Delivering the benefits of the new PSUR for healthcare professionals and patients – efficient and effective implementation

An Industry perspective

Klaudija Marijanovic Barac
Director, Global PSUR & RMP Unit
Teva Periodic Reports & Risk Management Centre

Periodic Safety Update Report Information Day
28 October 2016 | London, UK

DIA DEVELOP INNOVATE ADVANCE

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organisation with which the presenter is employed or affiliated.

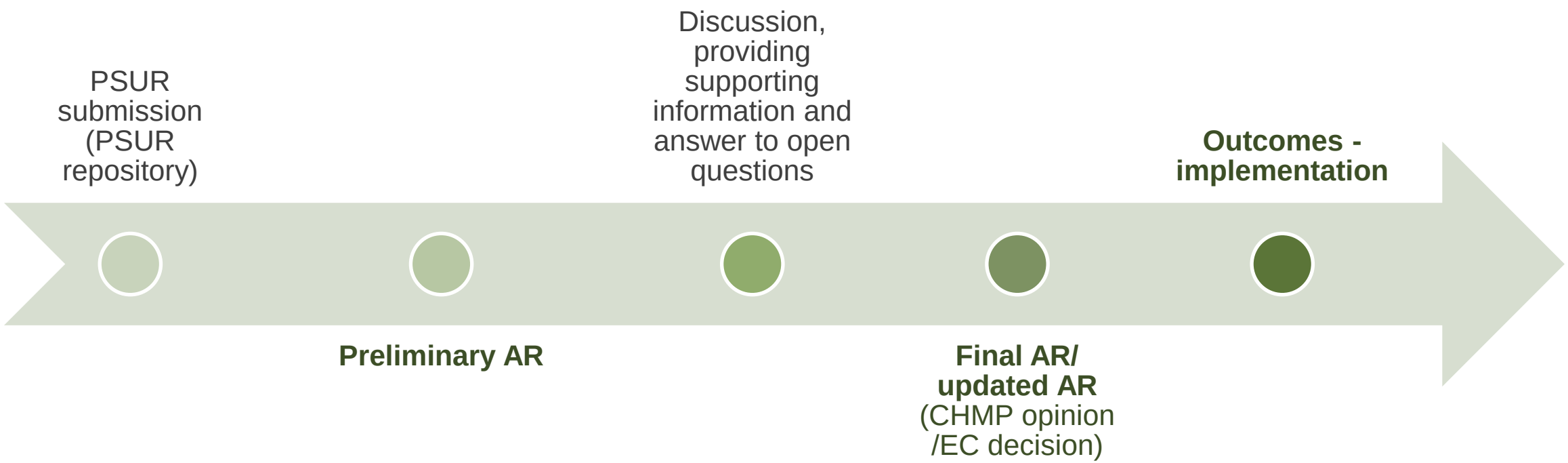
Background

- PSUSA outcomes
- Implementation process
  - Centralized company coordination of PSUR process
  - Process with national authority
  - Generic and branded experience
  - Main challenges
- Key focus on public health protection

Joint PSUR assessment accomplishments

- Transparency
- Better product overview (pooled data from all stakeholders, referent product data)
- Focus on providing better information to healthcare providers and patients

PSUR assessment



PSUR repository

- Access for industry to the PSUR repository
- MAH could check timelines and information around PSURs
- Better streamline and handling of procedures for efficient national implementation

Assessment report influencing national implementation

- EMA sends assessment reports only to MAHs that are involved in the process
- Proposal to extend the distribution of Final AR to all MAHs in the EU – all MAHs need to implement the outcomes
- Final ARs are published on EMA websites – not easy to search
- EMA could facilitate using Art 57 which is directly linked to the EMA repository

Main PSUR assesment outcomes

- Monitoring of safety issues
- SPC/PL update*
- Update of existing RMP
- Additional minimization measures*

