EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory Optimisation Group (ROG)
Update on Type IAs business case: Opportunities and Challenges

EU IDMP/SPOR TF face to face meeting
London, 23 March 2018

Evdokia Korakianiti, ROG member
Head of Procedure Management Dpt, EMA

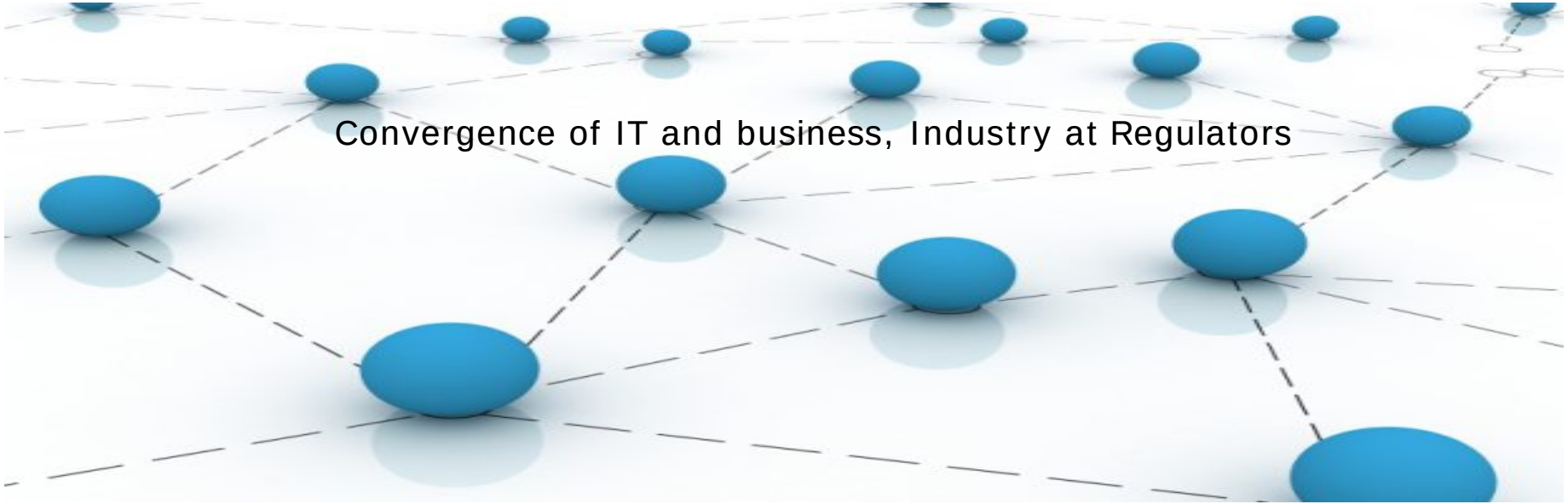
Aim

Provide an overview of the draft ROG business case on Type IA variations, which is pending HMA approval

Regulatory Optimisation Group (ROG)

ROG is about connecting the dots and building links

Building a common language and common vision



Type IA notifications business case - Problem statement

Minor (low risk) changes that occur in **high volumes,**

creating an **administrative burden**

Simple Do and tell changes

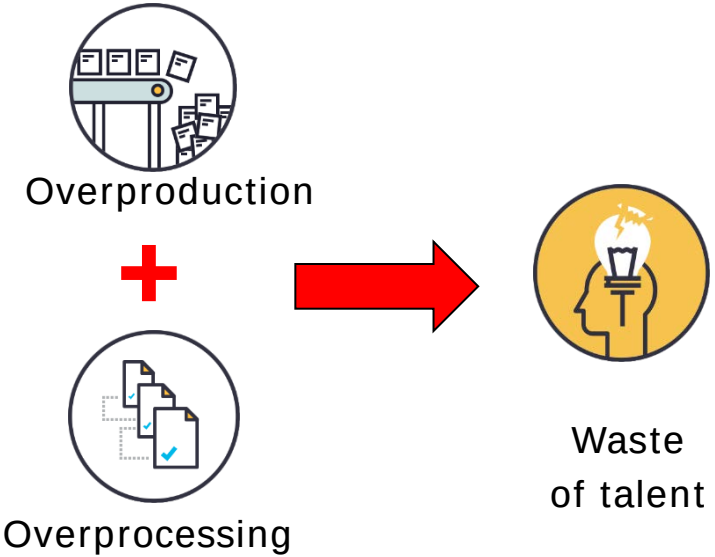
requiring more resources than desirable

To free up time for more value-adding activities to ultimately benefit the patients

‘As is’ scenario – NCAs resource Estimates[1] to process Type IA variations

ROG has attempted to baseline the amount of effort spent by NCAs to process Type IAs, the figures are estimates not absolute values that can be used to understand the proportion of savings from the ROG proposals.

