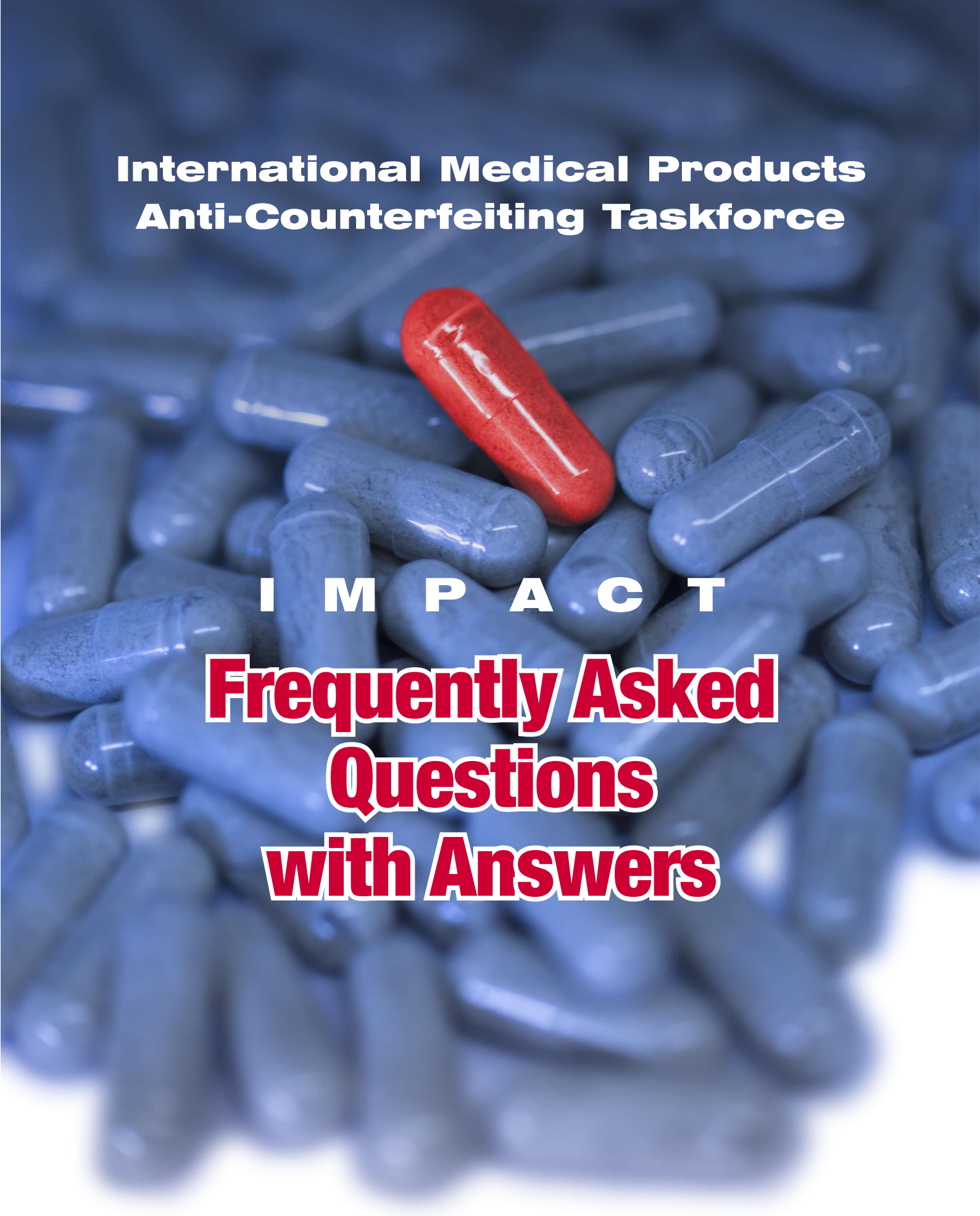
International Medical Products Anti-Counterfeiting Taskforce



I M P A C T

Frequently Asked Questions with Answers

World Health Organization

IMPACT
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WHO Open Forum: IMPACT frequently asked questions

1. What is the background to WHO's and Member States' activities on counterfeit medicines?

World Health Assembly (WHA) **resolution 41.16 (1988)** requested "governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations" and requested the Director General "to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations". Responding to this resolution, a meeting, convened by WHO in Geneva, **1–3 April 1992,** gathered experts representatives of governmental institutions of WHO Member States, the International Criminal Police Organization (INTERPOL), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the International Narcotics Control Board, the International Organization of Consumer Unions, the International Pharmaceutical Federation (FIP) and the World Customs Organization (WCO) (at the time known as Customs Cooperation Council).

