



## AIPPI Day 2016

**Second Medical Use Patents - enforcement in harmony or conflict with the regulatory system?**

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### Background

- Q 238 – Second medical use and other second indication claims
- "Second medical use(s) refers to new therapeutic use(s) of known compound or substances."
- The Resolution deals with both infringement aspects and regulatory aspects.



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### Background - Resolution

- 13)The **regulatory frameworks** governing the importation and marketing of pharmaceuticals, their labelling, prescription, distribution, dispensing and reimbursement **should facilitate transparency as to whether such pharmaceuticals are being dispensed for patented medical uses, and**, while not preventing the legitimate commercialization of pharmaceuticals for non-patented medical uses, **facilitate enforcement of patent protection for second medical use.**
- 14)AIPPI urges the relevant authorities to implement the necessary measures so that effective protection of second medical uses is not jeopardized by **regulatory frameworks.**



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**Issues in relation to enforcement and regulatory systems**

- A product with a non-patented active ingredient (compound) is marketed/sold with or without instruction on the label how to use the drug (i.e. not the second patented medical use). Infringement?
- A Medical Products Agency has issued a decision on substitutability without any instruction or restrictions. Infringement?
- A pharmacy has (because of the substitution principle) sold the generic drug without any instruction or restrictions. Infringement?
- A physician (hospital) has prescribed the generic drug with instruction. Infringement?



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**Kontaktuppgifter - Håkan Borgenhäll**



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