

## ISDB 2021 Newsletter

Message from the President of ISDB, Dr. Dick Bijl

We are happy to send you the second newsletter of ISDB this year with several high quality contributions by our members including some articles on COVID-19. I hope you will enjoy it.

The sad news we share with you is that Jordi Llinares Garcia has passed away very suddenly. Those of you that attended the General Assembly in Paris in October 2019 will remember him as a speaker in the Drug regulatory environment, guality of evidence needed-round. ISDB has always been critical of the European Medicines Agency especially regarding their transparency policy. It was therefore very good to see that a representative of EMA was willing to speak at our meeting and engage in discussions with our members. An obituary is written by Luis Carlos Saiz.



Dick Bijl, Chairman of ISDB

Contacts of ISDB with representatives of the regulating authorities and the pharmaceutical industry are quite scarce. Yet, in the current aftermath of the corona-pandemic it is becoming more necessary. One reason is that people working within the industry are increasingly sharing concerns about the registration of vaccines and drugs and how science is being distorted.

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#### Message from the President, continued

Many of us have grave concerns about how the regulating authorities have put paid little attention to the principles of consumer safety. The petition written by Linda Wastila, Peter Doshi, Hamid Merchant and Kim

Witczak to the FDA is linked in this newsletter. Slow down get the science right, challenges the FDA's decision to grant Pfizer a full marketing authorization for their mRNA-vaccine.

This is not the way to go forward. Lessons learned in the Softenon-affair might easily be forgotten and ISDB should always play a role in alerting the public to past mistakes so we can avoid them in the future. We also signed the amendment of the petition.

Good work by Alan Cassels who interviewed Wolfgang Becker Brüser of Arznei-Telegramm® in Berlin. Arznei-Telegramm® is one of the oldest and most-established ISDB members and their impressive work can be an example for other members.

Part of the goal of the ISDB newsletter is to share the research produced by so many highly skilled ISDB members. Expect more interviews to follow.

I have emailed all our members regarding issues especially regarding the organisation of the next General Assembly in 2022 and please take the time to send me your thoughts. We are most interested to learn whether our member support us organizing a physical meeting or some kind of online meeting. It is especially important because there should be an election for the new ISDB Committee. Although we need to hold a board election according to our Constitution yet there is no real urgency to do so in 2022 as long as the members agree and we may delay the election until 2023.

Finally, I ask the members to alert us to articles they have published that might be of interest to other members and people outside ISDB. Feel free to contact me or our newsletter editor, Alan Cassels. alan. cassels@ubic.ca

Best wishes, Dick Bijl

### ISDB mourns the passing of Jordi Llinares Garcia



Dr. Jordi Llinares Garcia

The International Society of Drug Bulletins (ISDB) (https://www.isdbweb.org/) is saddened to hear of the unexpected passing of Dr. Jordi Llinares. On behalf of the EMA. Dr. Llinares participated as a speaker in our last General Assembly (2019) held in Paris and showed a strong commitment to building a fruitful dialogue between the EMA and the ISDB. As a worldwide network of independent bulletins and journals on drugs and therapeutics, we would like to praise his open and collaborative character. All this inspires us to persevere in a constructive exchange between EMA and ISDB, in order to better promote high standards of health among the European citizens.

Jordi Llinares García was physician and clinical pharmacologist by training, having started his career at the Hospital Universitari de la Vall d'Hebron and the Hospital de la Santa Creu i Sant Pau in Barcelona, Spain. Then he moved to UK in order to do a master's degree in Epidemiology at the London School of Hygene and Tropical Medicine while working for the EMA. In this institution he served as Head of the Orphan Medicines Section and Head of Scientific and Regulatory Management, among other tasks, before his current position as Head of Research and Innovation. He was the driver behind the PRIME strategy, a scheme to enhance support for the development of priority medicines that target unmet medical needs in Europe.

Jordi Llinares was specially linked to the rare disease community, delivering frequent presentations on orphan medicinal products. He also loved running half marathons for charity in relation to this and other relevant topics. Making the EMA's words our own, he was a man full of kindness, knowledge, generosity and commitment.

Jordi Llinares Garcia died on July 17, 2021 at the age of 52, leaving behind his wife and four children.

Find the EMA announcement here.

## **MEMBER NEWS**

Feature Interview with Wolfgang Becker-Brüser from the German drug information service, Arznei-Telegramm®

What is your background and how did you come to work for Arznei-Tele-gramm®?

