EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Limited markets: what is in for SMEs?

Veterinary Info Day for SMEs

Susanne Thiele, 28 October 2021
Scientific Administrator, V-Division of EMA

Contents

Introduction

Activities to promote VMPs availability are continued

EMA MUMS/limited market policy ceases to apply; legal basis instead

-> Articles 23 and 24 of Regulation (EU) 2019/6 cover limited markets applications

EMA/CVMP work on practical implementation

Legal Framework – today and under VMP-Reg

	Current MUMS/ LM policy	Future LMs provisions
Legal basis	None	Article 23-24 of Reg. 2019/6
Definition	No legal definition in Dir. 2001/82/EC	Article 4(29) (**note: salmon**)
Eligibility	Evidence that product is intended for MUMS	Evidence that product is intended for LM **+ 'benefit of availability'**
Scientific standards applied	MUMS data requirements GLs - Satisfactory quality - Safety adequately characterised - Proof of efficacy	- Quality - Annex II compliant - Not required to provide the comprehensive **safety or efficacy** data required by Annex II => **data gap**
Authorisation status	Standard ('full') MA	**Labelled as limited market product** to differentiate it from a standard MA
Post-authorisation requirements	As for standard ('full') MA	**Valid for five years**, can be renewed. Otherwise as for standard MAs. An 'unlimited' MA may be granted, if MAH addresses the data gap.
Data protection	As for standard ('full') MA	Article 18 does not reference Article 23 (itself, a derogation from Article 8(1)) - a **generic of an Article 23 product is not possible**

Classification, eligibility and data requirements

Development of

Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets) [EMA/CVMP/235292/2020]

Published: end July 2021; Coming into effect: 28 January 2022

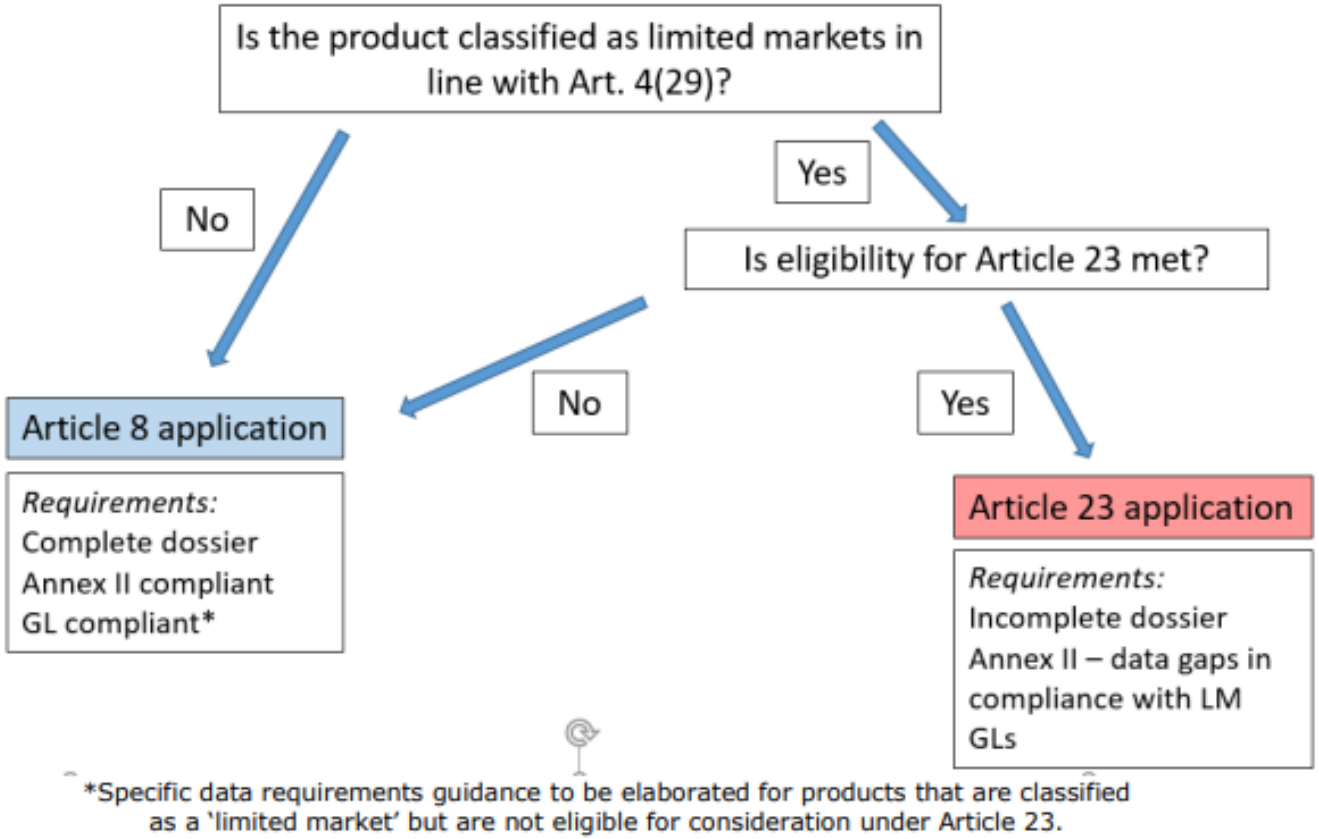
Scope: approach by CVMP applies to relevant products considered for authorisation under central, decentralised or mutual recognition procedures

