



USAID
FROM THE AMERICAN PEOPLE

April 27, 2006

ACTION MEMORANDUM

TO: The Administrator

FROM: AA/GH, Kent D. Hill /s/
GC, Arnold Haiman (Acting) /s/

SUBJECT: Expedited Acquisition and Assistance Procedures for Activities and Programs Related to USAID's Avian Influenza Pandemic Emergency Preparedness and Response Efforts

ISSUES FOR DECISION

Whether to approve the use of other than full and open competition in soliciting and awarding contracts and assistance agreements, as well as other waivers, to facilitate and expedite the conduct of USAID emergency response efforts related to Avian and Pandemic Influenza (AI) Emergency Management and Response efforts.

ESSENTIAL FACTORS

The U.S. Government's response to AI will require the rapid initiation of surveillance, response, preparedness, stockpiling of medical equipment, behavior change, and communication to enhance the world's capacity to identify, treat, and isolate animal and human outbreaks of AI infections. Any delay in making assistance available could compromise the ability of the United States to protect the health of its own citizens as well as affect its ability to achieve foreign policy goals.

This Action Memorandum seeks approval of four waivers in order to expedite acquisition and assistance related to AI efforts. These waivers are critical for USAID's rapid response. They are similar to other packages of procurement

waivers, most recently for tsunami response, Afghanistan, Iraq, and HIV/AIDS, which relied on waiver authorities provided for in the authorities establishing regular USAID procedures. Although notwithstanding authority accompanies most accounts funding AI activities, the waivers recommended in this memorandum do not rely upon notwithstanding authority. USAID policy is to use other waiver authorities before relying upon notwithstanding authority. This memorandum so states, and sets out limitations on any use of notwithstanding authority.

- The four waivers are:

- A. One-year Authorization for Initiating Activities Not Covered by Existing Strategic Objectives

This is a waiver of the Automated Directive System (ADS) policy planning requirement that obligations always be covered by an existing approved strategic objective. This authority is provided under ADS 201.3.4.5.

- B. Other than Fully Competitive Procedures for Assistance

This waiver authorizes:

- non-competitive amendments to existing grants and cooperative agreements; and
- new grants and cooperative agreements using other than fully competitive procedures.

Under USAID regulations, competition is not required for assistance awards under circumstances determined to be critical to the objectives of the foreign assistance program. This authority is provided under ADS 303.5.5d(5).

- C. Other than Fully Competitive Procedures for Acquisition

This waiver authorizes:

- non-competitive amendments to existing contracts; and
- new contracts using other than fully competitive procedures.

Under USAID regulations, you may determine that compliance with full competitive procedures would be inconsistent with the fulfillment of the foreign assistance program. This authority is provided under AID Acquisition Requisition 706.302-70(b)(3)(ii). Tab A, which you also sign, provides the mandated “Determination and Finding” as well as further guidance to this effect.

D. Source, Origin, and Nationality for Goods and Services

This waiver authorizes procurement of goods and services in any country (other than foreign-policy restricted countries), rather than only in the United States. The waiver includes motor vehicles and pharmaceuticals; specific approvals are required for pharmaceuticals. This waiver is authorized when necessary for efficiency in the use of foreign assistance resources. This authority is provided under ADS 312.5.3c(2) for vehicles and 22 Code of Federal Regulations (CFR) 228.51(a)(3) for pharmaceuticals. Tab B provides operational guidance for this waiver.

1. Waivers

GH will lead the Agency-wide, multi-sector team responsible for planning and implementing the proposed program of assistance. USAID will need to use every resource at its disposal to be able to respond quickly and appropriately to the crisis and meet the objectives of the foreign assistance program. Consistent with and drawing upon recent experience with the emergency programs for the tsunami-stricken areas and other disasters, Afghanistan, Iraq, and HIV/AIDS, GH has identified the areas of normal USAID implementation procedures that, with specific regard to the urgent needs of those who will be affected by the AI crisis, may lead to unacceptable delays in program implementation. In particular, one “lesson learned” from the pandemics of the past century is that we cannot wait for the virus to present itself as a human-to-human infectious disease—a point at which any preparation effort will be too late. We must now begin to initiate surveillance activities and plan for containment of the virus’ potential emergence as the first pandemic of the 21st century. To this end, we recommend that you approve the blanket waivers discussed below that are needed to enable the Agency to expedite and implement activities undertaken in response to the crisis.

The waivers would be effective immediately, would be applicable to all acquisition and assistance to be carried out by USAID for the AI pandemic Emergency Preparedness and Response Program discussed herein, and would remain in force throughout the life of any activity carried out or initiated under this Program.

As a matter of law and policy, USAID’s normal preference is to follow standard procedures, including full and open competitive procedures, for routine procurements. This enables USAID to obtain the benefits that flow from the standard terms and procedures that have been developed over the years on a Government-wide basis. While we recognize that preference, in emergency

circumstances these interests must give way to the overriding objective of providing immediate, timely assistance in a situation that is constantly evolving. However, we acknowledge the benefits that flow from competitive procedures could well outweigh the advantages of expedited or modified procedures. Accordingly, the use of the authorities approved in this memorandum will be reviewed annually and, should conditions warrant, we would make a recommendation as to whether the waiver authorities should be extended, modified (e.g., by limiting subsequent uses of the authorities to particular countries or activities), or expanded in reliance upon available authorities.