I studied pharmacy and medicine in Berlin and joined the Arznei-Telegramm® in 1976. I have been the editor for 25 years

## To what do you attribute the success and longevity of Arznei-Telegramm®?

The most important attributes for the success of Arznei-Telegramm® are our independence, which is assured by our financing which is entirely by subscription fees. That, and the high quality of our articles.

# What are some of the major therapeutic areas have you tackled most succes-sfully?

Some examples include combination contraceptives with new progestogens (a class of steroid hormones that bind to and activate the progesterone receptor) and antidepressants. We frequently published articles critical about these drugs. Subsequently we lost a lot of subscribers (gynecologists and neurologists) who disagreed with our views mostly encouraged by their professional societies which were sponsored by drug companies. Another example was our detailed information about swine flu won us many new subscriptions. (link here)

#### How is your organization making a positive difference in prescribing in Germany, and how do you measure your success?

We're pretty sure Arznei-Telegramm® influences prescriptions of doctors in a positive way. Subscribers tell us that our articles are important for their drug choices yet we have not studied this systematically. Ten years ago we received the Federal Cross of Merit, due to our "contribution to the rational and safe drug use" which tells us we might be doing something right.

#### Is it difficult to maintain a newsletter that is independent from the pharmaceutical industry?

Arznei-Telegramm® has 17 staff full and part-time staff members including nine physicians and one pharmacist. This means, that we have to pay a lot of salaries and our revenue is by subscriptions only.

About the pharmaceutical industry, in our first two decades pharmaceutical companies filed lawsuits, with very high amounts at stake yet we have never lost a court case in more than 50 years. The pharmaceutical industry usually accepts our evaluations. However sometimes pharmaceutical referents give comments to physicians and/or pharmacists trying to discredit an article of Arznei-Telegramm® Currently the industry which sells dietary supplements is more aggressive, but we see them as no real danger if our articles reflect the (missing or weak) scientific basis of the supplements correctly.

What does the future look like for Arznei-Telegramm<sup>®</sup>, and are you planning any new initiatives in the future? We have two projects which other ISDB journals don't have: first a large internet based database with systematic information reaching from indication/dosage to pharmacokinetics for about 18.000 drugs and gives science-based classifications of the drugs from drug of choice to obsolete drugs. Secondly, Arznei-Telegramm® started in the 1980s database of adverse drug reactions which the readers report to us. Currently we are strengthening our digital content. At present about 60% of new subscribers order digital subscriptions, nearly 20% both (print and digital) and a bit more than 20% print only. But most of the existent subscriptions are still print subscriptions. But times are changing.

#### Would you have advice for smaller groups that are part of the ISDB and can you share any secrets of your success?

To give advice is difficult because of the very different situations of ISDB members. Most important in my view are independence and strict quality control of the articles. We should give evidence-based help for physicians and pharmacist to choose drugs for the best health of the patients.

## INR changes after a COVID-19 vaccination

The most recent English language article from Arznei Telegramm? Link <u>here</u>.

#### Petition: Why we petitioned the FDA to refrain from fully approving any covid-19 vaccine this year

Read the blog entry here.

#### Time for Transparency, DTB, May 2021

DTB Deputy Editor David Phizackerley calls for a national registry requiring pharmaceutical and medical device companies to report all payments (and other benefits) made to all healthcare professionals, healthcare organizations and patient support organizations. Link <u>here</u>.

#### Prescrire's Drugs to Avoid, 2021

Read the full list here.

### Vaccines for COVID-19: Is it useful in Japan?

Includes a critical appraisal of the vaccines. Article <u>here</u>.

#### Jean-Louis Montastruc from BIP: Efficacy of COVID-19 vaccines

In this <u>article</u> Jean-Louis writes about the need to express results of clinical trials, using not only RR, but also AR, ARR, and NNT in order to clearly present the clinical interest of drugs.

#### Drugs to avoid to improve quality use of medicines: how is Australia faring?

By Agnes Vitry and Barbara Mintzes. Link <u>here</u>.

Belgian Centre for Pharmacotherapeutic Information report: Controversial FDA approval for anti-Alzheimer's drug aducanumab

Read the article <u>here</u>.

### What matters to you?

We are reaching out to the ISDB Committee for your opinions about our future General Assembly, needed updates to our website and suggestions for the ISDB newsletter. If you have any suggestions please contact our Newsletter Editor, Alan Cassels at alan.cassels@ubc.ca.