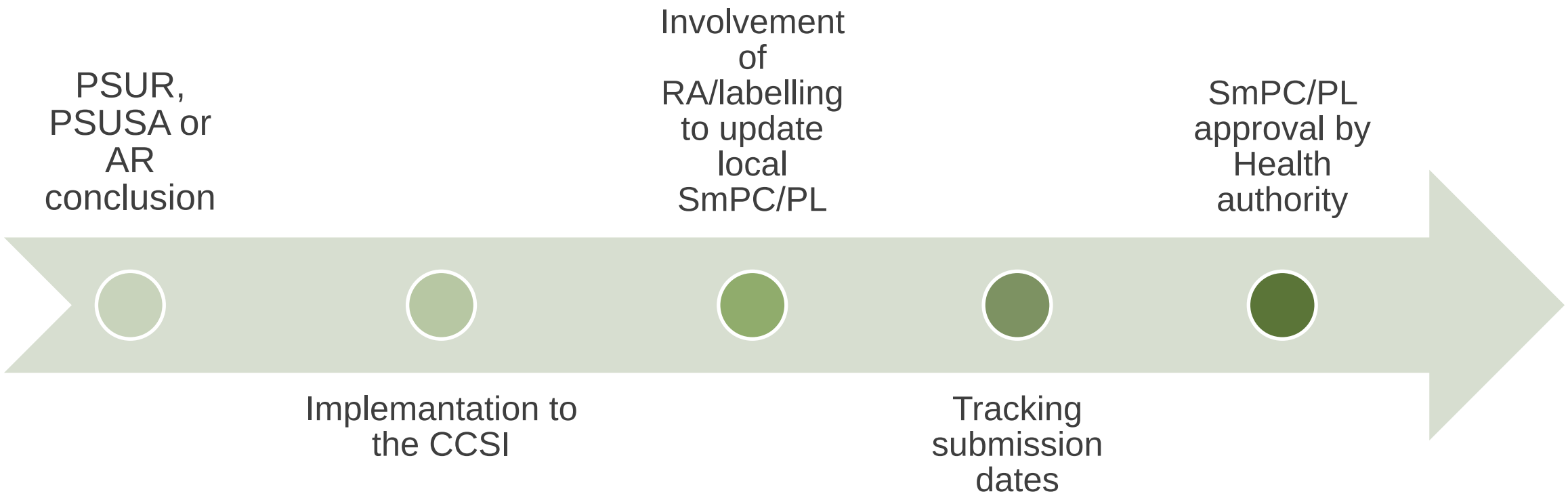
*national implementation

PSUR outcomes & industry organizational structure

	Monitoring of safety issues	SPC/PL update	RMP update	Additional risk minimization measures
Central PhV	√	√	√	√
Local PhV		√		√
Reg. Affairs (RA)		√	√	√
Other stakeholders				√

What to take into consideration at assessment level for better implementation				
High level remarks	Consistent use of terms „signal – safety issues – risk” (per GVP /ICH definitions)	Company internal process & Timelines	Clear instructions what should be changed in the RMP	Provide feedback to all stakeholders (MAHs)

From CCSI update to SPC/PL implementation



Sources of CCSI updates

- EU PSUSA (PSUR) Assessment Reports
- EU Referrals (30, 31, 45, 46)
- PRAC recommendations on signals
- CMDh advices
- Alignment with innovator (generics)
- Requests from other national authorities
- Internal signals from database, literature, studies, license partners

National implementation coming from PSUSA/PSUR AR

- Clear expectations
- Usually smooth process of national approval
- Agency publishes the translations in all EU languages
- Type IAIN

National implementation coming from PSUSA/PSUR AR - challenges

- Complexity of company process & timelines
- Translations on agency website published late
- Majority Type IB variations
- Long initial validation
- Multiple PI updates - Simultaneous evaluations regarding the same INN (PSUSA, PRAC recommendations, article 31 referral)
- Additional measures require approved up-to-date SPC/PL

Branded vs Generic - Data evaluation before & during procedure

Branded

- Driven by company/ own data
- Discussion between originator and HA

Generics

- Partial info (signal)
- Sometimes asked for additional info

Branded vs Generic – Submission & assessment on national level

Generic

CCSI/SmPC discrepancy in some countries (outside the current variation)

