play true

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

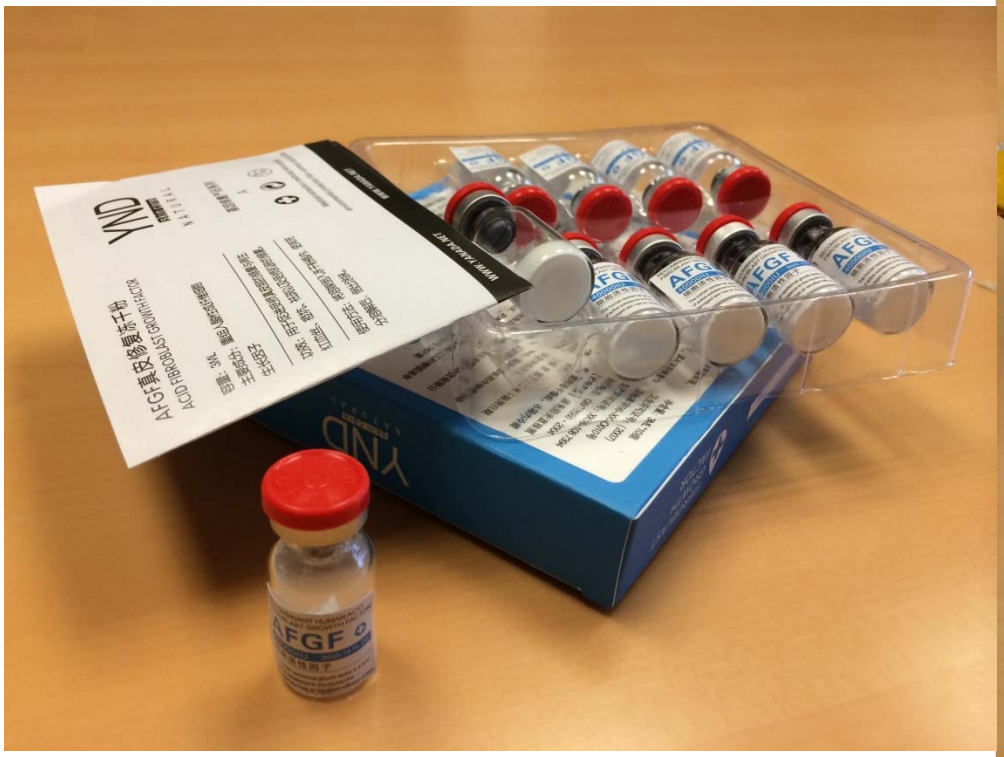
Collaborations with Pharmaceuticals

- 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.

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