



**Draft Guidance for Industry Tropical Disease
Priority Review Vouchers**

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Draft Guidance for Industry Slide 2

Tropical Disease Priority Review Vouchers

Encouraging a business model for
the development of new medicines
with limited market potential in
under-developed nations



Tropical Disease

Slide 3

Applications that Qualify for a Priority Review

Applying the Guidance for Adding
to the List of Qualifying Diseases



Tropical Disease Priority Review Voucher

Slide 4

Proposed Criteria for Adding Named Diseases to the Qualified List

Any other infectious disease for which:

- ***There is no significant market for treatment in developed nations***
- ***Disproportionately affects poor and marginalized populations***



Proposed Qualification Criteria		Slide 5
No Significant Market in Developed Nations	Affects Poor Marginalized Populations	
<ul style="list-style-type: none">• Prevalence in developed nations• Incidence intermittent or unpredictable• No reasonable expectation to recover costs• Identified by WHO as neglected disease	<ul style="list-style-type: none">• Primarily affect under-developed countries• Affect areas with minimal healthcare• Health care workers at higher risk• Zoonotic disease• Identified by WHO as neglected disease	
		

No Significant Market Developed Nations	Slide 6	
Low Prevalence in Developed Nations		
<ul style="list-style-type: none">• “rare disease” definition of the Orphan Drug Act		
Intermittent or Unpredictable		
<ul style="list-style-type: none">• Due to pathogens not generally present in human populations		
Cost Recovery		
<ul style="list-style-type: none">• Small sales expectations due to both incidence of disease and healthcare economics within affected nations• Stockpiling and distribution challenges		
WHO Classification		
<ul style="list-style-type: none">• Neglected disease definition considers lack of market in developed nations		
		

Effects Poor Marginalized Populations

Slide 7

Affects Underdeveloped Countries

- Ratio of incidence in under developed vs developed nations

Minimal Health Care Infrastructure

- Implicit in definition of “underdeveloped country”

Healthcare Workers at Risk

- Loss of healthcare workers compounds problems of treatment and care

Zoonotic

- Poor marginalized populations and proximity to possible disease reservoirs

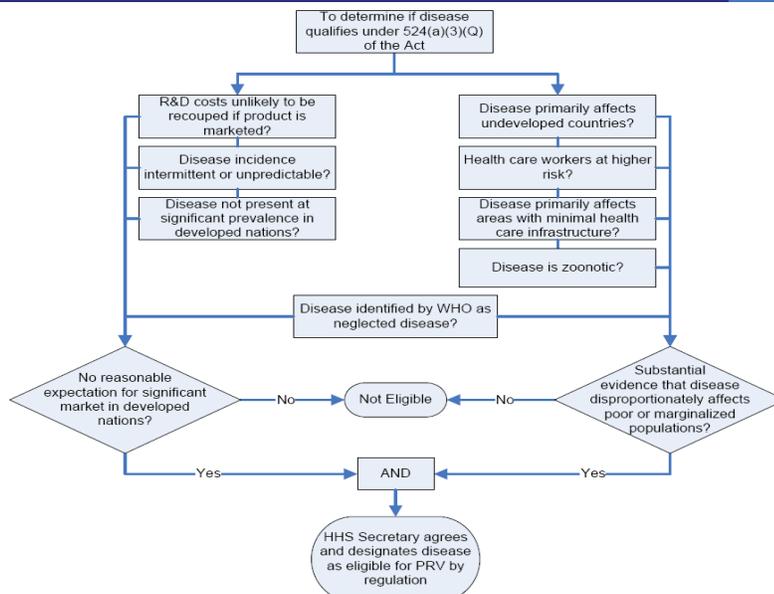
WHO Classification

- Neglected disease definition considers primary affects on poor or disadvantage populations



The Proposed Decision Paradigm

Slide 8



“Weight of Evidence”

Slide 9

- If a disease does not meet one of these specific criteria, it is not automatically excluded from eligibility.
- Rather does evidence support whether an infectious disease has both:
 - **no significant market in developed nations**
 - AND**
 - **disproportionately affects poor and marginalized populations.**



Adding to the List of Named Diseases

Slide 10

Eligibility for a Priority Review Voucher;

The Case for Ebola and Marburg
Hemorrhagic Fever



Ebola and Marburg Virus (CDC)				
	Ebola Virus		Marburg Virus	
	Human Infections	Fatalities	Human Infections	Fatalities
Africa	2245	1507	414	360
Europe	1	0	31	7
North America	6	0	0	0
Australia	0	0	0	0
Asia	2	0	2	0
South America	0	0	0	0



- | Do these Diseases Meet the Criteria? | |
|---|---|
| <ul style="list-style-type: none"> • Outbreaks are isolated and sporadic due to unknown reservoir for the Ebola and Marburg viruses • No known curative or preventative treatments • Treatment is limited to supportive care • Outbreaks of EHV limited strictly to African continent • Incidence of Marburg is >10-fold higher on the African continent than in the entire rest of the world combined • Economic hardship effects healthcare infrastructure |  |

Do these Diseases Meet the Criteria?

Slide 13

- Transmission due to direct contact, exposure to body fluids
- Disease transmission mode puts healthcare workers at risk
- Often transmitted to caregiver and family members; nosocomial infection of health care workers repeatedly documented
- Poor socio-economic status in health care facilities often favor disease transmission rather than containment
- Designated by WHO (and ASTMH) neglected tropical disease within the zoonotic disease classification



Ebola and Marburg Priority Review

Slide 14

