8th International Society of Pharmacovigilance Annual Meeting

“Strategies for developing Pharmacovigilance”
5th to 8th October 2008

Sheraton Hotel & Convention Center
Buenos Aires - Argentina

www.isop2008.org
Welcome

Dear Colleagues,

On behalf of the ISoP Executive Committee and the Argentinian Society of Pharmacovigilance as Local Organizer, we are deeply honored to welcome you to the 8th International Society of Pharmacovigilance Annual Meeting, the first ISoP Meeting in the American continent.

We now have the opportunity to participate in one of the most important annual international pharmacovigilance meetings and to learn from a scientific programme supported by an panel of the most acknowledged experts in drug safety and Pharmacovigilance.

“Strategies for developing Pharmacovigilance”, the title of this Meeting, strives to involve both the developed as well as the developing world, because Pharmacovigilance needs to evolve and to expand accordingly with pharmacotherapy development, drug production and medicines use in every country, region and economic and political setting. With this Meeting, we aim to contribute to build bridges between developed and developing countries in the field of drug safety, and to contribute to harmonization worldwide.

For this ISoP 2008 Meeting, the differences in organization, complexity and effectiveness of Pharmacovigilance in different countries have been considered: we have included sessions devoted to enhancing Methodology and others aiming to improve the efficacy of systems preventing counterfeit and substandard medicines. The need to enhance Pharmacovigilance in pregnant women, children and older people is also stressed. Different approaches for Pharmacovigilance in vaccines and a Round Table discussion on strategies of Risk Management, from a regulatory perspective, take care of two global main topics in Pharmacovigilance.

The session “Harmonization in Pharmacovigilance” aims to make consistent Pharmacovigilance approaches both in developed and developing world. The need for surveillance of a relatively new group of medicines is the basis for the session for biological products and advanced therapies. The crucial role of communication in Pharmacovigilance is also approached from different views and focuses on public and media communication.

The complex process of marketing authorization and its impact on patient safety is tackled in three plenary lectures dealing with benefit/risk balance, off-label use and the non commercial sponsorship of clinical investigations.

Both the ISoP’s lecture about Education and Training and “Lessons learned from the development of Pharmacovigilance in Spain” aim to contribute to a better and sounder knowledge of Pharmacovigilance, mainly in Latin-American countries.

We sincerely acknowledge the privilege of hosting this conference here, in Buenos Aires, Argentina, and we hope that in the future the ISoP’s stars will continue to enlighten the Latin part of the American continent.

Dr. Luis Alesso
Chairman, Local Organizing Committee

Prof. Nicholas Moore
International Society of Pharmacovigilance
President
Sunday
5th October - 09.00 h. to 18.00 h.

Pre-Conference Course I
Pharmacovigilance: from Fundamental Basis to Practice
Venue: Golden Horn conference room

Chairpersons
Luis Alesso, Córdoba National University, Argentina
Ronald Meyboom, Uppsala Monitoring Centre, Sweden

Faculty
Carmen Kreft-Jais, AFSSAPS, France
Marie Lindquist, Uppsala Monitoring Centre, Sweden
Nicholas Moore, Department of Pharmacology, University of Bordeaux, France
Ronald Meyboom, Uppsala Monitoring Centre, Sweden
Jan-Willem van der Velden, Pharmasset, Switzerland

Programme
08.30 Welcome registration
08.30 Registration Desk, Foyer of Catalinas and Golden Horn conference rooms
08.45 Coffee break (Foyer of Catalinas and Golden Horn conference rooms)
09.15 Basis for causality assessment
Ronald Meyboom
12.15 Pharmacovigilance from industry perspective
Jan-Willem van der Velden
14.15 Risk/Benefit evaluation: Basis and consequences
Carmen Kreft-Jais
15.50 AMMAT representative

12.15 Sandwich Lunch (Golden Horn conference rooms)
14.15 Pharmacovigilance from industry perspective
Jan-Willem van der Velden
14.45 The WHO Database and the UMC
Marie Lindquist
14.45 Pharmacoepidemiology in Pharmacovigilance
Nicholas Moore
16.20 Coffee break (Foyer of Catalinas and Golden Horn conference rooms)
16.50 Risk/Benefit evaluation: Basis and consequences
Carmen Kreft-Jais
17.50 Closure
18.00 ANMAT representative

