



Università Commerciale
Luigi Bocconi

CERGAS
Centre for Research on Health
and Social Care Management

BocconiALUMNI
ASSOCIATION

SDA Bocconi
School of Management



CONVEGNO OASI 2016

Il Rapporto OASI 2016

Governo dell'assistenza farmaceutica in Italia

Possibili traiettorie di cambiamento

Claudio Jommi

N. Amoroso, P. Armeni, F. Costa, M. Otto
CERGAS e SDA Bocconi

In collaborazione con:



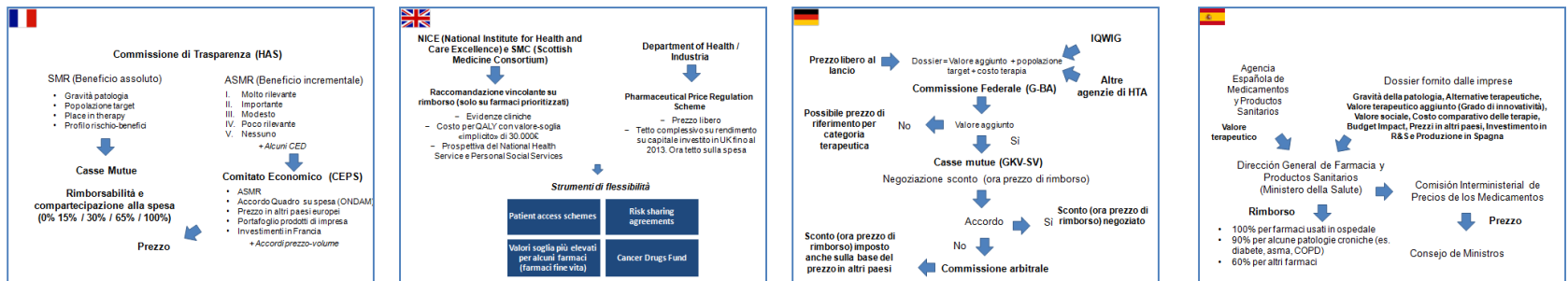
Science For A Better Life

Medtronic

Milano, 14.11.2016



Guardare a esperienze e raccomandazioni internazionali per sostanziare le proposte di riforma della politica del farmaco in Italia



EUneHTA JA2 WP8 DELIVERABLE
HTA Core Model Version 3.0

for the full assessment of
Diagnostic Technologies,
Medical and Surgical Interventions,
Pharmaceuticals and
Screening Technologies

The EUneHTA JA 2 (2012-2015) has received funding from the European Union, Framework of the Health Programme

EUROPEAN NETWORK FOR HEALTH TECHNOLOGICAL ASSESSMENT

EUneHTA Guidelines

The development of the methodological guidance in the areas where such guidance is missing, was included already in the work plan of the EUneHTA JA (2010-2012). Contribution to developing and testing a methodological basis for European cooperation on HTA including guidelines for distinct methodological issues was one of the objectives of the EUneHTA JA2 (2012-2015). Specifically in EUneHTA JA2 (2012-2015), the scope of work on producing methodological guidelines focused on development of "methodological guidelines on pertinent issues of assessment (e.g. for devices) or update existing guidelines according to needs and resources".

The primary aim of the guidelines is to help the assessors of evidence to process, analyse and interpret the data.

The links to all published EUneHTA methodological guidelines can be found below:

EUneHTA JA2 (2012 - 2015)

a) Updated EUneHTA JA (2010 - 2012) Methodological Guidelines for rapid relative effectiveness assessment (REA)

The EUneHTA JA2 Work Package 7 member organisations reviewed the contents of the EUneHTA JA (2010-2012) methodological guidelines on REA of pharmaceuticals (see below). They decided to extend the scope of the text and recommendations from pharmaceuticals only to the assessment of all health technologies. Content and recommendations remained unchanged.