WHA resolution 47.13 (1994) requested WHO to assist Member States in combating counterfeit drugs. This led to the creation of the **WHO Project on Counterfeit Drugs** (funded by the Government of Japan). Project staff conducted a several field studies on the occurrence of counterfeit drugs and oversaw drafting of the **WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs**, published in **1999.** Additional funding was later received from the Governments of Australia and the UK for the support of specific activities.

In 2000, WHO, IFPMA, the European Generic medicines Association (EGA), and Pharmaciens Sans Frontières established a working group that presented a technical briefing during the WHA in 2001 and further disseminated the 1999 Guidelines.

2. What is the background to international collaboration on combating counterfeit medicines?

The problem of counterfeit drugs has been high on the agenda of the biennial International Conference of Drug Regulatory Authorities (ICDRA) since 1992. The recommendations emanating from these ICDRA meetings, led, inter alia, to the organization of an ad hoc ICDRA meeting on counterfeit medicines in Madrid, Spain in **February 2004** in conjunction with the 11th ICDRA. The ad hoc meeting requested WHO, in collaboration with other stakeholders, to draft an **international convention on counterfeit drugs** and to convene a meeting of drug regulatory authorities and other stakeholders, prior to the 12th ICDRA (April 2006), to review the draft.

Exploratory work showed, however, that there was no consensus among Member States on the appropriateness of or need for an international convention on counterfeit medicines. The main reasons given by Member States as to why a convention should not be developed at this time were that developing a convention would be extremely costly and time-demanding, and that a convention would have been justified if there were a need to establish limitations to the use of products/technologies that were legally available (e.g. narcotics, tobacco) but that this was not so in the case of counterfeit products which have no legal status anywhere.

3. When and how was IMPACT established?

WHO organized an international conference in Rome, 16–18 February 2006 The conference was attended by representatives of 57 national medicines regulatory authorities, seven international organizations, and 12 international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers. The Declaration of Rome was adopted by all 160 participants and stated that WHO should take the lead in establishing a taskforce, the purpose of which would be to lead international collaboration on combating counterfeit medicines. The Declaration also contained a set of principles and a conceptual framework for the task force's work aimed at ensuring that it takes account of public health interests.

The task force was named the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and defined as a voluntary coalition of stakeholders that coordinates international activities aimed at combating counterfeit medical products for the purpose of protecting public health. Terms of reference were developed and a circular letter announcing the establishment of IMPACT was sent to all WHO Member States in September 2006.

The First IMPACT General Meeting took place in Bonn, Germany, in November 2006. It elected an IMPACT chair and vice-chairs, chairs of IMPACT's five working groups, and established a work plan for 2007. It also established a secretariat, to be hosted by WHO's anti-counterfeiting programme. However, the secretariat and governance are independent of WHO's structure (see IMPACT terms of reference). Examples of similar multi-stakeholder partnerships that exist under the auspices of WHO include the WHO Global Health Workforce Alliance and the WHO Partnership for Maternal, Newborn and Child Health.

4. Why is a global taskforce to combat counterfeit medicines needed?

Counterfeit medical products put people's health and lives at risk. They are a major obstacle to improving global health. The medical product supply chain is global and counterfeiting threatens everyone. Even those who make and sell counterfeits risk consuming counterfeits made by others. IMPACT serves as the only global forum that can bring all concerned stakeholders together to discuss effective measures and exchange experience and expertise, particularly with respect to public health issues.

The broad spectrum of IMPACT stakeholders' mandates, roles, interests and experience reflect the recognition that combating the counterfeiting of medical products cannot be successfully achieved by the health sector alone. Rather, it is dependent on the coordinated efforts of and effective collaboration among a number of sectors, including the health sector, enforcement, border control, justice (at all administrative levels) and the private sector. (The private sector includes manufacturers, importers, distributors, health professionals, media, patients/consumers and civil society.) The need for such extensive collaboration has long been recognized, as indicated by resolution WHA41.16 and in the aforementioned WHO guidelines. What is new is that a large number of distinct stakeholders now recognize the public health implications of counterfeiting of medical products and that WHO is the organization most suited to taking the lead role in the task force. Moreover, the recommendations, policy advice, and training materials developed by IMPACT are more likely to be effective at both national and regional levels than any such tools developed by individual organizations of countries.