09.00 Introduction
Ronald Meyboom
09.00 Why do we need risk management?
Robert Ball
09.10 Concept and components of risk management
Xavier Kurz
10.45 Risk management from an Industry perspective
Nicholas Moore
10.50 Coffee break (Foyer of Catalinas and Golden Horn conference rooms)
11.15 Risk management in the United-States: the REMS
Gerald Dal Pan
11.45 Risk management in Europe: the EU-RMP
Xavier Kurz
12.15 Risk management in Latin America
Murilo Freitas-Dias
12.45 Lunch (San Telmo conference room, ground floor)
13.30 How to prepare a risk management plan/strategy?
Anália Mota
14.00 Risk mitigation and its measurement
Gerald Dal Pan
14.30 Gerald Dal Pan
15.30 Risk management in Latin-America
Murilo Freitas-Dias
16.00 Closure

18.30 Welcome Reception
San Telmo Conference Room, Sheraton Buenos Aires Hotel & Convention Center

Pre-Conference Course II
Drug-related Risk Management
Venue: Catalinas Conference Room

Chair:
Xavier Kurz
Scientific Administrator, Risk Management Team, Sector Pharmacovigilance and Safety & Efficacy of Medicines, European Medicines Agency (EMEA), London

Faculty:
Gerald J. Dal Pan, Director, Office of Drug Safety, Center for Drug Evaluation and Research (CDER), FDA
Murilo Freitas-Dias, Head of Pharmacovigilance, Brazilian Health Surveillance Agency - ANVISA, Brazil
Anália Mota, Senior Director of Pharmacovigilance Analytics, Benefit Risk Management, Johnson and Johnson
Anália Pérez, Head of Medicines Evaluation Department, National Administration for Food, Drug and Medical Technology (ANMAT), Argentina

Programme
08.30 Welcome registration
08.30 Registration Desk, Foyer of Catalinas and Golden Horn conference rooms
08.00 Introduction: Objective of the course
Anália Mota
09.00 Why do we need risk management?
Robert Ball
10.00 Concept and components of risk management
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18.30 Welcome Reception
San Telmo conference room, Sheraton Buenos Aires Hotel & Convention Center
### Monday
6th October - 09.00 h. to 17.50 h.

**Opening of the 8th Annual ISoP Meeting**

Nicholas Moore  
President of International Society of Pharmacovigilance (ISoP)

Luis Alesso  
President of Argentinian Society of Pharmacovigilance (SAFV), Chairman of the Local Organizing Committee

**Opening address**

Lic. Graciela Ocaña  
Argentine Minister of Health

**ISoP's presentation:**

ISoP's comprehensive modular pharmacovigilance curriculum: the result of worldwide interdisciplinary teamwork  
Jürgen Beckmann  
Former Director Drug National Agency, Germany

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<td>09.00</td>
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<td>Early Licensing versus Greater Safety?</td>
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<td>Where's the Balance?</td>
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<td>Michael Rawlins</td>
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<td>Chairman of National Institute for Health and Clinical Excellence (NICE), United Kingdom</td>
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<td>10.20</td>
<td>ISoP's presentation:</td>
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Monday
6th October - 09.00 h. to 17.50 h.

11.10 - 12.40 Parallel Sessions Morning
Liberador A
1. Reports of Lack of Effectiveness
Chairpersons
Pedro Lipszyc
Thierry Trenque

11.10 - 11.30 1.a Keynote presentation: Medicaments interchangeability: are all the drugs alike?
Pedro Lipszyc

11.30 - 11.50 1.b Drugs associated with ineffectiveness as adverse drug reaction
Sander Borgsteede

11.50 - 12.10 1.c Programme of Bioequivalence in Argentina
Ricardo Bolaños

12.10 - 12.30 1.d Cholinesterase inhibitors in demented patients: impact of treatment non-persistence on institutionalization or death
Yolí Moride

12.30 - 12.40 Discussion

12.40 - 14.00 Lunch (San Telmo Room)

Liberador B
2. Pharmacogenetics and Drug Interactions in Pharmacovigilance
Chairpersons:
Eveline Jaquenoud-Sirot
Paula Márquez

11.10 - 11.30 2.a Keynote presentation: Drug plasma levels and ADRs
Eveline Jaquenoud-Sirot

11.30 - 11.50 2.b Genetic polymorphisms and risk of ADRs in NSAID and SSRI users
Adolfo Figueras

11.50 - 12.10 2.c Association of cardiovascular drugs and NOS1AP with QT prolongation
Charlotte van Noord

12.10 - 12.30 2.d Genotyping in the TDM laboratory – necessary for Pharmacovigilance
Astrid Hader