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ISPOR TASK FORCE REPORT

Multiple Criteria Decision Analysis for Health Care Decision Making—Emerging Good Practices: Report 2 of the ISPOR MCDA Emerging Good Practices Task Force

Kevin Marsh, PhD^a, Marwan Samaan, PhD^b, Phagen Thakke, MSc, PhD^c, Rob Bellman, PhD^d, Michael Brennan, MSc^e, Zoran Slob, MSc, PhD^f, Thomas L. Johnson, MEd (Pharm)^g, Filip Mecklin, MEd, PhD^h, Stuart Peacock, MSc, DPhMⁱ, John Warkles, PharmD, MPH, ScD^j, Nancy Gattell, PhD^k

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ISPOR TASK FORCE REPORT

Multiple Criteria Decision Analysis for Health Care Decision Making—An Introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force

Phagen Thakke, MSc, PhD^a, Nancy Gattell, PhD^b, Kevin Marsh, PhD^c, Rob Bellman, PhD^d, Michael Brennan, MSc^e, Zoran Slob, PhD^f, Thomas L. Johnson, MEd (Pharm)^g, Stuart Peacock, PhD^h, John Warkles, PharmD, MPH, ScDⁱ, Marwan Samaan, PhD^j

^aOffice of Health and Service Research, University of Toronto, Toronto, The Netherlands; ^bUniversity of Washington, Seattle, WA, USA; ^cNational Institute for Health Care, Vilnius, The Netherlands; ^dThe Netherlands; ^eDepartment of Health Policy and Health Economics, Bristol Medical University (Bristol), Bristol, UK; ^fThomas Research Institute, Budapest, Hungary; ^gMSA Group LLC, US and Sweden; ^hThomas (University) Corporation of Illinois & Johnson, Arlington, Virginia; ⁱCarlsson Center for Digital Health in Care Center, Swedish Clinical Care Agency, Stockholm, SE; ^jCanada; ^kTask Force Chair in Cancer Technology, Dana-Farber Cancer Center, Cambridge, MA, USA; ^lUniversity of Washington, Seattle, WA, USA; ^mDepartment of Health Technology & Service Research, University of Toronto, Toronto, The Netherlands

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ISPOR TASK FORCE REPORTS

Performance-Based Risk-Sharing Arrangements—Good Practices for Design, Implementation, and Evaluation: Report of the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force

Luca P. Carrasco Jr., PhD (co-chair)^a, Adnan Thakke, MA, MPH (co-chair)^b, Andrea Boffa, MSc, DPhM^c, Gerard J. Heuser, BA, PhD^d, Jens Granger, PhD^e, Nancy E. Miller, MA^f, J.L. Blazing Science, PhD^g, Roda Skonec, BA^h

^aPharmaceutical Outcomes Research & Policy Program, Department of Pharmacy, University of Washington, Seattle, WA, USA; ^bOffice of Health Economics, London, UK; ^cThomas Research Institute, Budapest, Hungary; ^dMSA Group LLC, US and Sweden; ^eThomas (University) Corporation of Illinois & Johnson, Arlington, Virginia; ^fCarlsson Center for Digital Health in Care Center, Swedish Clinical Care Agency, Stockholm, SE; ^gCanada; ^hTask Force Chair in Cancer Technology, Dana-Farber Cancer Center, Cambridge, MA, USA; ⁱUniversity of Washington, Seattle, WA, USA; ^jDepartment of Health Technology & Service Research, University of Toronto, Toronto, The Netherlands; ^kAgency for Health Care Research and Analysis, Ottawa, Ontario, Canada; ^lTask Force Chair in Cancer Technology, Dana-Farber Cancer Center, Cambridge, MA, USA; ^mOffice of Health Economics, London, UK

