INTERNATIONAL PLANNED PARENTHOOD FEDERATION

17-18 November 2020

BOT/11.20//3.5-be
Refers to agenda item 3.5-be

Agenda Item 3.5-be

Summary
Policy 3.4 has been updated to include the current guiding principles to allow procurement and supply of medical health commodities against international quality standards. To limit the risk of damages and/or loss of valuable commodities during the whole of the supply chain, insurance requirements have been determined. Finally, due diligence vetting of suppliers of health commodities has been updated against current standards and tools available. Policy 3.4 has been rewritten entirely, which is why 2 versions are provided: 1 version with all track changes, and 1 clean version for easy reference.
Next plans and timelines
Updated Policy 3.4 is submitted to the Board of Trustees for approval at its 17-18 November meeting, to allow for fair and transparent procurement of medical health commodities on behalf of IPPF MA's, against up-to-date international quality standards and properly insured along the whole of the supply chain.
Action Required
The Board of Trustees is asked **to approve** the updated Policy.

~~**Policy 3.4**~~

Policy 3.4

PURCHASE OF MEDICAL HEALTH PRODUCTS, INCLUDING CONTRACEPTIVES, CONDOMS, ~~AND~~ REPRODUCTIVE HEALTH MEDICINES, DEVICES AND DIAGNOSTICS

Introduction:

1. IPPF's purchasing policy and operational guidelines reflect the need to ensure that contraceptives and other ~~reproductive health supplies~~medical health products[1] meet ~~acceptable~~ adequate levels of quality and that adequate insurance arrangements are in place to protect against the risk of poor product supply.

2. This policy outlines the conditions to ensure that medical health products procured and supplied meet international quality standards~~Over the past decade unprecedented changes have taken place in the hormonal contraceptive manufacturing and supply environment and more generally with reproductive health commodities. As the patents for the formulations for contraceptives have lapsed, many of the pharmaceutical companies that have provided products in the past have ceased to manufacture as they have faced competition from manufacturers in lower cost environments. Whilst the emergence of these lower priced generic alternatives has been welcomed, many of the generic manufacturers have struggled to gain the required international quality assurances that had been provided by the traditional pharmaceutical companies.~~, that order placement can only take place at duly vetted suppliers and that products are properly insured during all steps of the supply chain process.

Product Quality:

3. All Medical health Products that IPPF procures must be authorized by the relevant authority in the country of use, following its standard practices for registration (or other forms of authorization, such as import exemptions and/or authorizations for special use).

4. Quality standards - Finished Pharmaceutical Products:

All Finished Pharmaceutical Products, including IPPF's core products such as contraceptives and other reproductive health medicines, must meet 1 or more of the following standards:

a) Prequalified by the WHO/UNFPA Prequalification Programme.

b) Authorized for use by a Stringent Regulatory Authority (in future to be replaced by WLA ML4), which is a regulatory authority that is:
   - A member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry

[1] Within this policy, the use of term "product" includes to the extent applicable, drugs, devices and diagnostics

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of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or

- An ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swiss Medic and Health Canada; or
- A regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.
- Reviewed and permitted for use by the Expert Review Panel (ERP), for a time limited period not exceeding 12 months, until the product is WHO prequalified, or SRA approved.

c) Procured from internationally approved wholesalers that are audited and approved by United States Agency for International Development (https://2012-2017.usaid.gov/sites/default/files/documents/1866/USAID-OFDA_Pharm_Annex_GP_requaled_Suppliers.pdf)
   - o Action Medeor, Germany www.medeor.de/en/
   - o AmstelFarma, Netherlands www.amstelfarma.nl
   - o ASRAMES, Democratic Republic of Congo www.asrames.com/en/
   - o CHMP Kenya, Kenya www.chmp-kenya.org
   - o IDA Foundation, Netherlands www.idafoundation.org
   - o IMRES, Netherlands https://www.imres.nl/en
   - o Medical Export Group (MEG), Netherlands www.meg.nl
   - o Mission for Essential Drugs and Supplies (MEDS), Kenya www.meds.or.ke
   - o MissionPharma, Denmark www.missionpharma.com
   - o UNICEF, Denmark www.unicef.org

d) Procured from Humanitarian Procurement Centre that are audited and reviewed by Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO - https://www.dgecho-partners-helpdesk.eu/_media/actions_implementation/procurement_in_humanitarian_aid/hpc_register_en.pdf)
   - o Begeca, Germany, www.begeca.de
   - o Farmamundi, Spain www.farmamundi.org
   - o International Federation of Red Cross and Red Crescent Societies, Switzerland http://procurement.ifrc.org
   - o Médecins sans Frontières Logistique/Supply, France/Belgium, http://www.msflogistique.org/, http://www.msfsupply.be/
   - o Oxfam GB, United Kingdom http://www.oxfam.org.uk/equipment
   - o WFP Humanitarian Response Depot, Italy www.unhrd.org
   - o United Nations Office for Project Services (UNOPS) https://www.unops.org/expertise/procurement

Contraceptives that are not finished pharmaceutical products, such as e.g. male condoms, female condoms and IUDs follow the same approval standards as listed above.

