Monitoring of New Legal & Illegal Medicines in Development

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Observations / Facts

• Athletes are constantly looking for performance edge.
• Athletes are risk takers.
• Interest of some Athletes/Entourage for new drugs:
  • Newer is perceived as being better
  • Newer means less chances to be detected by anti-doping authorities
• Sport market is a driving force for counterfeiting
• Significant impact of mafias on the world of sport
Selected historical facts

- **2003 Balco Affair:**
  - Few elite athletes enrolled in a doping program
  - 3 designer steroids and special formulations (T and EpiT) prepared
  - Complacent private analytical laboratory
  - Revealed by investigations, not analytical results

- **Operation Gear Grinder (2005):**
  - Massive importation of steroids from Mexico to the US
  - Thousands of amateurs athletes involved

- **Doping cases of SARMs/CERA/GW501516:**
  - All drugs in development or discontinued
  - Found in Athletes’ samples
  - Drugs not from legal sources
Drug sources – 3 main categories

- **Medicines:**
  - Active principle(s) known
  - Effects, characteristics & toxicity published
  - Reference material accessible
  - Detection method(s) often accessible

- **Substances in pre-clinical and clinical development:**
  - Limited or no information available
  - Confidentiality
  - Under the responsibility of the biopharmaceutical company

- **Illegal substances:**
  - Designer drugs
  - Street drugs
Collaborations with Pharmaceuticals

• IFPMA and WADA signed a collaborative agreement.

• Global/specific collaborative agreements with pharmas (e.g. Roche, GSK, Amgen, Pfizer, Novartis, …)
  • Information on doping potential of new drugs in clinical development.
  • Information on ADME/detection methods
  • Access to Reference Materials (Parent compound, metabolites)
  • Distribution of information and material to WADA accredited laboratories
Collaborations with investigation forces

• Illegal/designer drugs:
  • Collaborations police/custom forces & drug enforcement agencies
  • Undercover order / intelligence (information gathering) to identify drugs distributed illegally and suppliers
Examples of deliveries at WADA
Deliveries at WADA - II
Summary of Analytical Results

- Substances ordered:
  - ACE-011; ACE-031; AOD-9604; CJC-1295; hexarelin; ipamorelin; MGF; GHRP-2; TB500 (thymosin β4); follistatin; sermorelin; …

- Drug content:
  - Most contain the advertised substances
  - Biological products: some incomplete or wrong protein(s)
  - Content from 30 to 215 % of announced dose
Health risks

Why:

- Unknown fusion protein (instead of MGF)
- Variable doses. Risk of overdosing
- Heavy metals (arsenic, mercury, lead, chromium)
- Solvents
Conclusions

• Drugs in early or late clinical development sold quickly on the Internet.
• Majority contain claimed products but sometimes in very variable quantities
• Quality is questionable and could present health risk
WADA Perspectives

- Develop relationship with biopharmaceutical industry
- Continue undercover orders.
- Continue monitoring of discussion forums
- Support to laboratory analytical capacity development
- Information in support of prioritization strategy
- Sharing of information and substances with other drug agencies.