12.30 - 12.40 Discussion

14.00 - 15.30 Parallel Sessions Afternoon
Liberador A
3. Pharmacovigilance in Hospitals
Chairpersons:
Jan-Willem van der Velden
Raquel Herrera Comoglio

14.00 - 14.20 3.a Keynote presentation: Off-label use in psychiatric inpatients - Data from the AMSP Study Group
Anastasios Konstantinidis

14.20 - 14.40 3.b Profile of Drugs Related to Adverse Events at Brazilian University Hospitals
Adriano Max. Moreira-Reis

14.40 - 15.00 3.c Pharmacovigilance within the Internal Medicine Division of Argerich Hospital
Marcelo L. Ponte

15.00 - 15.20 3.d Admissions by bleeding or high INR caused by drugs in a Private Non-profit Hospital, Montevideo, Uruguay
Ismael Ólmás

15.20 - 15.30 Discussion

Liberador B
4. Methodology in Pharmacovigilance I
Chairpersons:
Saad Shakir
Nicholas Moore

14.00 - 14.20 4.a Keynote presentation: The role of prescription event monitoring in the risk management of medicines
Saad Shakir

14.20 - 14.40 4.b Analysis of a depletion of susceptibles effect in the risk of MI and diclofenac: a field case referent study with the PGRx Information System
Lamiae Bensouda-Grimaldi

14.40 - 15.00 4.c The monitoring of serum electrolytes and creatinine in patients treated with antihypertensive drugs: a retrospective analysis in UK general practice
Jamie Coleman

15.00 - 15.20 4.d MedDRA as a standard: approach to version updates and primary SOC allocation
Tomás Moraleda

15.20 - 15.30 Discussion

15.30 - 16.00 Coffee-break and poster viewing
### Monday
6th October - 09.00 h. to 17.50 h.

**Libertador A**
**5. Counterfeit Medicines and Illegitimate Drugs**
Chairpersons:
- Luis Alessio
- María José Sánchez

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| 16.00 | 5.a **Keynote presentation:** Counterfeit and illegitimate medicine: a view from the Americas  
José Luis Castro |
| 16.20 | 5.b **Argentine Programme of Detection of Illegitimate Medicines**  
María José Sánchez |
| 16.40 | 5.c **Administrative traceability requirements in medicines purchasing**  
Rodolfo Rodríguez |
| 17.00 | 5.d **Industry commitment in the battle against fraud and medicines counterfeiting**  
Miquel Mato |
| 17.20 | 5.e **Combating Drug Counterfeiting: the Nigerian Experience**  
Dora Akunyili |
| 17.40 | **Discussion** |

**Libertador B**
**6. Intensive Pharmacovigilance Programmes**
Chairpersons:
- Eugène van Puijenbroek
- Deirdre McCarthy

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| 16.00 | 6.a **Keynote presentation:** Web-based intensive monitoring, a new method for active surveillance of drugs  
Eugène van Puijenbroek |
| 16.20 | 6.b **Novel approach for intensive Pharmacovigilance Studies application to Hepatitis C treatment in Mexican patients**  
Ricardo Jiménez-Méndez |
| 16.40 | 6.c **Monitoring of haematological safety of Leponox (Clozapine). Results of 14 years.**  
Monica Fuentes-Vargas |
| 17.00 | 6.d **Priority groups identification for the development of intensified pharmacovigilance in Bogotá**  
Rosa Angela Caro Rojas |
| 17.20 | 6.e **Safety profile of modaanafil used in GP in England: a modified PEM study**  
Saad Shakir |
| 17.40 | **Discussion** |

### Tuesday
7th October - 09.00 h. to 17.50 h.

**Libertador A**
**7. Pharmacovigilance in Special populations**
Chairpersons:
- Geral Dal Pan
- Anthony Wong

**Libertador B**
**8. Harmonization in regulatory aspects of Pharmacovigilance: How do you do it?**
Chairpersons:
- Ulrich Hagemann
- Ricardo Bolaños

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<th>Time</th>
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| 09.00 | 7.a **Keynote presentation:** Pediatric Pharmacovigilance - New FDA and EMEA Requirements and new WHO Focus: Impact on Pharmaceutical Industry and other Stakeholders  
Klaus Rose |
| 09.20 | 7.b **Identifying and Evaluating Teratogenic risks of Drugs in Humans**  
Myla Moretti |
| 09.40 | 7.c **Only few Serious Adverse Drug Reactions are due to drugs of Beers’ list of inappropriate medications for the elderly**  
Marietta Rottenkolber |
| 10.00 | 7.d **Psychotropic drug used for Attention-deficit/ hyperactivity disorder (ADHD) in Italian children and adolescent population**  
Pietro Panei |
| 10.20 | 7.e **Adverse Drug Reactions with Donepezil:**  
Hervé Le Louët |
| 10.40 | 7.f **Pharmacovigilance and the Pan American Network for the Drug Regulatory Harmonization**  
José Luis Castro |