If approved, the waivers proposed here would cover AI Emergency Preparedness and Response Program-related activities in non-presence countries as well as presence countries. The waivers also would cover activities funded from all sources of Agency funding—including U.S.-owned/controlled local currency or jointly programmed host country-owned local currency accounts. Finally, the waivers would apply to prior year funding as well as current and future fiscal year appropriations (unless special rules for these appropriations are enacted by the Congress).

Guidance as to the specific use of the waiver authorities (criteria for use, documentation, and reporting) will be developed by GH, M/OAA, and GC no later than thirty days from the date of your approval.

2. Notwithstanding Authority

Much of the funding available for the AI Program, such as Child Survival and Health (CSH), International Disaster and Famine Assistance (IDFA) funds, and Transition Initiative (TI) funds, has been made available to the Agency “notwithstanding any other provision of law.” This means that these types of funds may be used to provide assistance notwithstanding prohibitions against assistance to particular countries, activity level restrictions, and/or restrictions relating to competitive procedures or source/origin requirements. Emergency assistance requires special and expedited procedures; notwithstanding authority permits USAID to respond to emergency needs in a timely fashion, in spite of statutory requirements that otherwise might restrict our ability to respond in a timely fashion.

However, notwithstanding authority is an extraordinary authority granted to USAID by the Congress. As a matter of Agency practice, USAID has used more conventional waiver authorities when practicable. Therefore, notwithstanding

authority should be relied upon only if other expedited acquisition and assistance procedures proposed in this memorandum are either unavailable or inappropriate for purposes for which notwithstanding authority is available. Because notwithstanding authority flows with the funds that carry notwithstanding authority, rather than being vested in any particular office, it is the Bureau, Office, or Mission that will obligate the funds that will have the authority to determine whether to rely upon notwithstanding authority. All decisions to rely upon notwithstanding authority should be documented and cleared by either GC or the appropriate Regional Legal Advisor.

In general, USAID should never use notwithstanding authority to eliminate financial accountability provisions such as those relating to vouchering, audits, reports, and similar matters from its agreements. Notwithstanding authority should not be used to circumvent USAID policies with regard to responsibility determinations. Regulations on government ethics or employee conduct likewise cannot be disregarded through use of this authority.

Funds appropriated under notwithstanding authority still must be used for the purposes of the particular account or appropriation, i.e., the authority does not change the nature of the funds appropriated. Thus, notwithstanding authority cannot be used to charge an OE cost to a program account nor can this authority be used to provide economic assistance to the military or to fund abortions, among other prohibitions.

3. Additional actions

In addition to the waivers recommended below, the AI Task Force in GH will consider other actions, in conjunction with M/OAA and GC, to facilitate the speedy implementation of AI emergency preparedness and relief activities. These actions include:

- (1) Ensuring maximum use of existing instruments designed to enable fast track assistance and acquisition processing, e.g., IQCs, grants under contract mechanisms, Leader/Associate assistance instruments if appropriate;
- (2) Encouraging the use of Public International Organizations (PIOs) to the extent their programs and goals are similar to USAID's; and
- (3) Encouraging Minority Serving Institutions and small and disadvantaged business utilization to the degree it can expedite the A&A process.

In addition to the possible use of the notwithstanding authorities referred to above, we recommend approval of the following waivers in reliance upon the waiver authorities set out in each recommendation below:

A. One-year Authorization to Initiate Activities prior to Completion and Approval of a Strategic Plan. USAID, working through the Agency's AI Unit in GH, will undertake AI containment efforts on an emergency basis. In such a situation, USAID will be unable to prepare a strategic plan for AI-related assistance in advance of obligations. In this regard, ADS 201.3.4.5 provides that "[c]ertain programs are exempted from the mandatory procedure described in [ADS 201] including (1) emergency disaster assistance..." ADS 201.3.4.5 also provides that, in special foreign policy situations where it is necessary to initiate activities prior to completion and approval of a strategic plan, a temporary one-year exemption may be issued. Taken together, the provisions of ADS 201.3.4.5 provide an exception for the emergency activities contemplated within the scope of this memorandum, and, if approved, a one-year exemption for these activities. As required by ADS 201.3.4.5, PPC and GC have cleared on the proposed one-year exemption.


During this initial period, the AI Unit will take the steps to initiate development or modifications of strategic plans, where necessary, for Agency approval.

RECOMMENDATION

That you waive, as set forth above, the ADS policy planning requirement that obligations always be covered by an existing approved strategic objective.

