

Data and cost sharing

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Working together brings benefits

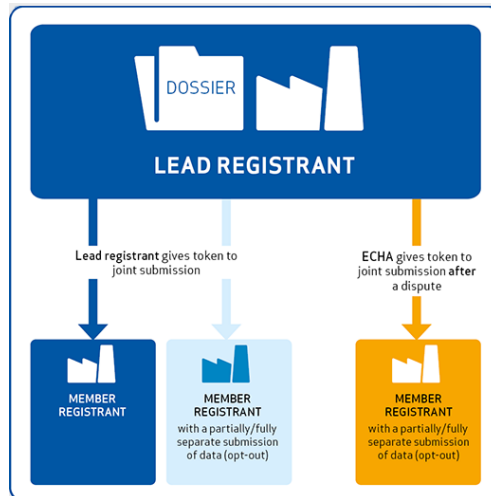
- Shares the cost among all co-registrants of the same substance
- Minimises tests on animals
- It's fair

...and it's a legal requirement



Joint submission

- Typically all co-registrants agree and submit all information jointly
- Opt-outs
 - partial
 - full
- Disputes
 - on data
 - on token



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Sharing data and cost

- Not for profit
- Must be fair, transparent and non-discriminatory
- The more people register, the less cost for everyone



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Item	Tonnage band	Cost of study	Administration cost	Justification
Study 1	1-10 t	1 000 €	100 €	Justification 1
Study 2	1-10 t	2 000 €	80 €	Justification 2
Study 3	10-100 t	3 000 €	130 €	Justification 3
Token	N/A	-	50 €	Justification Token
SIEF	10-100 t	-	500 €	Justification SIEF

Transparency

- Itemisation of data and **administrative** costs
 - Must be in relation to information requirements
 - Must be justified
 - Must be provided upon request without undue delay
- Cost-sharing model must include a **reimbursement** mechanism
- Co-registrants must agree on a mechanism for sharing **future** costs (e.g. spontaneous dossier updates, substance evaluation, dossier evaluation)

Fairness and non-discrimination

- Equal rights for all co-registrants
- Unanimous agreement needed for waiving from itemisation and reimbursement
- Model 'fair' in 2010 might not be 'fair' to 2018 registrants



DOs and DON'Ts for effective data sharing

- ✓ Be reliable, consistent and open in all negotiations
- ✓ Act within the legal deadlines
- ✓ Keep written records of all steps of the negotiations, every email, call and meeting
- ✓ Treat the company/person you are negotiating with as you would expect to be treated
- ✓ Be clear and unambiguous in what you are seeking
- ✓ Be sensitive to the capacity, size and situation of the party you are negotiating with
- ✓ Reply promptly to all reasonable requests/questions/communications
- ✓ Give the other party a fair and reasonable amount of time to reply to you
- ✓ Base negotiations on the data and their value
- ✓ Assess critically each information you receive during negotiations
- ✓ Be concrete if you disagree with the proposed offers



DOs and DON'Ts for effective data sharing

- ✗ Expect the other party to do your work for you
- ✗ Give an unreasonable timeframe in which to complete the negotiations
- ✗ Disclose confidential or commercially sensitive information
- ✗ Ignore the costs (time, resources, etc.) involved in the negotiations
- ✗ Delay
- ✗ Send confusing signals
- ✗ Ignore issues raised
- ✗ Negotiate the price without considering objective criteria



Disputes

- Measure of last resort - every effort to be made first to reach voluntary agreement
- For free and no lawyer needed
- Can be on data or on token
- Reasons could be:
 - lack of transparent itemisation
 - discriminatory cost sharing mechanism (e.g. lack of reimbursement, not everyone pays its share)
 - price not dependent on information requirements
 - administration cost not related to tonnage band
 - unjustified annual increases of prices
 - risk premium applied on everything



Key messages



- Take the initiative in SIEFs that are crucial for your business – prioritise your most important substances
- Spend money and time on right substance – pay attention to substance sameness before kicking off data sharing
- Focus your discussions on getting things done
- Preparing a dossier is a shared and individual responsibility – check regularly that the work is progressing – don't just rely on the lead. Your registration is your "business card".
- Sharing data is not for profit – must be fair, transparent and non-discriminatory

Support from ECHA – all in your language

- Practical advice for new SIEFs
- Joining an existing registration – negotiation tips
- Info about dispute mechanism
- Guidance on data-sharing



Coming soon:

- Illustrative examples

Thank you!

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