Classification, eligibility and data requirements

Objectives:

- Allow for the authorisation of products classified as a LM that are intended to treat a serious or life-threatening disease/condition or are considered to fulfil an unmet medical need, in the absence of some (confirmatory) data required by Annex II for adequate characterisation of safety and/or proof of efficacy.

- Ensure that the regulatory system can continue to issue MAs for the type of product that is being authorised currently as a MUMS/limited markets product



1st Question: Is the product classified as Limited Markets?

Art. 4(29)

(b) – classification as a limited market based on species is straightforward

(a) - VMPs for the treatment or prevention of diseases that occur infrequently or in limited geographical areas *for indications/products intended for cattle, sheep for meat production, pigs, chickens, dogs or cats*

Based on

$$\text{Estimated potential size of the market \%} = \frac{\text{total annual number of animals potentially treated}}{\textbf{EU (EEA)} \text{ target species population}} \times 100$$

Guidance thresholds for species populations:
Vaccines – 5%,
Other treatments – 0.5%

2nd Question: 'benefit of availability' (Art. 23(1)(a))

Criteria to be fulfilled are:

(1) The product is intended to treat a serious or life-threatening disease/condition or addresses an 'unmet medical need' and

(2) The absence of certain documentation typically required for adequate characterisation of safety and demonstration of efficacy can be accepted.

Definitions of 'serious or life-threatening disease/condition' and 'unmet medical need' in the context of limited market applications can be found in the Reflection paper.

Procedure for classification and/or determining eligibility

2-step process; allows for a separate determination of the LM status (Art.4(29)) and the confirmation of eligibility for an Article 23 MA application (compliance with Art. 23(1)(a) and (b)).

CVMP confirmation on classification/eligibility will be determined and agreed in advance and considered valid for a period of 5 years.

The period of validity will be renewable.

Request to the CVMP for classification of a veterinary medicinal product as intended for a limited market according to Article 4(29) and for eligibility for authorisation according to Article 23 (Applications for limited markets)

Classification, eligibility and **data requirements**

Guidelines on LM (Art. 23) data requirements:

- GL on data requirements for applications for **IVMPs** intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 - (EMA/CVMP/59531/2020)

- GL on efficacy and target animal safety data requirements for applications for **non-IVMPs*** intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 - (EMA/CVMP/52665/2020)

- GL on safety and residue data requirements for applications for **non-IVMPs*** intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 - (EMA/CVMP/345237/2020)

* Cover Biological products other than IVMPs

Published: end July 2021; Coming into effect: 28 January 2022

Re-assessment of LM MA under Art. 24

Validity of the LM MA shall be valid for a period of 5 years.

On the basis of a positive benefit-risk assessment the validity of the LM MA shall be extended for periods of 5 years.

A decision to extend the validity of the MA will be based on the following considerations:

- the acceptability of the safety profile, including any information relating to LEE;
- whether the product continues to satisfy the criteria for classification as a limited market; and
- whether a specific medical need is met.

