ANVISA
Brazilian Health Surveillance Agency

Banning Tanning Beds

Lessons From Brazil

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Time line

- 2001 - Public Prosecutor against ANVISA (Case A)
- 2002 - RDC ANVISA 308 (Ordinance) ->
  - Before 2002 – No regulation, many problems
  - IEC Standard 60335-2-27 based
  - Low level of Legal Compliance of the beds and manufacturers
  - Difficulty of assessing inspectors because the data collected need specific technical knowledge
  - Rule was rigorously and detailed
  - “State-of-the-art” - (no minors, alerts, etc.)
Time line

2008 - Public Prosecutor against ANVISA (Case B)
  - Many problems (burns, machines operating out of specification)
  - Inspectors fall in many requirements for not being the core of medical device
  - More problems in the States of South

2008 – Work Group in ANVISA (Internal Report)
  - RDC ANVISA 308 still been “State-of-the-art” (with few alterations).
  - New rule with 3th party certification (many levels, depends on the State of Brazil) - Negotiations needed to make it real – Too complex!
  - Studies from other countries reported the lack of conformity (USA, Australia, …)
2008 – Work Group in ANVISA (Internal Report) …
  o No safe limits of use. Many difficulties to establish safety measures.
  o Great risks, low benefits…

Stand Points (other countries):
  o Australia - Cancer Council of WA (Terry Slevin)\(^1\): “The Cancer Council’s position is clear: the best way to make the solarium industry safe is to ban it. These are dangerous machines and we do not encourage anyone to use them”.
  o Europe\(^2\) - EN IEC 60335-2-27:1997 - does not entirely cover the health and safety aspects (Ex. it does not provide limit values on the maximum effective irradiance of UV radiation for the types of tanning devices).


\(^2\) SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS - SCCP (2006) - Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes.
Time line

2009 - IARC Working Group has classified UV-emitting tanning devices as “carcinogenic to humans”.


2009 – Conclusion = we have enough evidences to ban tanning bed from Brazil…

Sunlight in Brazil:

nice all time (nearly) !!
Time line

• 2009 – Public consultation and one Public Meeting
  o Invited: Procon (Consumer Protection Agency), WHO (World Health Organization), INCA (National Cancer Institute of Brazil), Brazilian Society of Dermatology (Medical Association), Health Surveillance State in Southern Brazil and the Brazilian Association of Tanning Professionals.
  o Conclusion = we have evidences to ban tanning bed from Brazil
  o Low benefits

• 2009 - Publication of the normative banning the tanning bed

• 2009 - Public Prosecutor against ANVISA (Case C)
Time line

- Many Lawsuits and judicial actions (1º, 2º and 3º judicial levels)
  - Meetings to clarify with judges who decided the case against ANVISA
  - Many interviews for TV, Radio and Magazines
  - Many reports for the legislative, executive and judicial authorities.
  - The main question was the same: Why should we ban if no other country has banned? Risk to the user based on scientific evidences (scientific articles and reports from other countries).
• Nowadays
  o Almost all actions were finished. In all that we had take notices, ANVISA won or the prognosis is to win.
  o Some few places are clandestinely
Lessons Learned (next time?)

- Do more advertising before legal actions
- Do the prohibition process more clear and disclosed
- Do more public meetings
- Allow more time for lay people to think about it
- Create a response packet to of the judicial measures
- Presentations to key stakeholders
Lessons Learned (next time?)

In short: We care very much about the technical issues and forget the social issues
Thanks!

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