Approve: 

Disapprove: _____

Date: 3 May 2006


B. Authorization for Other than Fully Competitive Procedures for both Grants and Cooperative Agreements. For grants and cooperative agreements to non-governmental organizations or other eligible organizations, the competition requirements are considered to be met when an announcement is published and recommendation for award is made after an impartial review and evaluation of all applications. In accordance with USAID's need to expedite programs that address the emerging crisis, it is imperative that USAID be able to respond immediately to changing events and select its implementing partners or respond to unsolicited proposals and begin operation in the shortest time possible during this unpredictable and constantly evolving situation. It will not always be possible to compete grant applications in the manner required under ADS Chapter 303. To facilitate quick implementation of programs to be delivered by assistance agreements, we recommend the following:

- (1) Authorizing non-competitive amendments to existing grants and cooperative agreements for additional work similar to that performed under the initial agreement. These extensions would be limited to a two-year period in order to provide the time to obtain subsequent support on a more competitive basis and would count against the ten-year overall limit for non-competitive extensions (ADS 303.5.5d); and,
- (2) Authorizing awards of new grants and cooperative agreements using other than maximum competitive procedures. While formal advertising would not be required, applications would be solicited from as many sources as practicable under the circumstances. While our preference will be to solicit from a number of sources, there may be circumstances in which sole source awards are necessary.

Pursuant to ADS 303.5.5d(5), competition is not required for assistance awards when justified by circumstances which are determined to be critical to the objectives of the foreign assistance program. The crisis caused by the emerging AI pandemic threat calls for immediate action, and USAID's programs to enhance preparedness, communication, surveillance, and response are critical to U.S. foreign policy objectives and must be expedited if it is to be successful. If slowed by the standard competitive process, an opportunity to move quickly on vital preventative and preparatory measures would be squandered, placing worldwide public health at risk. We recommend that, by approving below, you make the

“critical objectives” finding described above and authorize the use of other than fully competitive procedures in making awards under assistance agreements.

RECOMMENDATION

That you authorize other than fully competitive procedures as set forth above for both grants and cooperative agreements.

Approve: 

Disapprove: _____

Date: 3 May 2006

C. Authorization for Other than Full and Open Competition for Contracts.

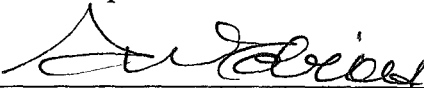
We recommend that flexible and expedited procurement procedures be approved for USAID direct contracting for the delivery of goods and services for related AI Pandemic Emergency Preparedness, and Response activities in affected regions. Specifically, we recommend that such procurement be undertaken through limited competitive procedures that are quicker as well as less labor intensive than the Federal Acquisition Regulation (FAR) full and open competitive procedures. As in (B) above, this would apply to all follow-on extensions of existing contractual efforts (again, with the two-year limit as described in (B) above) as well as to new procurements.

Under the USAID Acquisition Regulation (AIDAR), you may determine in writing, with supporting findings, that compliance with full and open competitive procedures would impair foreign assistance objectives and be inconsistent with the fulfillment of the foreign assistance program. Pursuant to AIDAR 706.302-70(b)(3)(ii), you have the authority to make such a determination with respect to the entire program, such as the programs and activities which will be developed, coordinated, or implemented by the GH Bureau and other Agency elements through the AI Task Force, as further defined by the formal written determination attached at TAB A (the Determination). In essence, the programs and activities would be those undertaken in direct response to the AI Pandemic Emergency Preparedness and Response effort. The expedited procedures would be utilized for quick reaction activities where the impact of U.S. assistance will be needed quickly.

The Agency Competition Advocate has reviewed the Determination. While formal advertising would not be necessary, solicitation would be made from as many sources as practicable under the circumstances. While our preference would be to solicit from a number of sources, there may be circumstances in which sole source awards are necessary. In those circumstances, your approval of less than full and open competition below, including the supporting findings at TAB A and the required Contracting Officer documentation as detailed in the last paragraph of Tab A, would constitute a written justification as required by FAR 6.303, AIDAR 706.302-70(c)(2), and ADS 302.5.8.

RECOMMENDATION

That you authorize other than full and open competition for contracts as set forth above.

Approve: 

Disapprove: _____

Date: 3 May 2006

Tab A, which you also sign, provides the mandated "Determination and Finding," as well as further guidance to this effect for contracting actions

D. Approval of a Source, Origin, and Nationality Waiver for Goods and Services. USAID source, origin, and nationality regulations generally require that goods and services be procured from Geographic Code 000 (United States). See ADS 310.5.1a. We recommend that Geographic Code 935 (which includes all countries except foreign policy restricted countries) be established as the applicable authorized source, origin, and nationality code for any goods and services procured in support of the USAID relief and containment efforts with respect to the AI emergency.

Services of local and regional contractors can be used in obtaining access to readily available equipment and materials in nearby countries, enabling implementation to get underway quickly. In addition, the ability to procure from Geographic Code 935 sources can enable USAID to "domesticate" certain aspects of the AI containment efforts (preparedness, surveillance, response, communication, and stockpiling). By using local suppliers, contractors, and subcontractors, we can ensure that the maximum benefits of our efforts will go to people of the affected countries. Absent this source, origin, and nationality waiver,

USAID would experience significant barriers in providing services in a timely manner and would have to expend significant time and resources to address individual source, origin, and nationality issues as they arise in multiple countries and for multiple agreements.

Motor vehicles are included in the waiver, and your approval below constitutes the “special circumstances” finding required by Section 636(i) of the Foreign Assistance Act of 1961, as amended (FAA), for vehicles procured in direct support of the Avian and Pandemic Influenza Management and Response efforts. Procurement of motor vehicles from non-U.S. sources may be carried out under these circumstances when necessitated by required specifications, a lack of spare parts, reliable, secure, and adequate service facilities, and/or an overall lack of availability of U.S.-manufactured vehicles, provided that the circumstances necessitating each such procurement are contemporaneously documented.