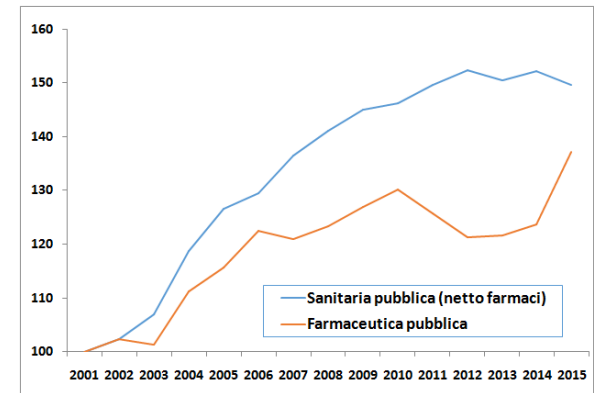


1. Rivedere il sistema dei tetti

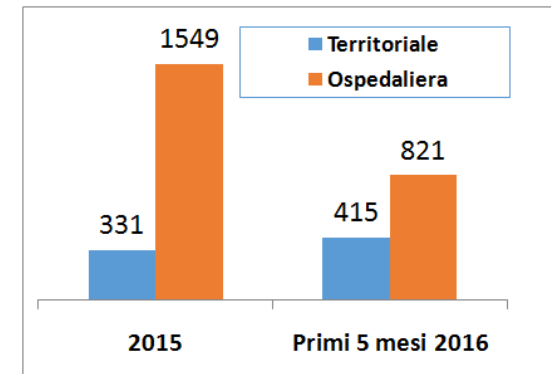
- Garanzia formale ex ante del controllo della spesa
- Logica silos
- Complessità della gestione del payback

 2 tetti, % Risorse SSN	 Target negoziato	 Target negoziato
	 No	 No

Spesa sanitaria e farmaceutica (2001=100)



Sfondamento tetti spesa (m.ni Euro)



Due tetti meno critici
nella gestione dei flussi



Previsto da nuova
Legge di Bilancio

Un solo tetto

Target


No target

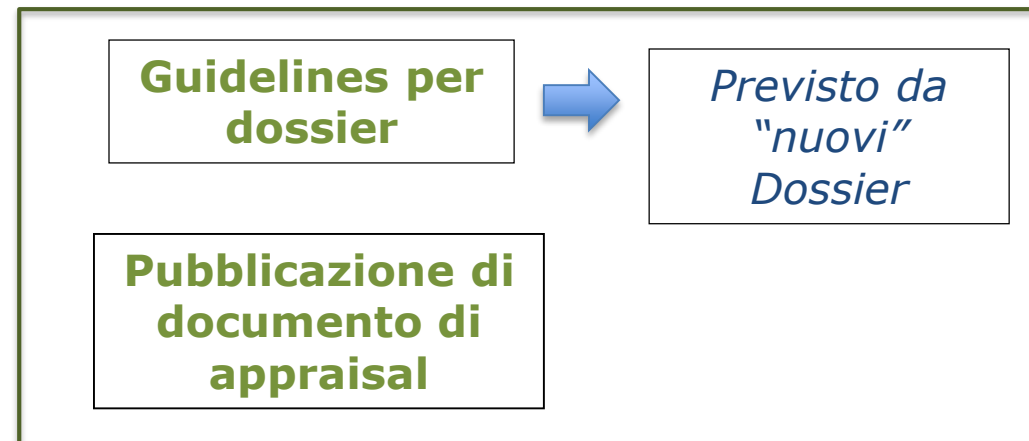


2. Aumentare il livello di trasparenza

- Dossier CIPE 3/2001 come uno dei primi Dossier P&R
- No trasparenza ex ante (criteri per la compilazione del dossier)
- No trasparenza ex post (documenti di assessment / appraisal)

Documenti di appraisal / assessment sul farmaco



 No	 Sì (HAS, Avis)	 Sì (NICE, TA; SMC, Advice)
	 Sì (G-BA, Beschluss)	 Nì (AEMPS, Informe) (solo 'place in therapy' raccomandato)



