Ministero della Salute
Direzione generale della sanità animale e dei farmaci veterinari

Benchmarking delle Agenzie Europee dei Medicinali: risultati dell'ultimo audit

12° INFO DAY
I medicinali veterinari

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BENCHMARKING

- Che cos'è
- Finalità
- Metodologia
- Risultati

Benchmarking

BENCHMARKING

*"… un approccio **sistematico e continuo** per identificare gli **standard di prestazione** (benchmark), **confrontare** se stessi con questi, e identificare le **prassi** (practices) che permettono di diventare il nuovo standard di riferimento (new best in class)".*

Confrontarsi per migliorare

BEMA

BEMA

Benchmarking of **E**uropean **M**edicines **A**gencies

Il programma BEMA, *iniziativa degli HMA (Heads of Medicines Agencies),* prevede audit internazionali e autovalutazioni periodiche, al fine di verificare l'applicazione delle cosiddette "Buone Pratiche Regolatorie" mediante la valutazione di una serie di indicatori di prestazione delle organizzazioni che ricoprono il ruolo di "Autorità Competente Nazionale" per il settore dei medicinali .

Finalità

- ✓ Supportare le Autorità competenti per i medicinali nel loro ruolo di salvaguardia della salute umana e veterinaria
- ✓ Contribuire ad un approccio regolatorio per i medicinali affidabile, sostenibile e armonizzato
- ✓ Garantire il miglioramento continuo, la coerenza e una maggiore efficienza
- ✓ Creare una rete di Autorità competenti

