



Monitoring of prescriptions for Voluntary Interruption of Pregnancy and Spontaneous Abortion within the first trimester of pregnancy

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WHAT WAS DONE?

To ensure appropriateness, a **specific prescription form** has been drafted to support clinicians in prescribing according to the correct reimbursement scheme gestational age, therapeutic indication and dosage must be reported in the prescription form.

WHY WAS IT DONE?

Mifepristone and misoprostol are provided for Voluntary Pregnancy Interruption (VPI) and Spontaneous Miscarriage (SM) according to different reimbursement schemes, based on different gestational age. According to Summary of Product Characteristics (SPC), the use of mifepristone and misoprostol is approved only within the first 63 days of pregnancy. Recently, access to treatment for VPI and SM has been extended by the Italian Medicines Agency by the I trimester of pregnancy. VPI within the first 49 days of gestation, the use of mifepristone and misoprostol is authorized according to SPCs. From 50th to 63rd days is guaranteed under the law 648/1996, that allows and reimburses the use of medicines for off-label indications. From 63rd to 90th is considered an off-label prescription. Regarding SM, mifepristone and misoprostol can be used within the I trimester under the law 648/1996. All these different reimbursement schemes are used as part of the Italian pricing-reimbursement system.

WHAT WAS ACHIEVED?

Prescription forms analysis showed that a total of 83 women were treated. In 53 cases the treatment was used for VPI and in 30 for SM. In 27% of cases, prescriptions were considered as per in-label. In 66% cases, prescriptions were allowed according to Law 648/96. In 7% of cases, prescriptions were off-label.

SAMPLE

- 83 Women
- 63,85% VPI
- 34,15% SM



PRESCRIPTIONS

- 27% In label
- 66% L. 648/1996
- 7% off label

MIFEPRISTONE AND MISOPROSTOL REIMBURSEMENT SCHEME IN ITALY

GESTATIONAL AGE	REIMBURSEMENT SCHEME
1st to 49th day	IN-LABEL, REIMBURSED ACCORDING TO SPC
50th to 63rd day	OFF-LABEL, REIMBURSED ACCORDING TO L.648/96
64th to 90th day	OFF-LABEL

HOW WAS IT DONE?

The development of the prescription form required a deep knowledge of both the law under which the right of abortion is guaranteed and Italian reimbursement schemes. The prescription form was introduced in October 2022. Prescriptions of all pharmacological treatments are ordinarily made through electronic software; therefore, the prescription form was uploaded. Prescriptions from 01/01/2024 to 30/06/2024 were collected and retrospectively analyzed.



Introduced in October 2022



Reimbursement schemes based on gestational age



Analysis from 01/01/2024 to 30/06/2024

7%

Interruption of pregnancy from 64th to 90th day of gestation

OFF-LABEL

27%

Interruption of pregnancy from 1st to 49th day of gestation

IN-LABEL

66%

Interruption of pregnancy from 50th to 63rd day of gestation

L. 648/1996

WHAT NEXT?

According to the development of reimbursement schemes, the prescription form will be implemented. Italy provides universal coverage for all citizens and residents; keeping it sustainable is one of the hardest challenges of these days. The contribution of hospital pharmacists in monitoring prescriptions has a pivotal role in making equal access to these treatments.