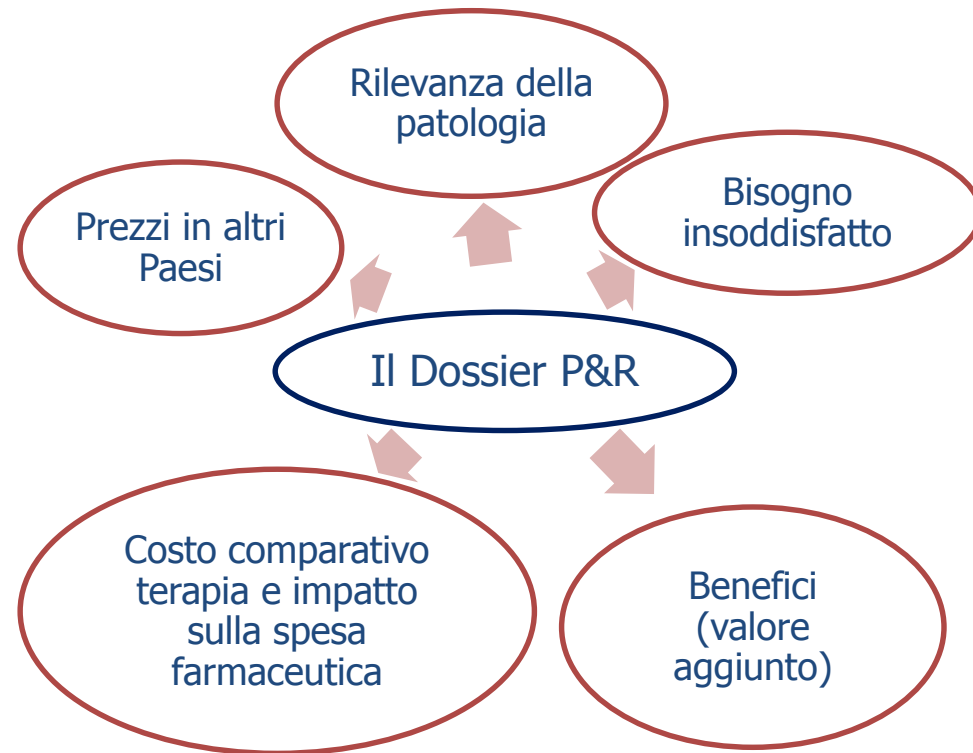
3. Modificare i criteri di valutazione senza stravolgere l'approccio multiplo (1)

- Approccio silos nella valutazione dell'impatto economico
- No criteri espliciti su "valore aggiunto"
- Legame prezzo / valore aggiunto non noto "ex ante"