5. Who participates in IMPACT?

According to its terms of reference, IMPACT is "open to the following collaborating parties involved in combating counterfeit medical products:

(a) intergovernmental organizations and institutions, such as the World Health Organization, the European Commission, the Commonwealth Secretariat, the ASEAN Secretariat

(b) governmental institutions and agencies;

(c) WHO Collaborating Centres competent in combating counterfeit medical products;

(d) international nongovernmental organizations, with an active involvement in combating counterfeit medical products;

(e) international associations/umbrella organizations representing health professionals such as physicians, pharmacists, nurses, dentists;

(f) international associations/umbrella organizations representing patients and consumers;

(g) international associations/umbrella organizations representing manufacturers, the medical product supply chain, other stakeholders and concerned parties (including technology and service providers) of medical products."

All WHO's Member States are eligible to become collaborating parties in the task force on a voluntary basis. Currently, the parties include nearly 40 Member States, representatives of the ASEAN Secretariat, the Commonwealth Secretariat, the Council of Europe, the European Commission, INTERPOL, the Organisation for Economic Co-operation and Development, WCO, the World Intellectual Property Organization, the World Trade Organization, and numerous nongovernmental organizations. In line with WHO's mandate, WHO's main role in the task force is to ensure its focus on patients' safety and public health. Several WHO departments and regional offices also actively contribute to combating counterfeit medicines. The IMPACT Secretariat ensures the necessary geographical balance among WHO Member States, as well as a balanced representation of governmental and

nongovernmental participants, and of representatives of relevant international organizations, and patients' and health professionals' organizations.

6. How does the IMPACT partnership work?

IMPACT works through five technical working groups which address the areas where action is needed to combat the spread of counterfeit medicines. The five groups cover; legislative and regulatory infrastructure; regulatory implementation; enforcement; technology; and communication. A senior WHO staff member was elected chair of two general meetings and representatives from drug regulatory authorities in Nigeria and Singapore were elected as vice-chairs of IMPACT. The main decision-making body is the General Meeting which convenes usually once a year and elects IMPACT officials for a two-year period. Activities are financed by voluntary contributions.

Diagram attached as Appendix.

IMPACT General meetings to date:

1. General Meeting held in Bonn (Germany), 25–26 November 2006

2. General Meeting held in Lisbon (Portugal), 10–14 December 2007

3. General meeting held n Hammamet (Tunisia), 3–5 December 2008

4. General meeting planned for second half of 2010

7. How do WHO and IMPACT tackle the issue of conflict of interest?

To date, participation in task force meetings has not required any declaration of interests. This procedure is not normally required for meetings whose participants are clearly identified by their affiliation and who thus represent the views of their respective organizations.

Participation by Member States in the three general meetings held since 2006 has been good (from 28 to 36 countries), with more than half the participants being representatives of medicines regulatory authorities and other governmental institutions and agencies. Participants also included representatives of international organizations and international associations of patients, health professionals, pharmaceutical manufacturers and wholesalers.

IMPACT tracks who participates in its meetings, but for reasons of privacy and security, the names of those participants remain confidential. Only the details of affiliation and representation of official institutions and national authorities are disclosed.

8. How is IMPACT financed?

During 2006–2008 the collaborative work of the task force and its secretariat was funded (nearly US$ 2.3 million) mainly by the European Commission and the Governments of Australia, Germany, Italy and the Netherlands (altogether 62%) and by WHO (30%). A special agreement has been signed between WHO and INTERPOL that seeks to strengthen the IMPACT secretariat. WHO's financing of, and fundraising for, the task force are governed by WHO's established policies and principles and subject to WHO's administrative procedures and practices.

The travel and subsistence costs of developing country participants and invited experts with respect to attendance at task force meetings have been covered by the task force. Not all funds spent for IMPACT related activities have been transferred to WHO. For some sources (e.g. The International Federation of Pharmaceutical Manufacturers & Associations), this may also include direct, in-kind contributions to the task force's meetings or activities. Additionally, numerous Member States and other stakeholders have made in-kind contributions to the task force: for example, by providing expertise, e.g. by sending their representatives to meetings of the task force, by collaborative effort in various working groups, or by organizing general meetings and/or working groups.