Audit BEMA: Approccio sistematico e continuo

2005
BEMA I

2010
BEMA II

2013
BEMA III

2018
BEMA IV

?
BEMA V

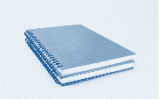
Struttura

Steering Group

- Metodologia
- Documentazione
- Pianificazione

Questionario

- POS
- Linee guida
- Modulistica

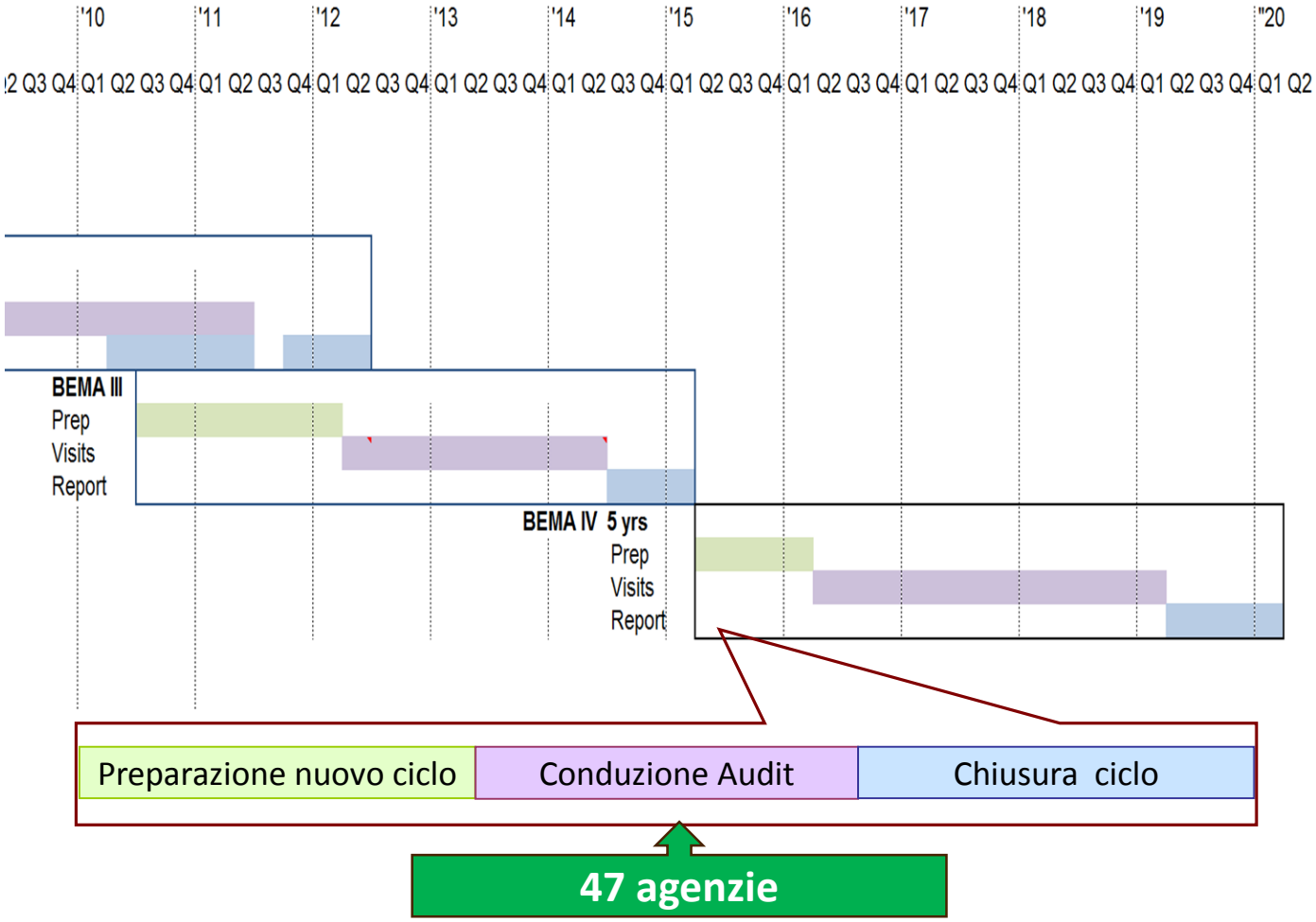


Training

- Team leader
- Assessors

Pianificazione audit

BEMA- Ciclo attività

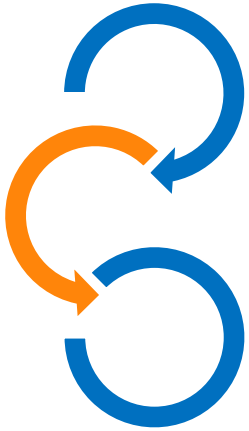


Con chi ci confrontiamo?

Autorità competenti per i medicinali veterinari	Staff
Bulgaria	0-49
Cyprus	
Hungary	
Italy	
Latvia	
Malta	
Slovak Republic	
Lithuania	
Portugal	
Czech Republic	
Croatia	
Germany BVL	50-99
France	
Romania	
United Kingdom	100-499

BEMA IV - processo

- Self-assessment (1.03.2017 – 5.03.2018)
- Valutazione/ attribuzione di un punteggio
- Individuazione di punti di forza e opportunità di miglioramento
- Data base



BEMA IV - Questionario

KPI	*Descrizione*
1	Strategy and planning
2	Leadership and culture
3	Stakeholders
4	Quality management
5	Risk management
6	Crisis management
7	Human resource management
8	Operations management
9	Information management
10	Interfaces
11	Scientific decision making
12	Impact/ effectiveness of regulation

- **Management systems;**
- **Assessment of marketing authorisation applications;**
- **Pharmacovigilance (drug safety) activities;**
- **Inspection services.**

Key **P**erformance **I**ndicators
12 KPIs

Specific **P**erformance **I**ndicators
41 SPIs

Questionario BEMA IV

BEMA IV QUESTIONNAIRE

INDICATORS

descrizione dei risultati attesi in relazione all'indicatore descritto

guida alla compilazione della risposta

Descrizione del livello di maturità per aiutare l'agenzia e gli assessors ad effettuare la valutazione individuando il punteggio corretto.

KPI	NAME OF INDICATOR					
KPI 1 Strategy and planning						
1.1 SPI	Setting objectives and targets	**Goal** Long-term planning ensures that an agency is fully-prepared for future challenges and opportunities. Setting good goals, objectives and targets ensures that its activities are directed towards the achievement of its mission, vision and strategic goals. **Assessment criteria** – Is the vision, mission, strategy set by top management, in line with the legislation? If so how is it done and for how long (e.g., three or five years)? – Is there input from stakeholders (legislators, ministry, healthcare professionals, patients, industry?) Is staff consulted? How are the strategic concerns of the EU network of agencies and other partners, national and international, taken into account? How is the input sought and used? Is there feedback to stakeholders on the input they have provided and how it has been taken into account in the strategy? – Does the strategy development use any particular methodology for the process or for the outputs? (SWOT, balanced scorecard, PESTLE, or other methods applicable?) What external and internal factors are taken into account: external factors such as new and revised legislation, new drug and device technologies and internal factors including structure, systems, infrastructure needs and development? – Is there a good structure to the strategic p… Are measures/indicators focussed on outputs or outcomes and/or i… programmes) brought in line with the strategy? How measurable a… – How is the strategy approved and by who… – How are the strategic plan and annual wo… – Has the process been reviewed and evalu… **Rating level maturity statements**				
		1	2	3	4	5
		The agency does not have a medium or long-term planning process; there is little evidence of objectives and targets at agency or department level.	Some elements are in place – perhaps a mission and some loosely connected objectives and targets - but there is no formal system for their development and little analysis of the current and future operating environment.	A mission, vision and strategy are in place, with a formal system for development using some external and internal environmental analysis. Some objectives and targets have been set based on the strategy.	There is a formal system for development of the strategy, using a range of analytical tools and inputs, including stakeholder consultation. Clear objectives and targets are set and accordingly being measured and reported	The agency has a strongly integrated planning system with rigorous analysis of the environment using a range of tools and methodologies. Objectives and targets are clearly related to the issues identified and