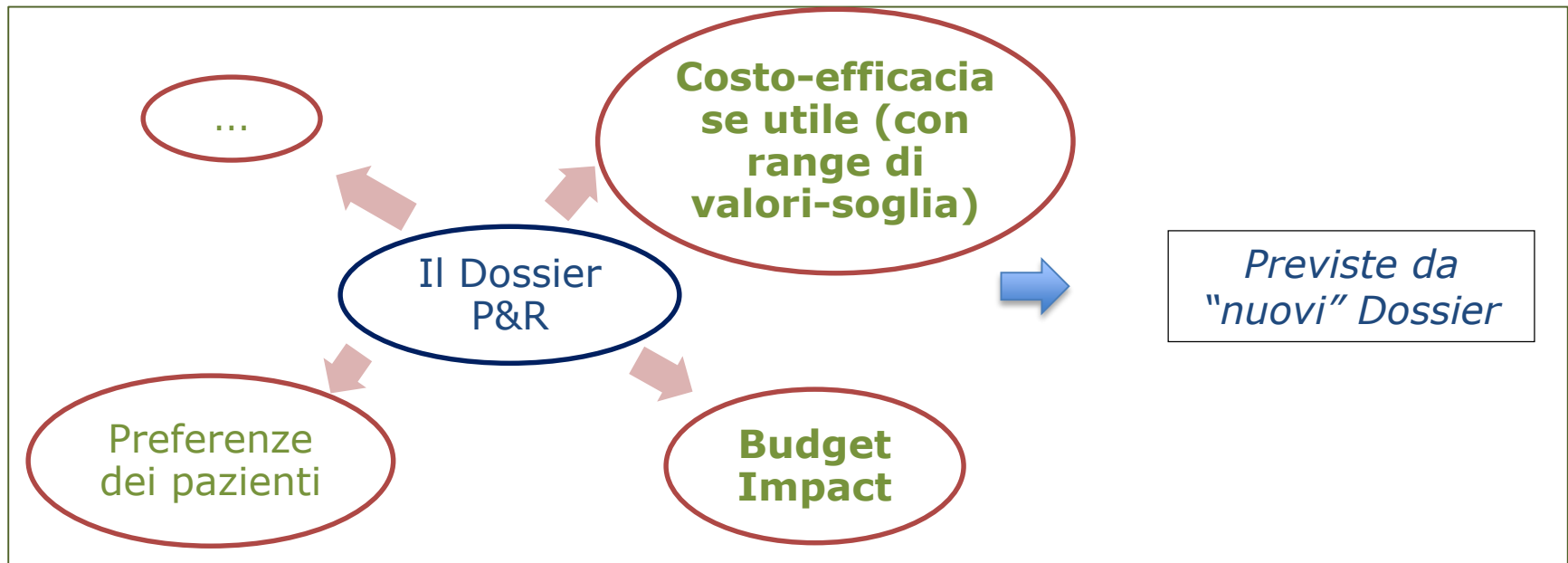
Innovatività nel sistema di P&R

 Approccio dicotomico (Nessun criterio esplicitato)	 Valore aggiunto (5 Livelli - Primi due livelli premium price)	 Incremento assoluto in QALYs (soglia costo-efficacia determina "value for money")
	 Valore aggiunto (6 livelli) (Rischio prezzo di riferimento in assenza di valore aggiunto e negoziazione sconto sulla base del valore aggiunto)	 Non noto (premium price del 10/20% se farmaco è innovativo)

I criteri oggi più rilevanti in Italia



3bis. Modificare i criteri di valutazione senza stravolgere l'approccio multi-criterio (2)



Cornice di priorità ai criteri (MCDA "blanda")

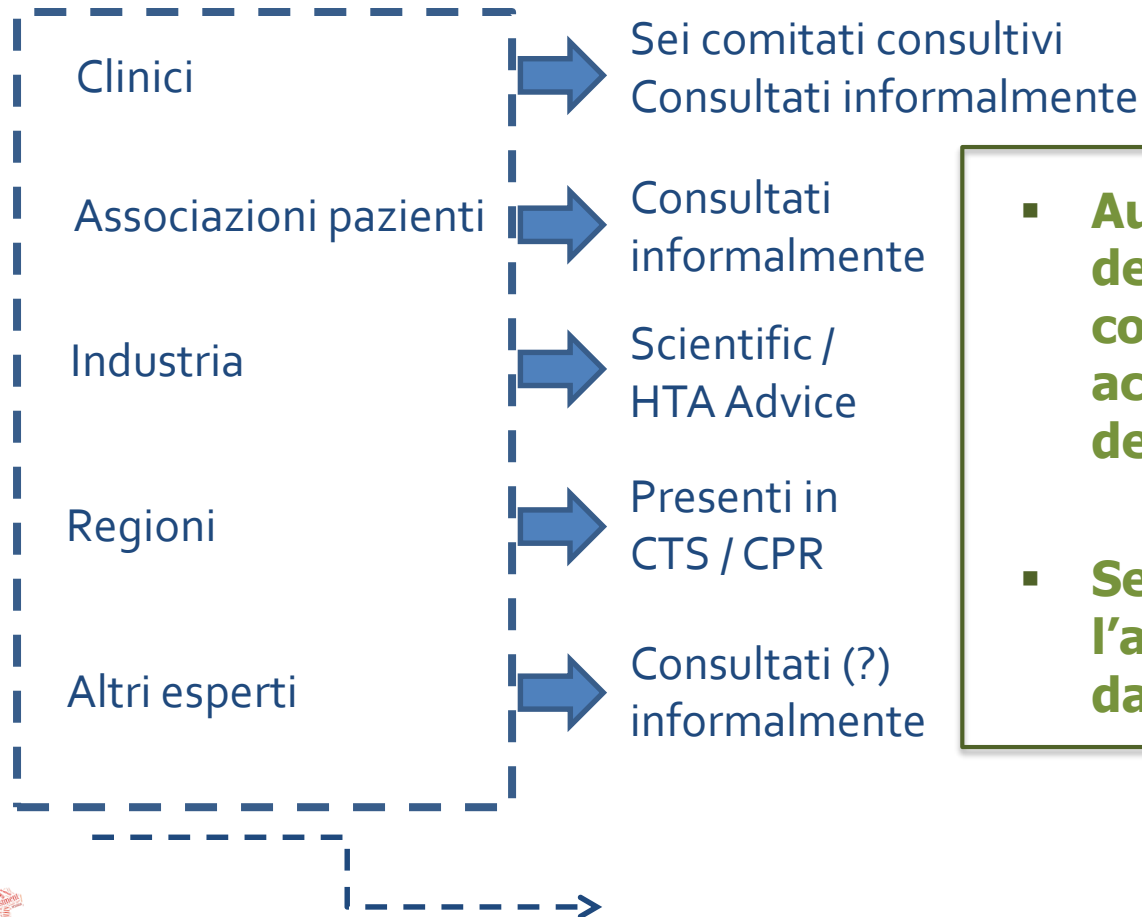
Criteri di valutazione dell'innovatività (preferenza per ranking) ed effetti sul pricing