5. Quality standards – Medical Devices:

IPPF recognizes and subscribes to the definition and standards of medical devices as defined by the WHO working in conjunction with the International Medical Devices Regulatory Forum (IMDRF) formally the Global Harmonization Task Force (GHTF)[2].

IPPF requires that all medical devices procured and distributed meet the essential requirements as set out in the EEC Directive: Council Directive 93/42/EEC, 90/385/EEC and 98/79/EEC and preferably are certified with the CE Mark. If the product is not CE-marked, then IPPF will purchase products that are recognized by at least one of the following regulatory authorities or an equivalent entity:
   - o MPALS License (Australia)
   - o Device License (Canada)
   - o Device License (Japan)

[2] WHO guideline – Medical Devices Regulations, a global overview to guiding principles - http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf

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- 510 k Device Letter (USA); and

Priority shall be given to candidates that have been accredited by a recognised accreditation entity, thus providing proof of compliance with at least one of the following standards or equivalent:

- Japan QS Standard for medical devices 1128
- ISO 13485 on quality management system of an organization
- ISO 9002/1994 on quality assurance in production, installation and servicing

6. Quality standards – Diagnostic tests:

IPPF subscribes to the WHO pre-qualification scheme for diagnostics tests. Where possible IPPF will procure tests from the list of prequalified products listed on the WHO list of prequalified in-vitro diagnostic products.[3]

Where tests are required that are not on the WHO pre-qualification list including rapid in vitro diagnostic pregnancy test kits, IPPF will seek products that are CE Marked or have equivalent certification or licensing from authorities by at least one of the regulatory authorities or an equivalent entity:

- MPALS License (Australia)
- Device License (Canada)
- Device License (Japan)
- 510 k Device Letter (USA);

Additional guidance on rapid in vitro diagnostic pregnancy tests can be found in the most recent version of the Reproductive Health Supplies Coalition (RHSC)'s Quality and Performance Guidance for Selection of Pregnancy Tests for Procurement.[4]

Priority shall be given to candidates that have been accredited by a recognised accreditation entity, thus providing proof of compliance with at least one of the following standards or equivalent:

- Japan QS Standard for medical devices 1128
- ISO 13485 on quality management system of an organization
- ISO 9002/1994 on quality assurance in production, installation and servicing

Product Insurance:

~~3. Three international quality assurance systems currently exist:~~

~~a) WHO pre-qualification system; although few contraceptives have been approved, and almost no generics have been put through this lengthy and costly process.~~

[3] WHO list of prequalified in-vitro diagnostic products - http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

[4] RHSC Quality and Performance Guidance for Selection of Pregnancy Tests for Procurement - https://www.rhsupplies.org/uploads/tx_rhscpublications/Quality_and_Performance_Guidance_for_Selection_of_Pregnancy_Tests_for_Procurement_May_2017.pdf

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b) WHO/UNFPA Expert Review Panel (ERP[5]); WHO & UNFPA through this panel assess the quality standards of the requesting manufacturers and will make a decision towards recommending or not the procurement of their commodities but this is only granted for a maximum period of 12 months.

c) Stringent Drug Regulatory Authorities (SRA[6]); this includes WHO as well as the regulatory authorities in specific countries (such as the US Food and Drug Administration (FDA)) that are subject to high standards of regulatory oversight.

4.7. The second issue arising from the changing supply environment relates to ensuring that pProducts supplied by IPPF and its Member Associations are need to be covered by appropriate (product liability) insurance. Such liabilities can arise at any point in the supply chain and are broadly divided into the following three areas:

Area of Responsibility	**Liability**
Product manufacture and supply	Manufacturer's Liability
Product delivery to Member Association	Procurement Agent's[3] Liability
Product receipt storage and use with clients	Member Association's Liability

8. Neglect can happen anywhere in the distribution chain from the manufacturer to the end user. Even if the procurement agency isn't found to be directly responsible for the cause of claims, the absence of adequate processes and precautions initiated by the procurer to prevent the occurrence of such problems at the point of practice of other involved parties may give reason to a claim. As the final supplier of the product to the client, Member Associations will generally find themselves as being the first point of contact dealing with product quality issues.IPPF acts as the Procurement Agent on behalf of its Member Associations when procuring products on its behalf, and ensures to have insurance in place to cover for any damages that occur to the products as long as the products are in IPPF ownership during transport, in transit or in storage per the ICC INCO terms 2020.