Pharmaceuticals are also included in this waiver. The purchase of pharmaceuticals under this waiver will comply with § 604(1) of the FAA, ADS 312.5.3c(2), and 22 CFR Part 228. These requirements are contained in TAB B.

22 C.F.R. § 228.51(a)(3) provides that a source, origin, and nationality waiver for goods or services may be authorized when it “is necessary to promote efficiency in the use of foreign assistance resources, including to avoid impairment of foreign assistance objectives.” The regulation, as well as the underlying statute, FAA § 604(1), provides that such waivers must be made on a case-by-case basis, and GC confirms that this proposed waiver for the AI emergency meets this standard.

We recommend that you make the above finding and authorize the waiver of source, origin, and nationality requirements for goods and services purchased in support of the USAID AI program under each of the circumstances set out in ADS 310.5.1a to permit procurement from Geographic Code 935 as the applicable source, origin, and nationality code.

RECOMMENDATION

That you approve a source, origin, and nationality waiver for goods and services as set forth above.

Approve: 

Disapprove: _____

Date: 3 May 2006

Attachments:

Tab A – Determination and Finding

Tab B – Pharmaceutical and Biological Source, Origin, and Nationality Waiver

CLEARANCE PAGE FOR ACTION MEMORANDUM entitled
 "Expedited Acquisition and Assistance Procedures for Activities and
 Programs Related to USAID's Avian Influenza Pandemic Emergency
 Preparedness and Response Efforts"

Clearances:

ES, Douglas J. Aller	<u>[Signature]</u>	Date	<u>5/2</u>
DAA/PPC, Walter E. North	<u>[Signature]</u>	Date	<u>4/5/06</u>
M/OAA/OD, Michael Walsh	<u>[Signature]</u>	Date	<u>3/23/06</u> note body comment
GC/A&A, Jeffrey Marburg-Goodman	<u>[Signature]</u>	Date	<u>3/27-06</u>
LPA/AA, J. Edward Fox	<u>[Signature]</u>	Date	<u>4/5/06</u>
M/OAA/TC, RCameron	<u>[Signature]</u>	Date	<u>3/23/06</u>
GH/HIDN, DCarroll	<u>[Signature]</u>	Date	<u>3.30.06</u>
GH/HIDN, RGreene	<u>[Signature]</u>	Date	<u>4/10/06</u>
SDAA/GH, GSteele	<u>[Signature]</u>	Date	<u>4/20/06</u>
DAA/GG, Miller	<u>[Signature]</u>	Date	<u>4/21/06</u>
GH/HIDN, JIce	<u>[Signature]</u>	Date	<u>4-16-06</u>
GH/HIDN, EFox	<u>[Signature]</u>	Date	<u>4/16/06</u>
GH/SPBO, LWhite	<u>[Signature]</u>	Date	<u>4/27/06</u>

GH:MFotheringham: 2027120537:03/22/06

J:AI Unit.AAPD_AI. Procurements & Waivers . AAPD_AI_3/23/06_draft/dpc

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2006 APR 31 A 7:48
 EXECUTIVE SECRETARIAT
 USAID

DETERMINATION AND FINDING

*The U.S. Agency for International Development (USAID) Administrator's
Determination Regarding Expedited Procurement Procedures
for Programs and Activities Related to
Avian and Pandemic Influenza Management and Response Efforts*

Pursuant to the authority set forth in the AIDAR § 706.302-70(b)(3)(ii), I have determined that it is necessary to use other than full and open competition for programs and activities related to preparedness and relief of the emerging Avian and Pandemic Influenza threat in order to avoid impairment of foreign assistance and U.S. foreign policy objectives. This determination is made in consideration of the supporting findings set forth below, and will be effective from the date of this signature, subject to annual review, and will remain in force for the period of the programs and activities carried out by USAID with respect to Avian and Pandemic Influenza Management and Response efforts.

Supporting Findings

It is imperative that USAID rapidly mobilize contractors and recipients for preparation of and potential relief from the AI pandemic threat. In particular, quick action is necessary to put into place programs and activities designed to monitor the spread of AI, immediately identify and appropriately treat human infections, and prepare for the initial outbreaks that could lead to the emergence of a pandemic—all designed to ultimately save lives and limit the potential scope this event will have on global economic and social infrastructure. Maintenance of civil order, gaining public confidence in central governing authorities, and the promotion of U.S. foreign policy interests require that the flow of assistance take place immediately, without resort to the standard competitive procedures of USAID. The timeframe required by fully competitive contracting procedures, if followed, will not enable USAID to act in a manner consonant with U.S. foreign policy in the affected regions. The magnitude of this potential public health crisis and the urgency of the need for immediate assistance both call for expedited procurement procedures.

USAID, by seeking offers from as many sources as is practicable under the circumstances, should be able to achieve beneficial, healthy competition while

ensuring that assistance is delivered as rapidly as possible. Prior to using informal or expedited procedures for a particular procurement, as authorized by this determination, implementing offices will consider the feasibility of using full and open competitive procedures as described in the Federal Acquisition Regulation as well as small business Section 8(a) procurement authorities and minority serving institutions.