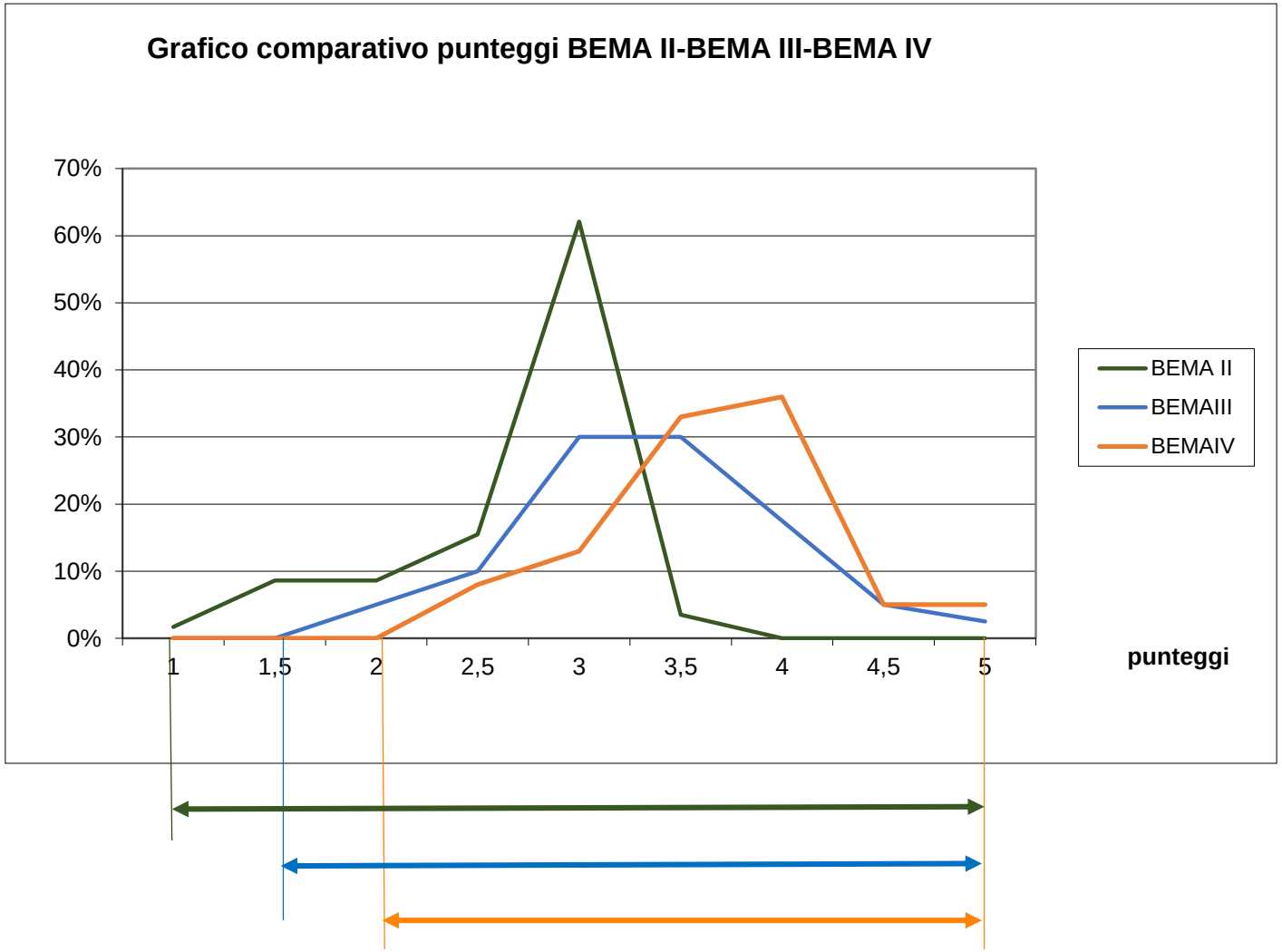
BEMA IV - risultati

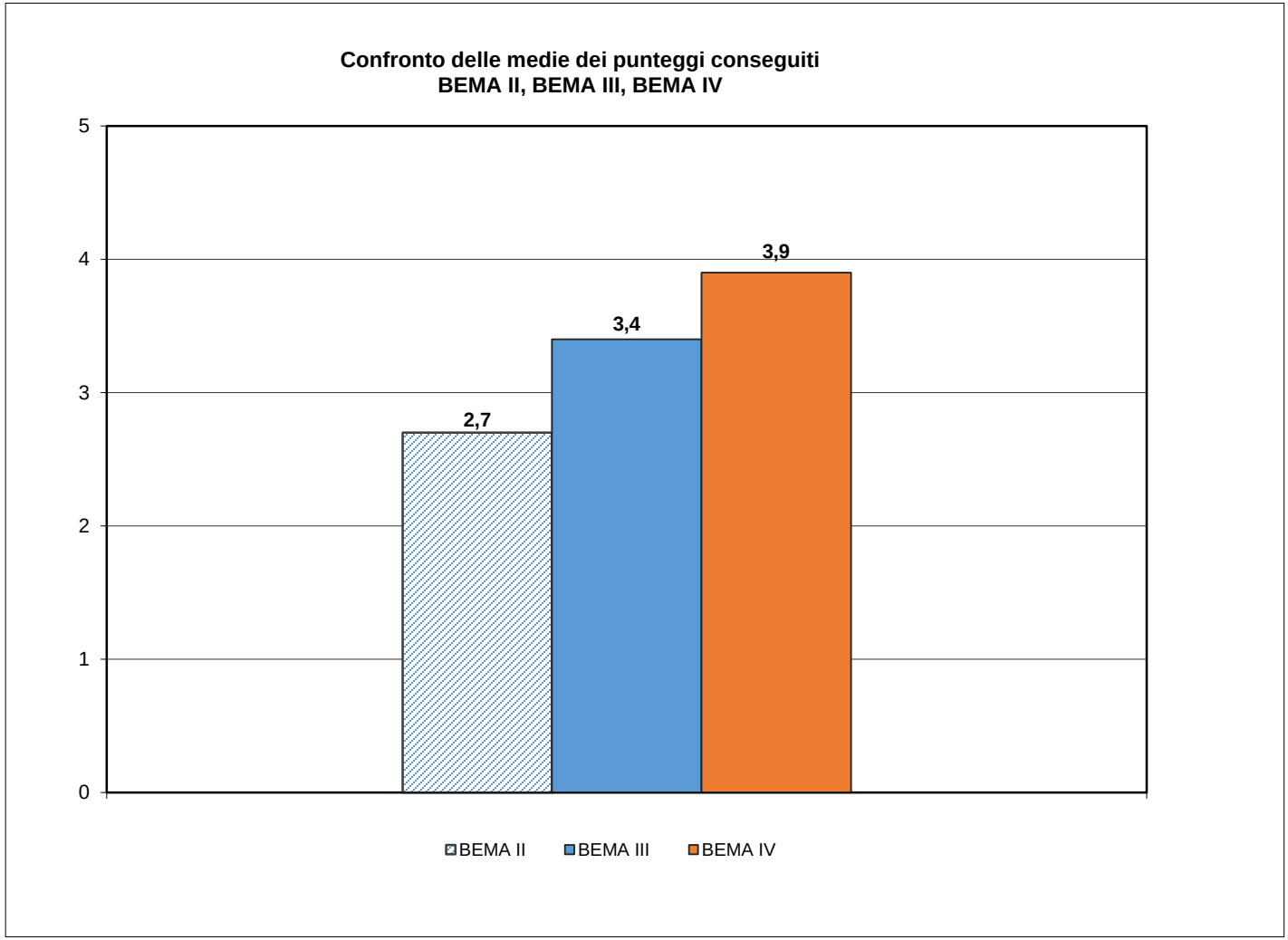
KPI	Descrizione	Punteggio medio
1	Strategy and planning	3.9
2	Leadership and culture	3.7
3	Stakeholders	4
4	Quality management	4
5	Risk management	3.2
6	Crisis management	3.5
7	Human resource management	3.2
8	Operations management	3.4
9	Information management	3.5
10	Interfaces	3
11	Scientific decision making	3.8
12	Impact/ effectiveness of regulation	4

Transparency (SPI 3.2)
Punteggio 5

Inspections (SPI 12.5)
Punteggio 5

BEMA IV - risultati




Confronto delle medie dei punteggi conseguiti
BEMA II, BEMA III, BEMA IV
5
4
3
2
1
0
2,7
3,4
3,9
BEMA II
BEMA III
BEMA IV

Grazie per l'attenzione