Lack of reference or supporting material within generic company

Branded

Similar problem for established products

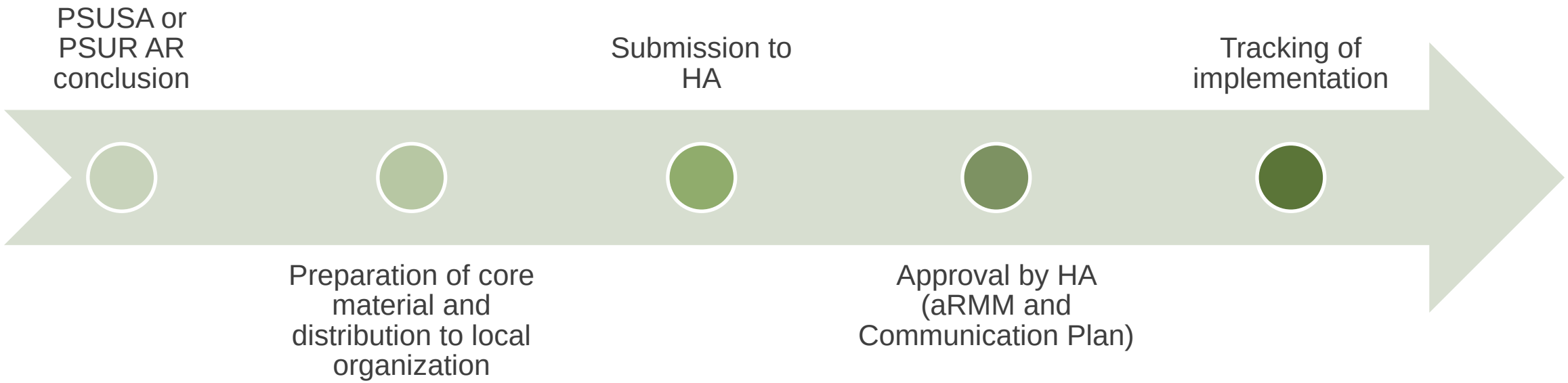
Regulation Reg 726/2004 Article 16(3)

3. The marketing authorisation holder shall ensure that the product information is kept up to date with the current scientific knowledge including the conclusions of the assessment and recommendations made public by means of the European medicines web-portal established in accordance with Article 26.

Current challenges of national SCP/PL implementation

- Latest safety updates not a problem
- Variations submitted and rejected due to „old text”
- EMA changed the practice and eliminated CSPs from PSUR assessments
- Harmonisation of generic labels cannot be solved by generics alone, there are regulatory procedures for that (referral 30 in Europe)
- Similar challenges for well established products („old” national MAs)

Implementation of Additional risk minimization measures (aRMMs)



Additional minimization measures coming from PSUSA

- Trastuzumab PSUSA[1]
  - DHPC on cardiac monitoring
- Ibandronic acid/sodium ibandronate PSUSA (Pareneteral bisphosphonates)[2]
  - Patient reminder card on Osteonecrosis of the jaw (ONJ)

1 http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2016/06/WC500207977.pdf

2 http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Conclusion/human/000101/WC500206406.pdf

Current challenges of national aRMMs implementation

- Availabilty of core material (material is agreed between HA and innovator, post-PSUSA)
- Translations (published text on local language from originator)
- Alignment with SPC/PL
- Different implementation requirements across 28 member states (based on different health systems, practice etc.)

TIPS & TRICKS FOR SUCCESSFUL IMPLEMENTATION

- Defined company process
  - Clear procedures to meet compliance
  - PhV – RA/labelling cooperation is essential
  - Support local process by available tools (eg Translations)
  - Knowledge & experience sharing
- National implementation
  - Clear guidelines and expectations (GVP revision, Q&As, trainings)
  - Communication with authorities (eg Industry stakeholders meetings)
  - Decrease administrative burden
  - Assessment process improved

Objectives of national implementation

- Protection of public health by delivering information to healthcare professionals and patients
- Efficient and effective national implementation
  - Accurate information (better leaflets, joint aRMMs)
  - New information delivered in a timely manner
  - Distributed to the relevant target audience
  - Focus on public health impact
  - Raise awareness on industry and regulator’s level

Ask

klaudija.marijanovic-barac@pliva.com