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<td>10.40</td>
<td><strong>Coffee-break and poster viewing</strong></td>
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### Schedule

**Monday**
- **09.00 - 12.40** Parallel Sessions Morning
- **16.00 - 17.50** Parallel Sessions Afternoon

**Tuesday**
- **09.00 - 12.40** Parallel Sessions Morning
- **16.00 - 17.50** Parallel Sessions Afternoon
Tuesday
7th October - 09.00 h. to 17.50 h.

11.10 - 12.40 Parallel Sessions Morning

Libertador A
9. Vaccine Pharmacovigilance
Chairpersons:
Murilo Freitas-Dias
Corina Piertita

11.10
9.a Keynote Presentation: Conduct of Pharmacovigilance of vaccines- why is it different from pharmacovigilance of other medicinal products
Brigitte Keller-Stanislawski

11.30
9.b Brazilian Vaccine Safety Monitoring System
Murilo Freitas-Dias

11.50
9.c Post-authorization Safety Surveillance of a new pentavalent vaccine within a National Childhood Vaccination Program in Central America
Katharina Hartmann

12.10
9.d Vaccine Pharmacovigilance: are we asking the right questions?
Robert Ball

12.30
Discussion

12.40 - 14.00 Lunch (San Telmo conference room)

Libertador B
10. Methodology in Pharmacovigilance II
Chairpersons
Marie Lindquist
Anders Sundström

11.10
10.a Keynote presentation: Signal management: Can you see the wood for the trees?
Eugène van Puijenbroek

11.30
10.b Risk Validation against internal and external Data Source
Peter Schulz

11.50
10.c Data mining on health record databases for detecting adverse reactions: which events to monitor?
Gianluca Trifirò

12.10
10.d Creating Pharmacovigilance Quality Assurance
Tyler Cochran

12.30
Discussion

12.40 - 14.00 Plenary Sessions Afternoon (Libertador A/B)

13.15
ISoP General Assembly (Libertador A)

14.00
Keynote lecture:
14.45 Monitoring adverse events in an off-label use setting
Gerald Dal Pan
Director of Center for Drug Evaluation and Research (CDER), Food and Drug Administration, USA

14.45
Keynote presentation:
15.30 Lessons learned from the development of pharmacovigilance in Spain
Joan Ramon Laporte
Director of Catalan Institut of Pharmacology Foundation (FICF), Spain

15.30 - 16.00 Coffee-break and poster viewing

16.00 - 17.50 Plenary sessions afternoon (Libertador A/B)

16.00
Pharmacovigilance and clinical trials: experience of the first European non commercial sponsor
Hervé Le Louët
Head Pharmacovigilance Regional Centre Creteil, France

16.20
Round table discussion: Customising Risk Management: Global or local?
Chairperson
Joan-Ramon Laporte

Tailoring Emerging Vaccine Safety infrastructures: Recent advances in Monitoring Vaccine Safety
Nelson Arboleda
Centers for Disease Control and Prevention (CDC), USA
Round table with:
- Xavier Kucz
- Chabi Bekahia
- Dora Akumyili
- Joan-Ramon Laporte
- Nelson Arboleda
- Latin America Regulatory Agencies
Wednesday
8th October - 09.00 h. to 17.30 h.

From 08.00
Registration Foyer Libertador Room

09.00 - 12.40 Parallel Sessions Morning

Libertador A

11. Estimating AE/ADR seriousness, causality and frequency as the basis of risk assessment
Chairpersons
Jürgen Beckmann
Ronald Meyboom

11.00 - 11.20
11.a Keynote Presentation: Sense and non-sense in case-causality assessment
Ronald Meyboom

11.20 - 11.40
11.b Ventricular arrhythmia and sudden unexpected death and domperidone
Charlotte van Noord

11.40 - 11.50
11.c Hospital admissions due to severe adverse drug reactions: EMIR, a nationwide study
Ghada Miremont-Salamé

11.50 - 12.10
11.d Patients starting anti-obesity drugs carry higher psychiatric and cardiovascular baseline risk
Marjolein Willemen

12.10 - 12.30
11.e Allergic reactions to oral drugs: a case/non case study from an Italian spontaneous reports database (GIF)
Francesco Salvo

