July 14, 2026
Pharmaceuticals and Medical Devices Agency, Japan

Summary of Investigation Results

Doxorubicin hydrochloride (liposome formulations)

<table>
<tr><td rowspan="2">Non-proprietary name
Brand name</td><td>Non-proprietary name</td><td colspan="2">Brand name
(marketing authorization holder)</td></tr>
<tr><td>Doxorubicin hydrochloride</td><td colspan="2">Doxil Injection 20 mg (Baxter Japan K.K.)</td></tr>
<tr><td>Japanese market launch</td><td colspan="3">February 2007</td></tr>
<tr><td>Indications</td><td colspan="3">○Ovarian cancer that has progressed after cancer chemotherapy
○AIDS-related Kaposi’s sarcoma</td></tr>
<tr><td>Summary of revisions</td><td colspan="3">1. A cautionary statement regarding “Renal-limited thrombotic microangiopathy” should be added to the 8. IMPORTANT PRECAUTIONS.
2. “Renal-limited thrombotic microangiopathy” should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS.</td></tr>
<tr><td>Investigation results and background of the revision</td><td colspan="3">Cases involving renal-limited thrombotic microangiopathy were evaluated. Cases in which a causal relationship between doxorubicin hydrochloride (liposome formulations) and renal-limited thrombotic microangiopathy was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.</td></tr>
<tr><td rowspan="2">Reference:
Number of cases involving renal-limited thrombotic microangiopathy* reported in Japan and overseas</td><td>Japan</td><td colspan="2">Overseas</td></tr>
<tr><td>A total of 4 cases have been reported to date (including 1 case in which a causal relationship between the drug and the event was reasonably possible).
A total of 1 death has been reported to date (including 0 cases in which a causal relationship between the drug and the death following the event was reasonably possible).</td><td colspan="2">A total of 16 cases have been reported to date (including 3 cases in which a causal relationship between the drug and the event was reasonably possible).
No deaths have been reported to date.</td></tr>
</table>

*: Among cases collected in the PMDA's safety database for drugs, cases for which information on blood cells or information on kidney biopsy is available and the drug administered can be identified were retrieved from those corresponding to either of the following MedDRA ver. 28.1 PTs: “Thrombotic microangiopathy,” “Haemolytic uraemic syndrome,” “Thrombotic thrombocytopenic purpura,” “Renal-limited thrombotic microangiopathy,” or “Microangiopathy.”

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).