5. Estimated values of insured voyages and the relevant terms and conditions are to be reviewed and contracted on an annual basis. For voyages to excluded territories, insurance will be agreed on a case by case basis.

9.

[5] *The WHO/UNFPA Expert Review Panel Process* is acceptable as an alternative, interim standard for those products/manufacturers currently undertaking WHO Pre-Qualification that have not yet completed the process.

[6] *Stringent Drug Regulatory Authority (SRA)* means a regulatory authority which is (a) a member of ICH (as specified on www.ich.org); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time)." In effect this currently means: the regulatory authorities of EU, USA, Japan, Switzerland, Canada, Australia, Norway, Iceland and Liechtenstein and WHO.

[3] 'Procurement Agent' refers to any internal or external service provider delivering products

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6. ~~Whilst all manufacturers~~IPPF will validate and keep record of ~~should~~ manufacturers havinge product liability insurance to cover manufacture and supply (i.e. quality and safety of the product)~~, the reality is that some manufacturers do not~~. Where ~~Some have far reaching product liability cover that protects them against manufacturing risk and product malfunction. Their procedures and processes for liability protection are highly elaborate and sophisticated to distance the company and the product from neglect in having made the product available.~~

10. ~~A number of producers have been found not to provide adequate product liability coverage to indemnify third parties, such as a procurement agency, from liability claims, or if~~ product liability coverage does not exist~~;~~ or where the amount of coverage is ~~normally~~ low, IPPF~~.~~ ~~This situation requires the~~ or its contracted external procurement agency ~~to~~ will confirm the necessity to establish its own product liability coverage to be protected against claims, justified or unjustified, and their related costs.

11. ~~-~~IPPF will notify any manufacturer immediately in case it receives any third-party claims and liability for damages, losses or costs resulting from or caused by the product, so that the manufacturer can take necessary steps for the protection of its interest. IPPF will provide manufacturers with reasonable evidence that such damages, losses or costs were caused by defective product.~~Benefiting from its own product liability coverage a procurement agency is then free to procure from generic manufacturers who do not have third party liability coverage in place and distribute these products into markets of its choice.~~

12. Where locally feasible, Member Associations supplying health products must ensure that adequate product liability insurance cover (manufacturer's / procurement agent's and Member Association's liabilities) is in place in order to indemnify against claims and their related costs, minimize risk and safeguard the reputation of the Federation.

~~7.~~

~~Policy~~ Supplier Due Diligence:

~~8. It is IPPF's Policy:~~

~~i. Only to offer hormonal contraceptives, condoms, IUDs and other reproductive health commodities whose formulation and specifications have been reviewed and recommended by WHO;~~

~~ii. To procure and supply only hormonal contraceptives, condoms, IUDs and other reproductive health commodities that are manufactured in accordance with current Good Manufacturing Practice (cGMP) quality assurance standards, from facilities which have obtained quality approval for these products from Stringent Regulatory Authorities, and/or have been assured under the appropriate WHO prequalification programme or the WHO/UNFPA Expert Review Panel Process. This is to ensure that all products procured and/or supplied by IPPF and its Member Associations are of verifiable quality regardless of the manufacturer/supplier or country of origin;~~

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~~iii. Products received by IPPF Member Associations as a donation from the national government will be registered and approved for use in that country by that government and may therefore be accepted. This would also apply to products made available at subsidized price by governments;~~

~~iv. Products received by the Secretariat and Member Associations as a donation from another third party must meet the minimum requirements stated above in (i) and (ii);~~

~~Where locally feasible, Member Associations supplying reproductive health products must ensure that adequate product liability insurance cover (manufacture's / procurement agent's and Member Association's liabilities) is in place in order to indemnify against claims and their related costs, minimize risk and safeguard the reputation of the Federation.~~

~~v. IPPF, third party distribution agents and Member Associations must have clear processes that will provide rapid response to drug recalls and other safety concerns and will provide information to those impacted by recalls deemed to have serious safety concerns, or market withdrawal of drugs for safety reasons.~~

~~9. **Prevention of Terrorist Financing**~~

~~9.~~ IPPF is wholly committed to not fund or receive funds from terrorist individuals or organisations and has introduced and embedded actions into ~~our~~ policy and practice to ensure that necessary ~~we are taking~~ steps are taken to prevent any engagement with terrorism. IPPF is also taking these steps to ensure that it is fully compliant with banking regulations and donor compliance requirements, to limit the risk of the occurrence of illegal financial transactions such as fraud and bribery. ~~as well as to prevent the occurrence of fraud and bribery.~~

13. ~~These actions include~~IPPF will follow a 2-step due diligence vetting of all suppliers it intends to engage with. No Purchase Order can be released until the due diligence process of a supplier has been successfully executed.