Previsto da Legge di Bilancio (entro Marzo 2017), ma in logica dicotomica



4. Migliorare le relazioni con gli stakeholder

Coinvolgimento stakeholder e comunità scientifica in AIFA

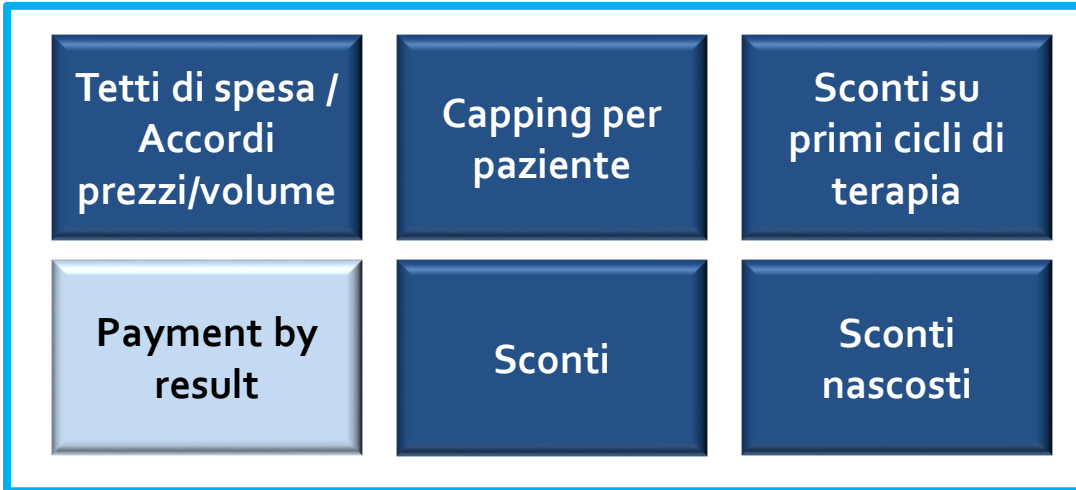


- **Aumentare il coinvolgimento degli stakeholder e della comunità scientifica (rete accreditata di "valutatori" dei dossier)**
- **Separare in modo più chiaro l'assessment tecnico dall'appraisal**



5. Gestire al meglio i Managed Market Entry Agreements (MMEA)

Uso estensivo di accordi



- **Uso selettivo degli accordi (e rimozione di quelli outcome-based dopo due/tre anni)**
- **Definizione standard applicabilità MMEA**
- **Adozione di accordi outcome-based su popolazione**
- **Trasparenza totale a livello interistituzionale**
- **Pubblicazione effetti accordi**



6. Chiarire rapporto Stato-Regioni



**Prontuario, Livello base
di compartecipazione,
Prezzo massimo di
acquisto, MMEA, Farmaci
soggetti distribuzione
diretta (o per conto)**



**Compartecipazioni
(integrazioni), Governo del
comportamento
prescrittivo, Acquisti,
Implementazione di forme
alternative di distribuzione**





**La politica del farmaco non va
stravolta, ma modificata, resa più
trasparente e stabile nel tempo**

GRAZIE

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