

# LEGAL ASPECTS: AMPARO ACTION AND COMPASSIONATE USE

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## PURPOSE

To gain access to medication for certain patients from the Hemophilia Foundation of Salta through judicial amparo action and compassionate use concept.

## INTRODUCTION

Compassionate use is a concept used by ANMAT (National Administration of Drugs, Food and Medical Technology) in Argentina, which involves humanitarian reasons and whereby a drug that is not registered in ANMAT yet is authorized to enter the country through importation. Entry of a type of medication is allowed for a given patient, for certain period of time and amount through affidavit of the treating physician.

Amparos are legal actions that are not provided a name nor specific process in the procedural code. In general, they serve to take legal action on very different types of issues. For the specific case of Health Protection, they serve to achieve legal recognition for the rights regarding the restoration of health in a person, whether in terms of care and/or provision of drugs and supplies.

## METHOD

Three judicial amparo actions were filled for children (< 2 years old) from the Hemophilia Foundation of Salta in order to gain access to a fourth-generation factor VIII that is not registered for marketing yet in Argentina.

## RESULTS

Favorable judgments of first instance were achieved for all 3 children. Only in one case, the judgment of first instance was appealed by the counterparty; but, in that instance of appeal, the favorable judgment for the patient was confirmed.

## CONCLUSION

100% efficiency was achieved for all actions filled. It must be emphasized that for the third case a favorable judgment was obtained before the Court of Justice of Salta (being it the highest court in that province). It should be noted that these cases set precedence for the Argentinean justice.

Finally, we may consider that the opportunity of filling an amparo action arises whenever appear patients that can improve their quality of life with a drug that already exists worldwide but is not authorized for marketing in the country yet.



Poster Presented at:

DOI: 10.3232/jse.eu.WFH2016.2016

Capacity Building  
Daniel Adolfo

35--PP-W

WFH2016