Endemic countries	WHO or EMEA



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## Regulatory positioning of ASAQ different between 2 areas


Registered AS	Non-registered AS (NCE)
Morocco Endemic countries WHO	EMEA

Registered Arsucam Range extension « Abridged » dossier	Non-registered Arsucam New fixed-dose combination Full Dossier
Morocco Endemic countries	WHO or European Agency



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## An « abridged » dossier...

**Step 1**


*Morocco*

*Endemic Countries*


Full pharmaceutical Dossier

Pre-clinical dossier  
Cross-referenced to Arsucam

Clinical dossier  
Cross-referenced to Arsucam  
  
+dose  
+PK  
+clinical confirmatory



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**Separate components and ASAQ status lead to differences between WHO and Europe ....**

Artesunate and ASAQ never assessed in Europe

Arsumax prequalified by WHO, but Arsucam not yet prequalified

**STEP 2**


*WHO*  
*Europe*



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**Full dossier for the combination....**


Full pharmaceutical Dossier

Full and updated preclinical dossier

Full clinical dossier:  
Arsucam studies  
+dose  
+PK  
+ FDC clinical study

**STEP 2**

*Prequalification*



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