All uses of this authority will be documented by the pertinent contracting activity and the cognizant contracting officer (the CO). Despite the existence of this blanket waiver, the CO will still need to include in the award file a written, albeit streamlined justification for other than full and open competition (JOFOC) which includes a brief discussion of the supplies or services required to meet USAID's needs, a description of efforts made to ensure solicitation from as many sources as possible under the circumstances (if under limited competition versus sole sourcing), a determination that the anticipated cost to the Government is fair and reasonable, a description of any market research conducted (if applicable), and a statement of the actions taken to overcome barriers to competition before subsequent acquisitions of the supplies or services required as a part of his/her determination to award a contract under other than full and open competition. The Agency Competition Advocate was consulted on this action. M/OAA and GC/A&A will provide additional guidance on the use of this waiver when awarding based on other than full and open competition. USAID will review this waiver on an annual basis to determine the adequacy of this waiver authority, its continued necessity, if any, or any need for modification.

Approve: 

Disapprove: _____

Date: 3 May 2006

Pharmaceutical and Biological Source, Origin, and Nationality Waiver

ESSENTIAL FACTORS

This source, origin, and nationality waiver is necessary to clarify the circumstances under which the procurement of essential drugs that have not been approved by the FDA for treatment of both animals and humans exposed to and/or infected by the H5N1 avian influenza (AI) virus and secondary infections will be permissible. The mobilization of the pharmaceuticals listed in Attachment 1 of this Tab B is essential to meet the current animal pandemic and to contain and limit the extent of human infections as well as to preclude or prevent a human H5N1 influenza pandemic.

The World Health Organization (WHO) is the lead global agency establishing the international treatment standards for human exposure to and infection of the H5N1 virus. As such, WHO has identified several categories of essential drugs needed to appropriately and effectively treat human infections, including antibiotic, antiviral, and anti-inflammatory medications as well as human vaccines. The animal health international counterparts to WHO, the Food and Agriculture Organization (FAO), and the World Organization for Animal Health (OIE) are operating as the lead global agencies on international treatment standards for animal H5N1 exposure and infection. USAID, in partnership with WHO, FAO, OIE, and the international community will follow the internationally established treatment protocols to guide its programmatic approach of treating AI exposure and infections among both animals and humans. These treatment protocols are expected to be revised and updated as the H5N1 virus evolves and changes over time and as new treatment methods are tested and approved in response to those changes. USAID will adopt these revisions and updates, as they are announced and endorsed by the WHO, FAO, and OIE.

The pharmaceutical and biological commodities recommended for treatment of H5N1 may be purchased with USAID funding to: 1) contribute to the international stockpile for emergency intervention in the case of isolated outbreaks through USAID/W, and 2) contribute to national stockpiles through individual USAID missions. These stockpiles are essential to build and maintain capacity for immediate H5N1 outbreak responses. As such, USAID's global AI program includes establishing a stockpile of AI-related pharmaceuticals and biological products intended to respond to outbreaks and contribute to containment strategies.

A. Waiver Process for Procurement of Other Non-U.S. Manufactured AI-Related Pharmaceuticals

The applicable statute and regulations covering USAID's source and origin requirements and pharmaceutical requirements appear in Section 604(a) of the Foreign Assistance Act of 1961, ADS 312.5.3c(2), and 22 CFR Part 228. Exceptions to the general rule that USAID-financed pharmaceuticals must be of U.S. source and origin will be considered if:

1. It is necessary to promote efficiency in the use of U.S. foreign assistance resources, including to avoid impairment of foreign assistance objectives (Subpart F of 22 CFR Part 228);
2. The pharmaceutical product is essential to the activity (ADS E312.5.3c);
3. The product, in the same or substantially equivalent form, is not available from the United States, or the delivered price from the United States would be at least 50 percent more than from another source (ADS E312.5.3c);
4. Information is available to attest to the safety, efficacy, and quality of the product or the product meets the standards of the FDA or other U.S. controlling authority(ADS E312.5.3c); and,
5. U.S. patent laws must be honored (ADS section E312.5.3c).

1. Necessary to avoid impairment of foreign assistance objectives

This waiver is necessary to promote efficiency in the use of U.S. foreign assistance resources; it will allow for the purchase of safe and high quality pharmaceutical and biological products of non-U.S. source and origin that are critical to successfully immunize and treat both animal exposure and human H5N1 infections and related secondary infections. This waiver and its list of approved pharmaceutical and biological products will expand the Agency's ability to rapidly respond to AI outbreaks while protecting our interests and ensuring compliance with applicable laws and regulations.

Animal Exposure and Infection. As of January 2006, over 200 million birds have been culled in an attempt to contain the virus and to limit animal and human exposure. Immediate culling of infected and exposed birds and vaccination of healthy animals is an effective way to limit the impact of the H5N1 virus on the remaining global population of domestic birds as well as limit human exposure to this dangerous virus. Therefore, large and continuous supplies of animal vaccine will be required.

