

Arakoda™ (Tafenoquine) Transition Planning Meeting Agenda

(b)(5) 0900-1000 (East Coast Time)

Location: USAMMDA Bldg 1430, (b)(5)

(b)(5)

1. Introductions, Purpose of Working Group

(b)(6)

(b)(6)

(b)(6)

2. Review of Issues

(b)(6)

3. Commercialization Plan

(b)(6)

4. Modification of DOD Guidance for Malaria Prophylaxis

(b)(6)

(b)(6)

5. Inclusion of Arakoda™ onto DOD Peacetime Procurement Vehicles and Contingency Contracts

(b)(6)

6. Inclusion of Arakoda™ onto DOD Formularies

(b)(6)

7. Final Discussion

(b)(5)

MEETING WITH 60P TO DISCUSS TAFENOQUINE COMMERCIALIZATION

PARTICIPANTS: (b)(6)

(b)(6)

DISCUSSION:

- Priority Review Designation received for TQ; 6 months for FDA review (completed NLT 8 August 2018)
- (b)(4)
- Timeline:

FDA approval	8 August 2018
Tablet validation	(b)(4)
Packaging validation	(b)(4)
Serialization validation	(b)(4)
Validation lots shipped to distributor	(b)(4)
Commercial launch	(b)(4)

- Trade name: (b)(4)
- 100mg tablets
- JPMPG: When are the future quarterly meetings?
- White paper for consultant community?
- Brief at MHSRS (60P brief)
- Who at DoD-HA can guide us as to how to approach them to get the word out?
- (b)(5)
- Can industry reps approach individual MTFs?
- Three (3) validation lots will have (b)(4)
 - **Unit of purchase** is (b)(4)
 - **One Unit of purchase will provide prophylaxis for one service member for 1 month.**
 - **Unit of purchase cost** = (b)(4) (estimate, based on estimated cost of (b)(4) per tablet)
 - Cost of the 3 validation lots is estimated at (b)(4)
 - (b)(6) could we commit to buying this amount to support placebo-controlled studies? Perhaps post-market night vision studies? Tolerability studies?
- Logistics: (b)(4) is the Third Party Logistician (part of (b)(4))
 - They can also do serialization
 - From (b)(4) → Wholesalers (b)(4) etc)
 - (My NOTE: I think (b)(6) reference to wholesalers is the same as what we term as prime vendor distributor)

- Is there a survey that we can generate to gauge potential use?

 - Summary of Potential Actions for USAMMDA:
 - Can the Army commit to buying a certain amount of TQ to support post-marketing studies?
 - Can industry reps approach individual MTFs?
 - (b)(4)
 - Who at DoD-HA can we contact reference TQ?
 - When are future JPMPG quarterly meetings?
 - Can we persuade DoD-HA to recommend TQ for malaria treatment?
 - Can we get TQ into the appropriate unit assemblages? Need to engage the USAMMA pharmacist.
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(b)(5) (on/about)

IMPROMPTU MEETING WITH (b)(6)
SUBJECT: POTENTIAL COURSES OF ACTION TO FUND PROCUREMENT OF TAFENOQUINE

According to (b)(6) some courses of action:

- (b)(5)
- (b)(5)
- (b)(5)