12.30 - 12.40
Discussion

Discussion

09.00 - 12.40 Parallel Sessions Morning

Libertador B

12. Pharmacovigilance in Biologics and Advanced Therapies
Chairpersons
Xavier Kurz
Michael Rawlins

12.00 - 12.20
12.a Keynote lecture: EMEA guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products
Brigitte Keller-Stanislawski

12.20 - 12.40
12.b Anti-Rheumatic Treatment in Sweden (ARRIS): Clinicians, Academia and Regulators in collaboration for the pharmacovigilance of biologics, including TNF-blocking drugs
Anders Sundström

12.40 - 14.00 Lunch (San Telmo Room)
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<td>14.00</td>
<td>Workshop: Widening Pharmacovigilance’s scope: Consumer reporting</td>
<td>Libertador B</td>
<td>John McEwen</td>
<td>Syed Rizwanuddin Ahmad: Do Consumer Reports of Adverse Drug Reactions Add Value or Noise to Postmarketing Safety Surveillance?</td>
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<td>14.00</td>
<td>FDA Experience with Consumer Reports</td>
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<td>Syed Rizwanuddin Ahmad</td>
<td>Keynote presentation: Myths and misinformation: cautionary herbal tales</td>
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<td>Syed Rizwanuddin Ahmad</td>
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<td>Deborah Shaw</td>
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<td>14.15</td>
<td>The Adverse Medicine Events (AME) Line: Australian experience with consumer pharmacovigilance</td>
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<td>John McEwen</td>
<td>Acute hypersensitivity reactions to Andrographis Paniculata containing products, as reported in international Pharmacovigilance</td>
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<td>John McEwen</td>
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<td>Ronald Meyboom</td>
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<td>14.45</td>
<td>Lise Aagaard</td>
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<td>14.45</td>
<td>10 years of experiences with consumer reporting to KILEN - a Swedish consumer organization</td>
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<td>Lina Westin</td>
<td>International Assessment of Herbal Medicines Pharmacovigilance</td>
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<td>Lina Westin</td>
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<td>16.00</td>
<td>Bengt-Erik Wiholm Lecture</td>
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<td>16.45</td>
<td>Beje Wiholm: putting the pieces together</td>
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<td>Ralph Edwards Director of the Uppsala Monitoring Centre, Sweden</td>
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**Wednesday**

8th October - 09.00 h. to 17.30 h.
Lise Aagaard  
Pharm PhD MSc, PhD, BEcon,  
Consumer Safety Division, Danish Medicines Agency; Faculty of Pharmaceutical Sciences, Institute of Pharmacology and Pharmacotherapy, Copenhagen, Denmark

Sandra Abraham MD, PhD  
Medical Director Bayer SA, Brazil

Syed Rizwanuddin Ahmad MD, MPH, FISPE  
Food and Drug Administration, USA

Dora Akunyili MD, PhD  
Director, NAFDAC, Drug Agency for Food and Drug Administration and Control, Nigeria

Luis Alesso MD  
Director Pharmacovigilance Center, Public Health School, School of Medicine, Córdoba National University; Head of AFproSS Drug Department, Córdoba Provincial Administration Health Insurance, Córdoba, Chairman of the Local Scientific Committee, Argentina

Nelson Arboleda MD, MPH  
Senior Medical Epidemiologist Immunization Safety Office (ISO) Office of the Chief Science Officer Centers for Disease Control and Prevention (CDC), USA

Héctor Arenoso MD  
Director of Specialty of Pharmaceutical Medicine, School of Medicine, Buenos Aires University; Argentine Society of Pharmaceutical Medicine, Argentina

Priya Bahri MD, PhD  
European Medicines Evaluation Agency, United Kingdom

Robert Ball MD, MPH, ScM  
Director, Office of Biostatistics and Epidemiology, Center for Biologies Evaluation and Research (CBER), Food and Drug Administration, USA

Jürgen Beckmann MD  
Former Director Drug National Agency, Germany

Inês Bignone MD  
Head Pharmacovigilance Department, National Administration of Food, Drug and Medical Technology (ANMAT), Argentina

Milena Oliveira Bittencourt  
Pharmacovigilance Office (GFARM), Brazilian Health Surveillance Agency, (ANVISA), Brazil

Ricardo Bolaños MD, PhD  
Head Studies and Projects Department, National Administration of Food, Drug and Medical Technology (ANMAT), Argentina

Churn-Shiouh Gau PhD  
Deputy Executive Director Centre for Drug Evaluation, Taiwan

Marianne Gerber MD, MSc  
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