Human Exposure and Infection. The potential demand for medication needed to treat human infection is staggering; hundreds of millions of people worldwide may become sick during the course of a pandemic, placing an unprecedented strain on the global supply of drugs essential for treatment. To prevent and/or delay as long as possible this potential outbreak, USAID, in accordance with international standards, is following a containment strategy designed to limit human exposure to H5N1 by quarantining and treating infected and exposed humans. For the containment strategy to work, delivery of medical treatment to suspected outbreak sites must be immediate. Access to immediate high quality, low-cost medication and vaccines approved under WHO's treatment protocols as discussed in this waiver will be a key determinant in successfully containing the H5N1 virus and limiting its impact.

Without access to the key, quality pharmaceuticals identified in this waiver, USAID will not be able to effectively contribute to the global effort to contain H5N1 outbreaks and forestall the potential pandemic.

2. The designated AI pharmaceutical and biological products are essential for the activity

For the reasons discussed above, the AI-related medications for both animal and human use itemized in Attachment 1 are essential for this proposed activity. By providing pharmaceutical and biological products (vaccines) in response to outbreaks of H5N1 among both animals and humans, the Agency is following international treatment standards established under the leadership of the WHO, FAO, and OIE. Without these treatment measures, containment of the H5N1 virus will not be successful.

3. Availability and cost of essential products in the U.S.

In response to outbreaks of H5N1 infections among both animals and humans, the Agency and implementing partners will be directed to, whenever possible, first purchase FDA-approved, U.S. manufactured pharmaceutical and biological products. However, it is anticipated that occasions will arise when: a) the U.S. market price of certain drugs may be prohibitively expensive and exceed international prices by 50 percent or more, b) essential drugs and biological products are simply not manufactured in the U.S., c) supply of U.S. manufactured drugs may be limited or reserved for domestic use only and unavailable for international use, and/or d) U.S. manufactures' production capacities for specific medication may be over extended, and the drugs cannot be procured in a timely manner.

Shortages for specific medications are expected to arise, as demand quickly outstrips supply. It is also anticipated that the cost for required drugs from UNICEF and the International Dispensary Association (IDA) will often be listed as less than 50 percent of prices available through the U.S. Federal Supply System (FSS). The average wholesale prices available in the U.S. are listed in the 2004 edition of the Red Book and are significantly above FSS listed prices. Given the price differentials, it is anticipated that there will be significant interest in procuring medications through UNICEF and IDA in order to maximize USAID operating units' impact on U.S. foreign assistance goals.

4. Safety, efficacy, and quality of animal and human pharmaceutical and biological products

For the pharmaceutical and biological products listed in Attachment 1, information is available to attest to the safety, efficacy, and quality of the product, or the product meets the standards of the FDA. Moreover, if the FDA-approved product is made at a plant outside of the United States, the plant has been inspected and certified and regulated by the FDA or another stringent regulatory authority. USAID has identified two organizations that have the capacity and expertise to act as responsible procurement agents for all medication purchased under this waiver: the International Dispensary Association (IDA) and UNICEF.

International Dispensary Association: IDA is a non-profit provider of pharmaceuticals and medical supplies located in Amsterdam, The Netherlands. IDA is a preferred supplier to WHO, International Committee of the Red Cross, Doctors without Borders, UNHCR, and has previously supplied pharmaceuticals to USAID funded projects. USAID personnel have visited

and inspected IDA to ensure that a quality assurance system has been established and is functioning. Items provided by IDA must pass an internal quality program before an item is offered to a customer for purchase. Products must be manufactured to the specifications of the British Pharmacopoeia, the United States Pharmacopoeia, or the European Pharmacopoeia. Manufacturer provided stability data and shelf life information is verified. The source of all products is the original innovator pharmaceutical manufacturer or holder of the international patent for the product. IDA also practices quality control of individual product batches. Each incoming batch of drugs is inspected for label, appearance, and shelf life.

Non-European Union drugs are sampled by the IDA laboratory. Retention samples are maintained to facilitate investigation of possible complaints until one year passed the end of useable shelf life. Certificates of analysis are retained for future reference and client copy requests. At random chemical analysis and long-term stability tests for tropical conditions are also performed.

Certificates of Pharmaceutical Product, Certificates of Free Sale, or Good Manufacturing Practice certification are requested from each manufacturer for each product. Certificates of Analysis are requested to be provided with each delivery of product. The label for each product is to include package size, dosage form, generic name, (e.g. the International Nonproprietary Name), strength, storage conditions, and pharmacopoeial quality if applicable. Labels for finished product are required to contain batch number, manufacturing date, and expiration date.

UNICEF: UNICEF requires all manufacturers responding to its solicitations to be pre-approved by the WHO and annually demonstrate that they comply with the standards set by the WHO. WHO Geneva Headquarters acts as an adviser to UNICEF on matters related to the quality of pharmaceutical and biological products and has formulated criteria for evaluating the acceptability of vaccines for purchase by UN agencies. All quality assurance functions are provided to UNICEF by WHO. These include random lot testing, inspection of the supplier's facility and the National Control Authority Laboratory by qualified experts, periodic re-inspection, and follow-up investigation of adverse events reported. Governments that lack a functioning National Regulatory Authority to ensure pharmaceutical quality are encouraged by WHO to procure through UNICEF in order to ensure the provision of pharmaceuticals of known quality. Procuring through UNICEF is the most effective means to ensure that medications of known quality are procured.