From 2009 onwards, major fundraising activities have been carried out by WHO. Currently, funds are available from Germany (US$ 80,000) and The Netherlands (Euros 150,000), to support IMPACT's activities end of 2009 and early 2010.

9. How is IMPACT monitored?

IMPACT's planning group, which consists of the chairperson and the vice-chairpersons of the General Meeting, the chairs of the working groups, the IMPACT Secretariat and other participants appointed by the General Meeting, has a key role in monitoring the work of the task force.

In between the annual General Meetings of IMPACT, all activities are monitored by the planning group.

Specifically, the responsibilities of the planning group include:

(a) coordination of reports and proposals of relevant collaborating parties for review by the General Meeting;
(b) review and overall presentation of the output/reports of the working groups to the General Meeting;
(c) review and acceptance of applications for participation as experts or observers in IMPACT;
(d) identification of the need for invited experts (as described above) to support the achievement of the IMPACT objectives;

(e) identification of the need for the establishment of ad hoc working groups to address and advise IMPACT participants on specific issues relevant to the IMPACT goal and objectives (for confirmation by the General Meeting); and

(f) submission of proposals for nomination of candidates for chairperson, vice-chairperson and rapporteur to the General Meeting.

In mid 2009, WHO established a programme to coordinate its work to combat counterfeit medicines (the WHO anti-counterfeiting programme), including coordination with the members of IMPACT and providing it with secretariat functions.

10. How does IMPACT address the issues relating to intellectual property rights?

IMPACT combats both counterfeit-branded products, as well as counterfeit generic medical products. But IMPACT's focus is the protection of public health. Issues related to intellectual property protection are not within the scope of the task force.

IMPACT promotes the use of legal instruments specifically designed to deal with the health consequences of counterfeiting of medical products.

However, many WHO Member States do not have legal instruments specifically designed for combating the counterfeiting of medical products. Moreover, in some Member States the existing specific legal instruments are outdated and even inadequate. In these instances, competent authorities tend to make use of other, non-specific, legal instruments already available. The non-specific legal instruments most commonly used are those related to the protection of trade marks.

11. Does IMPACT address the issue of substandard medicines?

It is recognized that certain issues for combating counterfeit medicines are similar to those that can be taken to reduce the incidence of substandard medicines. Although counterfeit medicines can be considered as being substandard, not all substandard medicines are counterfeit. However, strengthening regulatory, surveillance, and enforcement efforts to ensure the quality, safety, and effectiveness of distributed medicines can be useful for substandard, as well as counterfeit medicines.

Issues related to substandard medicines are addressed by the WHO Medicines Quality Assurance and the WHO Regulatory Support programmes.

12. What is the role of INTERPOL in the IMPACT Secretariat?

WHO has no mandate to deal with enforcement activities. But the criminal nature of counterfeit medical products requires close collaboration between NMRAs and enforcement authorities. Accordingly, an agreement was signed in January 2008 between WHO and INTERPOL, to enhance the collaboration between the two organizations.

In October 2008, during the INTERPOL's General Assembly, the INTERPOL member Countries adopted a resolution recognizing the necessity to support IMPACT and to improve international cooperation to combat counterfeit medical products.

In January 2010, INTERPOL created an independent unit, to support the IMPACT Secretariat, through development of coordinated enforcement activities.

13. Where can I find information about IMPACT?

IMPACT related information is available on the IMPACT web site (http://www.who.int/impact) currently hosted by WHO.

14. What has IMPACT achieved so far?

IMPACT's achievements are described in the document *Overview of the IMPACT Working Group activities*, which was prepared for the World Health Assembly (see http://apps.who.int/gb/e/e_wha63.html and the IMPACT web site http://www.who.int/impact). All IMPACT outcomes are based on the voluntary contributions of IMPACT members, including national authorities, regulators, etc

15. What is the difference between WHO and IMPACT Documents?

Different types of documents can come out of IMPACT's work, as follows:.

1. *Working IMPACT documents* — these are "living" documents, usually technical drafts, related to the objectives and initiatives of the five IMPACT working groups. They have no binding clauses for IMPACT members/participants nor for WHO Member States.

2. *Official IMPACT documents* — these are usually technical documents that are of significant importance to the work of IMPACT in combating counterfeit medical products. Their final drafts are reviewed and endorsed by the IMPACT General meeting. If all partners endorse and agree the document during that meeting, it will be available for use by any interested party. The final version

of these documents are treated as official IMPACT documents and posted on the IMPACT web site,

3. *WHO documents and WHO guidelines* — these are of the highest level of WHO advice and recommendations available to Member States for their implementation. IMPACT documents could become a WHO document if they undergo WHO procedures including review by the relevant WHO Expert Committee processes. (WHO documents generally undergo wide consultation with WHO Member States, experts and specialists. Development and publication processes must adhere to WHO rules and procedures.)