14. Prior to the release of any Purchase Order, IPPF will require the supplier to confirm it has in place documented policies or evidence of internal procedures to the following matters:

- Value for Money and Governance
- Ethical Behaviour
- Transparency and Delivery Chain Management
- Environmental Issues
- Terrorism and Security
- Safeguarding, Social Responsibility and Human Rights

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IPPF will also review and confirm the economic standing of its potential suppliers by requesting and analysing all financial updates and corporate accounts of the last 2 years and by confirming tax compliance per the applicable country's regulations.

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In step 2 of its due diligence vetting prior to order release, IPPF ~~A~~ commits ~~ment~~ to carry out searches for all IPPF ~~procurement~~ Purchase Orders (including existing and potential suppliers), new and existing IPPF Secretariat staff (under the pre-employment referencing process), partners/donors and Member Associations, against the ~~following~~ external databases consolidated in Accuity prior to order release.~~:~~

15.

- ~~System for Award Management (SAM) – US Government database~~
- ~~Specially Designated Nationals (SDN) – US Government database~~
- ~~UN Sanctions List~~
- ~~Any other relevant databases as per external donor or UK Government requirements.~~

~~These~~ Accuity's databases list individuals and organisations excluded from doing business with (both ~~–~~ national or international organisations), due to violations of regulations for involvement with terrorism, illegal financial transactions or any other criminal records.

~~ii. Identification in IPPF Procurement Principles and associated procedures of the risk of terrorist financing and the need to carry out appropriate due diligence to ensure this risk is mitigated.~~

~~iii. A Preventing Terrorism provision is included in 2016 unrestricted and restricted funding for all recipients and the risk of terrorist financing is to be included and monitored in the IPPF Risk Register.~~

Should any evidence of links with terrorist activity be found within our procurement, funding streams, staff or MAs, appropriate corrective action will be taken in compliance with local legislation. IPPF recognizes that, as per the international legal obligations of states, such legislation should comply with international law, in particular international human rights law. Please refer to the IPPF Fraud Policy Implementation section for further guidance on appropriate response protocol.

Policy Implementation:

To implement this policy:

16.~~10.~~ Member Associations supplying ~~reproductive~~ health ~~commodities~~ products must have in place documented policies, procedures and controls to ensure that all supplies meet the requirements of the procurement policy. These should cover both purchases made by the Member Association as well as donated items received from donors and third parties that are distributed by the Member Association.

17.~~11.~~ Member Associations should review and document on a regular basis their insurance coverage and recall policy and procedures to ensure that it meets with best practice in relation to product liability risks. Where ~~commodities~~ products are supplied through the Secretariat, Member Associations must ensure they have '*product receipt storage and use with clients*' cover in place. Where Member Associations obtain ~~commodities~~ products that have not been supplied through the Secretariat, they must ensure that liability insurance covers: '*product*

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manufacturer and supply', '*product delivery*' as well as '*product receipt, storage and use with clients*' where locally feasible.

18. ~~12.~~ Where donated products are supplied to the Federation for disbursement, the Secretariat will ensure that internal processes for accepting these donated items meet the requirements of this policy and are documented.

19. Products received by Member Associations as a donation from the national government will be registered and approved for use in that country by that government and may therefore be accepted. This would also apply to products made available at subsidized price by governments. Products received by the Secretariat and Member Associations as a donation from another third party must meet the requirements stated above in Product Quality, Product Insurance and Supplier Due Diligence.

20. ~~13.~~ The Secretariat will provide commodity procurement advice and guidance on matters in relation to the procurement policy to Member Associations in order that they can purchase ~~commodities~~ products that meet recognized quality standards but at the same time benefit from the reduced costs as a result of the generics market-place.

21. ~~14. Central Office~~ IPPF, third party distribution agents and Member Associations must have clear processes that will provide rapid response to drug recalls and other safety concerns and will provide information to those impacted by recalls deemed to have serious safety concerns, or market withdrawal of drugs for safety reasons. ~~Third parties when acting as a procurement agent will maintain product liability insurance cover or other alternate industry recognized and accepted measures to allow it to procure products from generic manufacturers who do not have third party liability insurance in place in order to allow it to distribute such products.~~

22. ~~15.~~ IPPF Secretariat will use all available mechanisms in the Federation to periodically and consistently monitor implementation and review the policy statement. The implementation of this statement should be adequately resourced and supported by the Secretariat.

As adopted by Governing Council, November 2007

~~*Last amended*~~*~~As proposed for approval by Governing Council~~Board of Trustees, ~~May~~ November ~~2016~~2020*

As proposed for approval by Board of Trustees, November 2020

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