USG representatives in-country will be required to ensure that the implementing organizations in control of all AI pharmaceutical and biological products purchased understand the importance of protecting all products during storage, handling, and distribution, from arrival in country to the point-of-use, from deterioration, damage and loss, and the products correspond to the nationally-approved standard treatment guidelines in the country in which they will be used.

5. U.S. Patent Laws

The animal and human pharmaceuticals listed in Attachment 1 do not infringe U.S. patent laws.

B. Decision Protocol

All of the AI pharmaceuticals *on the WHO Approved List of Essential Medicines for Influenza Infections (Attachment 1)* that are procured will be either of U.S. source, origin and nationality or from Geographic Code 935 countries. The decision protocol below will be used to determine the specific manufacturer/supplier/vendor for each brand. Pharmaceuticals *not* on the approved list must be added to the list prior to procurement (see F. Updating the WHO/FAO Approved List of Essential Medicines for Influenza Infections), be U.S.-produced and FDA-approved drugs, or have had an individual source, origin, and nationality waiver approved in accordance with ADS 312.5.3c, if they are non-U.S.-produced, non-FDA-approved.

1. If the product is manufactured in the U.S. only, the product will be procured from Geographic Code 000 sources.
2. If the product is manufactured in the United States only, but is distributed through an off-shore regional distributor, the product will be procured from Code 000 and Code 935 sources.
3. If the product is manufactured in the United States and another country, the product will be procured from the manufacturer/supplier/vendor that (1) meets the registration requirements of the recipient country, (2) has information from an internationally recognized regulatory authority on file to document the safety, efficacy, and quality of the products; and (3) ensures that the products do not infringe existing U.S. patent laws.
4. If the product is manufactured in the United States and another country, and the cost of the product in the United States is at least 50 percent more expensive than the price available from another country, the product will be procured from Code 935.
5. If the product is not manufactured in the United States, the product will be procured from the lowest cost, most programmatically appropriate supplier with Code 935 source and origin that (1) meets the registration requirements of the recipient country, (2) has information from a internationally recognized regulatory authority on file to document the safety, efficacy, and quality of the products, and (3) ensures that the products do not infringe existing U.S. patent laws.

This protocol gives priority to the purchase of AI-related pharmaceutical and biological commodities of U.S. source and origin whenever possible, but permits purchase of essential pharmaceuticals offshore, if necessary, in order to avoid inefficient use of foreign aid resources and impairment of foreign assistance objectives.

C. Human Vaccine

A human vaccine for a pandemic strain of the H5N1 virus is under development. Therefore, at this time, this waiver does not cover the purchase of human H5N1 influenza vaccine(s). When a vaccine has been created and deemed efficacious, appropriate, and necessary, a waiver will be requested by the AI Unit to address this specific issue.

Purchase of annual human seasonal influenza vaccine is included in this waiver. All purchases must comply with the conditions outlined in this waiver and be used in accordance with CDC and WHO recommendations on protecting health of those humans exposed to the H5N1 virus. A specific list of seasonal influenza vaccines will not be provided and prior approval from USAID/W will not be required so long as the annual seasonal human influenza vaccines purchased and used meet current CDC and WHO protocols at the time of purchase and use.

D. Antivirals

At the time of writing, use of Agency funds to purchase antivirals (including Tamiflu, the brand name, FDA-approved antiviral medication produced by Roche), is prohibited per General Notice, "Interim Budgetary Guidance for Reprogramming of Funds for Urgent Avian Influenza Related Activities," dated November 3, 2005. If this policy changes after the enactment of the subject waiver, all purchases of antivirals (including off shore produced Tamiflu) must comply with the conditions outlined in this waiver.

E. Animal Vaccines

FAO and OIE have made recommendations for the use of OIE-approved HPAI vaccines (see Attachment 1). If used in accordance with FAO/OIE recommendations, the vaccine provides excellent protection against clinical disease in poultry by reducing mortality and production losses. Missions interested in pursuing vaccination as part of a broader containment strategy and outbreak response are strongly encouraged to consult and receive vaccine implementation recommendations from FAO, OIE, and the national government.

F. Updating the WHO/FAO Approved List of Essential Medicines for Influenza Infections

As the H5N1 virus continues to evolve, the appropriate treatment protocols and the WHO-recommended essential medication for this infection are expected to become more refined and disease specific. Attachment 1 lists the current WHO-approved pharmaceuticals for human treatment and the FAO-approved vaccines for animal treatment of the influenza virus. As the international guidelines on H5N1 treatment are refined and updated, the list of pharmaceuticals approved under this waiver will also be updated in accordance with the following steps:

1. The AI Unit will be monitoring the status of the WHO-approved treatment guidelines and will determine when an update to Attachment 1, *WHO Approved List of Essential Medicines for Influenza Infections*, is required.
2. All updates will be requested by the AI Unit and submitted to the AA/GH for approval. All field requests for changes to Attachment 1 must be submitted to the AI Unit for consideration.
3. After a new medication is approved, Attachment 1 will be revised and the new medications will be added to it and posted on the AI web site

(<http://ghintranet.usaid.gov/AIUnit/index.aspx>).