16. Will combating counterfeit medicines affect the availability of generic and legitimate branded medicines?

No. A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products.

Measures adopted to combat counterfeit medicines are aimed at products that have never been and would never be approved by a national authority, that have been manufactured outside regulatory controls by those who wish to remain unknown, and/or have been traded by individuals who conceal the true origin of their products.

All these situations are not related to the trade of legitimate generic and legitimate branded medicines.

Therefore, such measures should not result in affecting the availability in legitimate generic and legitimate branded medicines.

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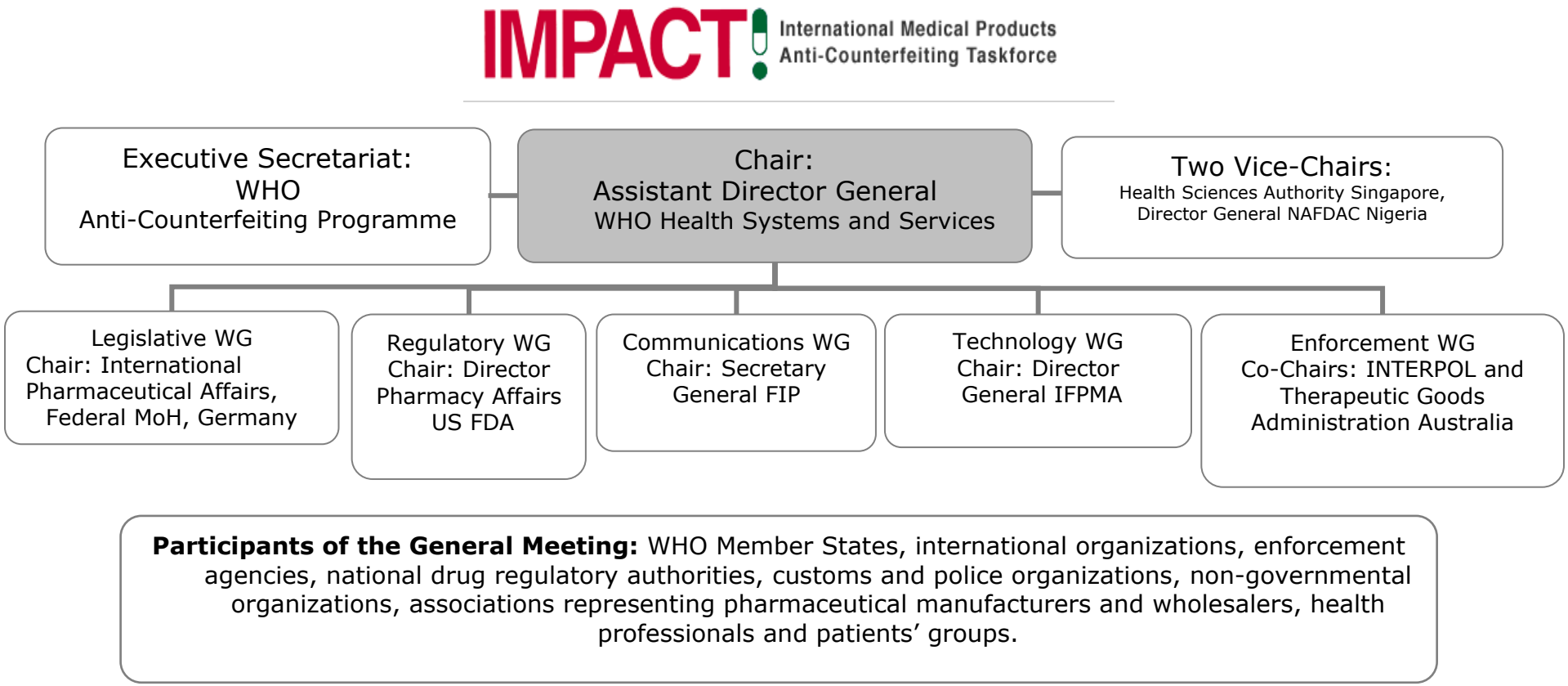

IMPACT's structure (2008-2010)

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