Authorities	Process	Average time spent (minutes) [1]	Volume 2016 [2]
	CP as EMA	148	1.852
	CP as NCA	46	14.446
	MRP as CMS	103	71.635
	MRP as RMS	205	15.912
	National	153	49.704
	Total	**555**	**153.549**



[1] The data demonstrate an average over the entire Network and should therefore be read as indicators of estimated benefits and not as actual values. Also, grouping and supergrouping of variations were only to some extent considered in the calculation. Lastly, the figures are based on the answers from a significant number of NCAs, but not all (h, v and mixed),

[2] Volumes used from NCA:s/EMA gathering. It is estimated that about 8% of all type 1A variations are related to veterinary products.

‘As is’ scenario –Resource Estimates for Industry

	No of type IA variations[1]	Time to prepare type IA variation / MAA (min) [2]
Human	141.265	101
Veterinary	12.284	209
Total	**153.549**	**310**

Industry spends a significant amount of its capacity in processing Type IA notifications

[1] It is estimated that about 8% of all type 1A variations are related to veterinary products,
[2] Mean total time needed to prepare & submit 1 type IA variation

Key Industry findings

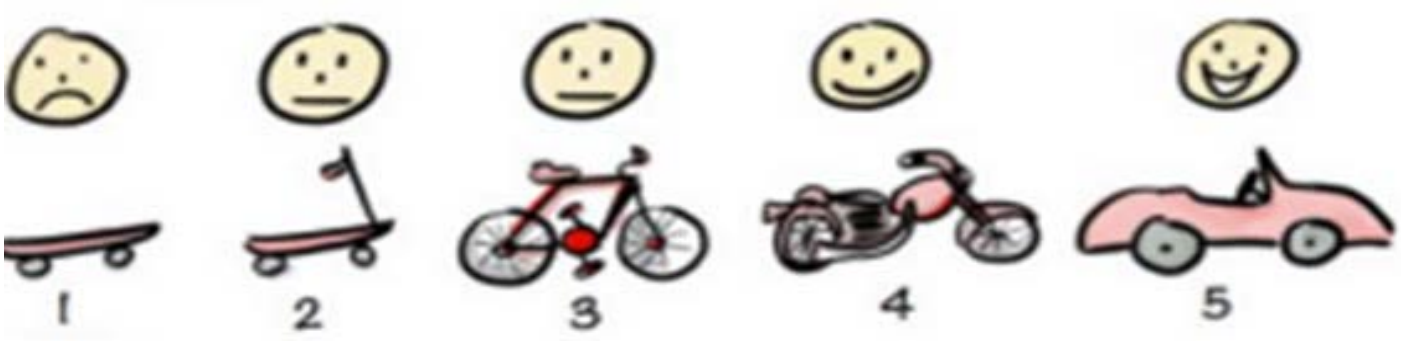
The most resource consuming cases:

- Certificate of Pharmaceutical Product (CEP) related variations,
- Handling national requirements
- Product Information variations
- Cover letter preparation

Submission via CESP significantly reduces time to process variations

ROG – Type IAs optimisation roadmap

Long term vision that will be delivered incrementally as IT solutions (existing and new) become available and the Variations Classification Guideline is revisited



ROG recommendations for the proposed Type IAs business case

Over processing

Use IT enablers e.g. SPOR, to remove duplication of checks and automate the process
→ ultimate goal: “QPPV” style handling

Simplify submissions by:

- Replacing the cover letter with an electronic delivery file;
- Replacing the copy of the Guideline and other confirmation checks with confirmations in the eAF
- Automatic updates of PI
- Use SPOR to remove duplication of checks relating to GMP aspects

Overproduction

Simplify certain scopes of the Classification Guideline e.g. CEP updates

Variations Classification Guideline to be amended to allow reporting via databases → ultimate goal: “QPPV” style handling

Solutions: reducing the process time spent and lowering the volume of Type IA submissions

By introducing solutions that reduce the average time spent, and lowering the volumes, a capacity increase of up to a max. of **65%** **for authorities** could be expected, if all recommended solutions are in place.

	Process	Average time spent (minutes)	Average time spent after process change (minutes)	Volume 2016	Estimated volume after reduction measures
Authorities	CP as EMA	89	42	1.852	1.111
	CP as NCA	46	22	14.446	8.667
	MRP as CMS	103	57	71.635	42.981
	MRP as RMS	205	103	15.912	9.547
	National	153	98	49.704	29.822
	Total			**153.549**	**92.128**

To realise the benefits of the business case

To enable the delivery of this vision ROG needs to work with its stakeholders responsible for elements that will enable the realisation of benefits.

- SPOR: for the expected delivery of “P” from
- CESSP and eAF
- EDQM, EC, CMDs on aspects relating to the optimisation of regulatory guidance

ROG also recommends to HMA to encourage initiatives like the ePI and the use of SPOR for inspection purposes

All IT related solutions to be approved through EU TMB governance

Summary

- ROG with its first business case proposes to HMA quantifiable solutions for Optimisation of Type IAs
- The solutions will be delivered by the relevant stakeholders
- Expected capacity increase will come with the need for development/updates of IT solutions and changes in working practices
- Short/medium/long-term deliverables, which could then be deployed to other regulatory procedures e.g. IBs, Type IIs etc

Any questions?

Further information

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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