4. For specific questions on the latest treatment protocols listed under this waiver or requests for updates to the approved list of medication, please contact Megan Fotheringham, mfotheringham@usaid.gov, ph. 202-712-0537.

WHO Approved list of Essential Medicines for Influenza Infections¹

For treatment of symptoms (fever, cough, muscle ache, headache, sore throat, etc.)

Analgesics and antipyretics:

Analgesics and antipyretics:

Acetylsalicylic acid (aspirin)	tablet, 100-500 mg; suppository, 50-150 mg *not recommended for children under 16
Ibuprofen	tablet, 200 mg, 400 mg
Paracetamol (antipyretic)	tablet, 100-500 mg; suppository, 100 mg; syrup, 125 mg/5ml * not recommended for anti-inflammatory use due to lack of proven benefit to that effect

Antivirals:

**prohibited purchase under the current USAID policy, per General Notice, "Interim Budgetary Guidance for Reprogramming of Funds for Urgent Avian Influenza Related Activities", dated November 3, 2005.

For treatment of flu complications (pneumonia and other infections):

Antibacterials	
<i>Beta Lactam medicines</i>	
amoxicillin	capsule or tablet, 250 mg, 500 mg (anhydrous); powder for oral suspension, 125 mg (anhydrous)/5 ml
amoxicillin + clavulanic acid	tablet, 500 mg + 125 mg
ampicillin	powder for injection, 500 mg, 1 g (as sodium salt) in vial
benzathine benzylpenicillin	powder for injection, 1.44 g benzylpenicillin (=2.4 million IU) in 5-ml vial
benzylpenicillin	powder for injection, 600 mg (= 1 million IU), 3 g (= 5 million IU) (sodium or potassium salt) in vial
Cefixime*	capsule 400mg * only listed for single dose treatment of uncomplicated ano-genital gonorrhoea
Cloxacillin	capsule, 500 mg, 1 g (as sodium salt); powder for oral solution, 125 mg (as sodium salt)/5 ml; powder for injection, 500 mg (as sodium salt) in vial
phenoxymethylpenicillin	tablet, 250 mg (as potassium salt); powder for oral suspension, 250 mg (as potassium salt)/5 ml

¹ WHO, *Model List of Essential Medicines, 14th Edition*, Revised March 2005. Web access at: <http://www.who.int/medicines/publications/essentialmedicines/en/index.html> last accessed on January 25, 2006.

Procaine benzylpenicillin		powder for injection, 1 g (=1 million IU), 3 g (=3 million IU) in vial
<i>Complementary List</i>		
ceftazidime		powder for injection, 250 mg (as pentahydrate) in vial
ceftriaxone		powder for injection, 250 mg, 1 g (as sodium salt) in vial
imipenem* cilastatin*	+	powder for injection 250 mg (as monohydrate) + 250 mg (as sodium salt), 500 mg (as monohydrate) + 500 mg (as sodium salt) in vial * only listed for the treatment of life-threatening hospital-based infection due to suspected or proven multidrug resistant infection
<i>Other antibacterials</i>		
azithromycin*		capsule, 250 mg or 500 mg; suspension 200 mg/5 ml * only listed for single dose treatment of genital <i>C. trachomatis</i> and of trachoma
chloramphenicol		capsule, 250 mg; oral suspension, 150 mg (as palmitate)/5 ml; powder for injection, 1 g (sodium succinate) in vial; oily suspension for injection 0.5 g (as sodium succinate)/ml in 2-ml ampoule
ciprofloxacin*		tablet 250 mg (as hydrochloride) * final selection depends on indication for use
doxycycline*		capsule or tablet, 100 mg (hydrochloride) * final selection depends on indication for use
erythromycin		capsule or tablet, 250 mg (as stearate or ethyl succinate); powder for oral suspension, 125 mg (as stearate or ethyl succinate); powder for injection, 500 mg (as lactobionate) in vial
Gentamicin*		injection, 10 mg, 40 mg (as sulfate)/ml in 2-ml vial * final selection depends on indication for use
metronidazole		tablet, 200-500 mg; injection, 500 mg in 100-ml vial; suppository, 500 mg, 1 g; oral suspension, 200 mg (as benzoate)/5 ml
nitrofurantoin		tablet, 100 mg
spectinomycin		powder for injection, 2 g (as hydrochloride) in vial
sulfamethoxazole trimethoprim	+	tablet, 100 mg + 20 mg, 400 mg + 80 mg; oral suspension, 200 mg + 40 mg/5 ml; injection, 80 mg + 16 mg/ml in 5-ml and 10-ml ampoules
trimethoprim		tablet, 100 mg, 200 mg
<i>Complementary List</i>		
clindamycin		capsule, 150 mg; injection, 150 mg (as phosphate)/ml
sulfadiazine		tablet, 500 mg; injection, 250 mg (sodium salt) in 4-ml ampoule
vancomycin		powder for injection, 250 mg (as hydrochloride) in vial

FAO/OIE Approved List of Essential Medicines for Animal H5N1 Infections

For Prevention of H5N1 Infection:

Vaccine:

Strain: H5	For a specific, updated list of OIE approved avian influenza vaccine manufacturers: see: http://www.oie.int/eng/avian_influenza/AI_kits.pdf
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