PART VI
Summary of Activities in the Risk Management Plan by Product

Active substance(s) (INN or common name):	Clotrimazole

Medicinal products to which this RMP refers:	1 % cream (1 g cream contains 10 mg clotrimazole) 1 % solution (1 ml solution contains 10 mg clotrimazole) 1 % powder (1 g powder contains 10 mg clotrimazole) 1 % spray (1 ml spray contains 10 mg clotrimazole)

Name of Marketing Authorisation Holder or Applicant:	Bayer AG

Data lock point for this module	01 SEP 2018

Version number of RMP when this module was last updated	3.0

VI.1. Summary of Risk Management Plan for Clotrimazole

This is a summary of the risk management plan (RMP) for clotrimazole topical dosage forms. None of the presented risks have been characterized as important according to the current guideline. The risks are well recognized by health care professionals, do not represent significant new information that would have an impact on the favorable risk-benefit profile, warrant further evaluation as a part of a pharmacovigilance plan, or require additional risk minimization activities. Considering that clotrimazole topical dosage forms have been widely used for decades, no gap in knowledge which may affect its safety profile has been identified. The clotrimazole labeling gives comprehensive information on how the product should be used.

VI.2. The medicine and what it is used for

Clotrimazole is used for the treatment of superficial fungal skin infections caused by dermatophytes, yeasts or moulds (i.e. athlete's foot, fungal infection of the hands, ringworm, jock itch, cutaneous candidiasis) and of erythrasma (superficial skin infection that causes brown, scaly skin patches). The topical treatments offer a first line simple therapy for patients who are able to recognize the condition thereby enabling immediate treatment of the condition without office visits to a primary care provider sparing the burden to the health care systems.

VI.3. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

None of the presented risks have been considered as having impact on the favorable risk-benefit balance of clotrimazole, or needed further evaluation as part of the pharmacovigilance plan or additional risk minimization measures.

Routine pharmacovigilance practices include

- comprehensive labeling
- collection, monitoring, evaluation and reporting of individual case reportss
- monitoring of adverse event data for detection and evaluation of signals
- periodic review of safety data and preparation and submission of periodic safety reports

These pharmacovigilance activities are deemed sufficient.

VI.4. List of Important Risks and Missing Information

None of the identified or potential risks listed are characterized as important identified or potential risks. No missing information has been identified.

VI.5. Summary of Important Risks

In the most recent EMA guidance for risk management planning,[114] important risks to be discussed in terms of risk management planning are not necessarily serious risks (e.g., hypersensitivity/anaphylaxis) but rather risks that require minimization measures beyond

routine pharmacovigilance (e.g., labeling). Risks that are fully characterized, appropriately managed, and well known to healthcare professionals, do not qualify as important risks for the purpose of risk management planning, and are therefore not included in the safety specification for the product.

The risks associated with the product have not changed, but these risks are well-known to health professionals, are adequately addressed in product labeling, and do not require any non-routine pharmacovigilance activities in order to minimize risk

Considering that clotrimazole has been widely used for decades, no gaps in knowledge which may affect its safety profile have been identified. As no measures beyond routine pharmacovigilance are in place or deemed necessary for clotrimazole, and as there is no gap in clinical knowledge, there are no important safety risks discussed in this RMP.

Table: Summary of safety concerns

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

VI.6. Post-authorisation Development Plan

No safety and/or efficacy post authorization studies are planned for clotrimazole.