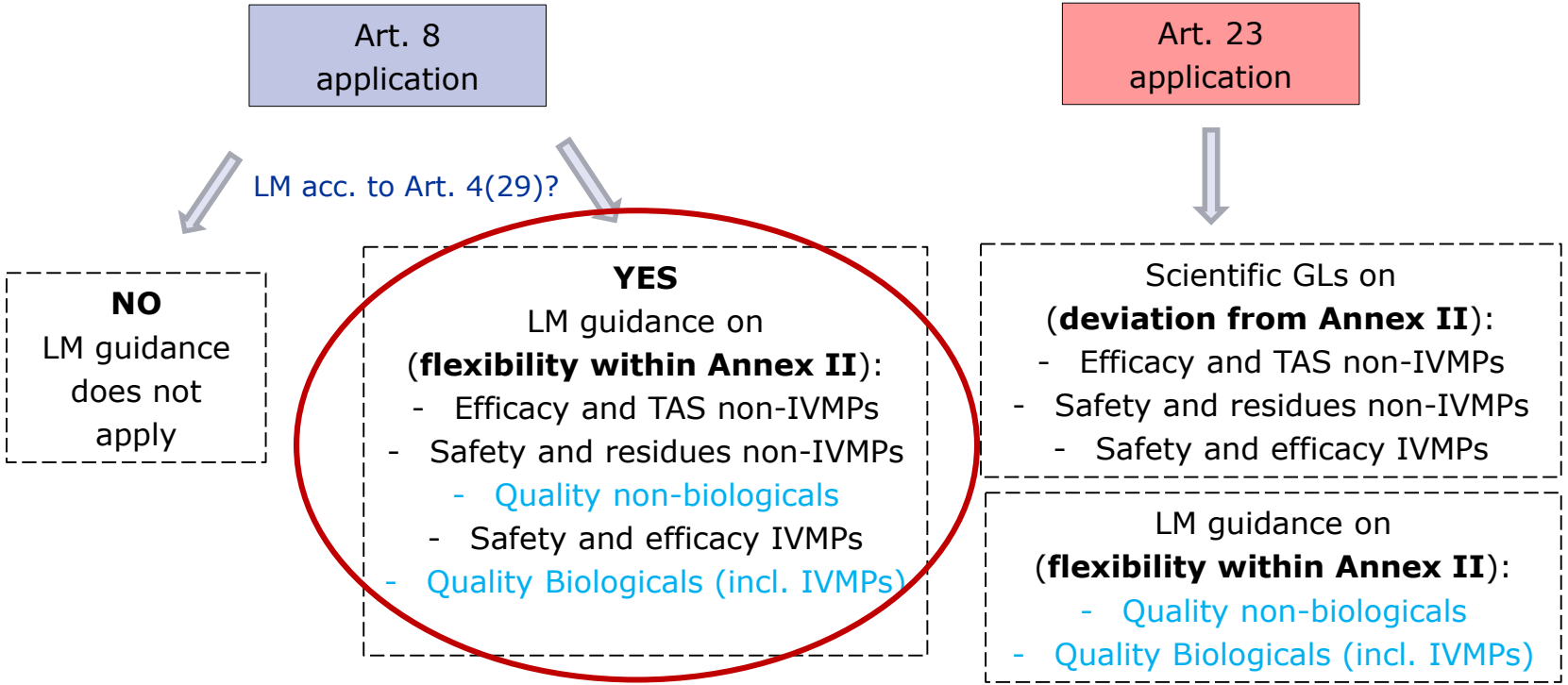
LM products deemed not eligible for Article 23 – work in progress

EMA/CVMP considered it necessary to develop additional scientific guidance in order to address the 2nd objective set for implementation of Art. 23:

"To ensure that the regulatory system can continue to issue marketing authorisations for the type of product that is being authorised currently as a MUMS/limited markets product."

A Concept paper on the development of scientific guidance was published for consultation on 15 October 2021.

LM products deemed not eligible for Article 23 – work in progress



Transition from MUMS to Limited Markets

- From 28 January 2022, the current EMA policy on MUMS/limited market classification will cease to apply.
- Products classified as MUMS under the current policy with no MA application validated by 28 Jan. 2022 will have to be re-considered in light of the provisions of Reg. 2019/6.
- Applications for MUMS products (classified under the current EMA policy) submitted and validated before 28 Jan. 2022 will be processed under the current legislation.
- Products classified as MUMS and already authorised are considered ‘standard’(full) MAs and Reg. 2019/6 will not affect the authorisation status.

Thank you for your attention!

Further information

Veterinary limited markets | European Medicines Agency (europa.eu)
vetlimitedmarkets@ema.europa.eu
Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**